

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: EF-243

Product name(s): Lontrel 300

Chemical active substance:

Clopyralid olamine, 395 g as/L (300 g ae/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: Corteva Agriscience

Submission date: 22/12/2021

MS Finalisation date: 05/12/2022

After commenting: 22/02/2023

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Corteva's amendment for onion use: July 2023

zRMS evaluation following Applicant's amendment: November 2023

zRMS correction: January: 2024

zRMS - update of the report in terms of additional study on onion and honey study submitted by Applicant: February 2024

zRMS - update of the report in terms of honey study (national approach)
– April 2024

After commenting (III round) - August 2024

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Version history

When	What
December 2021	Article 43 submission for re-registration of EF-243 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
December 2022	First zRMS evaluation.
February 2023	After commenting
July 2023	Corteva's amendment for onion use
September 2023	Updated by Corteva to include honey study and additional onion study
November 2023	rRMS evaluation following Applicant's amendment
January 2024	zRMS correction
February 2024	zRMS - update of the report in terms of additional honey study and onion study submitted by Applicant
April 2024	Update of the report in terms of honey study (national approach)
August 2024	After commenting (III round)

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation EF-243 are presented in Table 7.1-1.

In this part of the registration dossier the following uses were not evaluated: gladiolus, grass for seeds, lawn and onion for seeds due to the lack of consumer exposure.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for clopyralid as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of clopyralid residues are unlikely to present a public health concern. As far as consumer health protection is concerned, PL zRMS agrees with the authorization of the intended uses in cereals, maize, onion from seeds, beet and oilseed rape.

According to available data, no specific mitigation measures should apply.

Data gaps

~~Noticed data gaps are: none, however once the results of metabolism studies in oilseed rape and beet assessed at EU level are published, it will be necessary to verify the assessment performed.~~

- ~~• Oilseed rape – no plant metabolism studies evaluated at EU level~~
- ~~• Beet (fodder, sugar and red) – no plant metabolism studies evaluated at EU level~~

~~Lack of oilseed rape and beet plant metabolism studies.~~

~~When the results of the plant metabolism studies in oilseed rape and beets evaluated at UE level are available, it will be necessary to verify the evaluation performed.~~

~~Lack of residue studies in honey after application of the product in rapeseed.~~

~~When the results of the residue studies in honey are available, it will be necessary to verify the evaluation performed.~~

The applicant provided the honey study report. The zRMS found the study acceptable. The application rate used in the study was comparable to the proposed use rate for oilseed rape. The residues in honey were 3x <0.01, 0.0179, 0.0274 and 0.0695 mg/kg. Calculated STMR is 0.014 mg/kg and unrounded MRL 0.117 mg/kg (rounded 0.15 mg/kg). Current MRL for clopyralid in honey is 0.05 mg/kg and it is potentially exceeded. The Applicant submitted a request to the competent national authority in Finland to modify the existing MRLs for clopyralid in honey.

According to EFSA reasoned opinion (EFSA Journal. 2024;22:e8546.): “In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Corteva Agriscience International Sàrl submitted a request to the competent national authority in Finland to modify the existing maximum residue levels (MRLs) for the

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active substance clopyralid in honey. The data submitted in support of the request were found to be sufficient to derive MRL proposals for honey. Adequate analytical methods for enforcement are available to control the residues of clopyralid (including potential conjugates) in honey at the validated limit of quantification (LOQ) of 0.001 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of clopyralid residues in honey, resulting from the authorised use of clopyralid on oilseed rape notified in the MRL assessment, is unlikely to present a risk to consumer health.”

To accommodate clopyralid residues in honey from the authorised use on oilseed rape (identified as the critical GAP for residues in honey), it is proposed to raise the existing MRLs in honey from the limit of quantification of 0.05 to 0.15 mg/kg.

Taking into account national harmonisation arrangements, the use of Lontrel 300 in oilseed rape is accepted conditionally, until a new MRL value for honey is published. Once the new MRLs for honey are published in the Regulation, the report should be revised.

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Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8					9			10	11
GAP number (see part B.0)*	Crop and/or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg ae/ha min max		
1	Fodder beet, Sugar beet, Red Beet EU MRL Code: 0213010, 0900010, 0213010	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 12-39 (until July 1 st)	1	-		100-400	0.090-0.12	42	A
7	Winter Oilseed rape EU MRL Code: 0401060	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 30-51	1	-		100-400	0.12	NA	The use in rapeseed is accepted conditionally, until a new MRL value for honey is published.
10	Spring Barley Spring Wheat Spring Oat Spring Rye Spring Triticale EU MRL	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 30-39	1	-		100-400	0.09	NA	A

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1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/or situation**	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg ae/ha min max		
	Code: 0500010 0500090 0500050 0500070 0500990															
11	Winter Barley Winter Wheat Winter Oat Winter Rye Winter Triticale EU MRL Code: 0500010 0500090 0500050 0500070 0500990	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 30-39	1	-		100-400	0.09	NA	A
16	Maize (grain, forage) EU MRL Code: 0500030	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 30-32	1	-		100-400	0.102	60 (forage) 90 (grain)	A

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1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg ae/ha min max		
17	Onion for- from Seeds EPPO Code: ALLCE EU MRL Code: 0220020 Raw Human consumption Processed goods	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 11-16	I	I		100-400	0.120	42	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

NA: Not applicable.

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

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7.1.2 Summary of the evaluation

The preparation EF-243 is composed of clopyralid olamine. Clopyralid olamine is the 2-aminoethanol salt of clopyralid and in solution dissociates and behaves as clopyralid. Therefore the toxicological reference values for clopyralid are relevant.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of clopyralid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Clopyralid					
ADI	EFSA	2018a	0.15	Rat, 2-year chronic toxicity and oncogenicity study	100
ARfD	EFSA	2018a	0.17	Rabbit, developmental toxicity	300

7.1.2.1 Summary for clopyralid

Table 7.1-3: Summary for clopyralid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2, 3, 4, 5, 6	Fodder beet, Sugar beet, Red Beet, Mangels	Yes	Yes (8)	Yes	Yes	Yes	No	No
7, 8	Winter Oilseed rape	Yes	Yes (11)	Yes	Yes	Yes	No	No
10	Spring Barley Spring Wheat Spring Oat Spring Rye Spring Triticale	Yes	Yes (Barley:12, Wheat:10)	Yes	Yes	Yes	No	No
11	Winter Barley Winter Wheat Winter Oat Winter Rye Winter Triticale	Yes	Yes (Barley:12, Wheat:10)	Yes	Yes	Yes	No	No
16	Maize (grain, forage)	Yes	Yes (Grain: 9: forage: 4)	Yes	Yes	Yes	No	No
17	Onion from seed	Yes	Yes (Onion:89)	Yes	Yes	Yes	No	No

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* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of clopyralid residues have been investigated.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. No mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day plant-back interval is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid.

As the dietary burden intakes are within those calculated in the EFSA MRL Reasoned Opinion (EFSA, 2021), the existing animal MRLs accommodate the Article 43 uses presented in this submission (including consideration of rotational residues) and no further evaluation is warranted. The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

7.1.2.2 Summary for EF-243

Table 7.1-4: Information on EF-243 (KCA 6.8)

Crop	PHI and withholding period for EF-243 proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for EF-243 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clopyralid	Active substance 2	Active substance 3		
Fodder beet, Sugar beet, Red Beet, Mangels	42 days	Yes	NR	NR	NR (F*)	
Winter Oilseed rape	F**	Yes	NR	NR	NR (F*)	
Spring Barley Spring Wheat Spring Oat Spring Rye Spring Triticale	F**	Yes	NR	NR		Not evaluated
Winter Barley Winter Wheat Winter Oat Winter Rye Winter Triticale	F**	Yes	NR	NR		Not evaluated
Maize (grain, forage)	60 days (forage) 90 days (grain)	Yes	NR	NR		Not evaluated
Onion from seed	42 days	Yes	NR	NR	NR (F*)	

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for EF-243
Crop group	Led by Clopyralid	Led by active substance 2	Led by active substance 3	
Leafy and Brassica vegetables Oilseeds	NR	NR	NR	125 days after the initial application
All other food and feed crops not specified	30 days	NR	NR	
Sugar canes	125 days	NR	NR	

NR: not relevant

* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop)

EFSA, 2021: EFSA suggests to risk managers as risk mitigation measure to label clopyralid-containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown.

The Applicant submitted the study on determination of residues of clopyralid after one application clopyralid on bare soil in rotational crops. The study included leafy and brassica vegetables, root and tuber vegetables, tops of root and tuber vegetables, oilseeds and cereals. Following treatment o highest tested dose of 125 g/ha corresponded to the proposed use of 120 g/ha. No residues above the MRL were observed in edible parts of plants at the PBI of 30 days. In the individual samples of radish tops with leaves that were stored in excess of available frozen storage stability data, residues of clopyralid ranged from <0.01 to 0.54 mg/kg at the shortest PBI.

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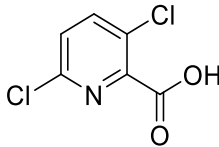
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7.2 Clopyralid

The preparation EF-243 is composed of clopyralid olamine. Clopyralid olamine is the 2-aminoethanol salt of clopyralid and in solution dissociates and behaves as clopyralid. Therefore data for clopyralid are relevant.

General data on clopyralid are summarized in the table below (last updated 2019/03/25)

Table 7.2-1: General information on clopyralid

Active substance (ISO Common Name)	Clopyralid
IUPAC	3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid
Chemical structure	
Molecular formula	C ₆ H ₃ Cl ₂ NO ₂
Molar mass	191.96 g/mol
Chemical group	Herbicide, pyridine compound
Mode of action (if available)	Auxin mimic. Taken up via leaves and roots and induces an epinastic response leading to chlorosis, cessation of normal growth and death.
Systemic	Yes
Company (ies)	Corteva Agriscience*
Rapporteur Member State (RMS)	Finland co-RMS: Poland
Approval status	Approved (01/05/2007, COMMISSION DIRECTIVE 2006/64/EC) Re-approval (01/10/2021) - Commission Implementing Regulation (EU) 2021/1191 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1191&from=EN
Restriction	Only uses as a herbicide may be authorised
Review Report	SANCO/10012/2006 – rev. 3, 04/04/2006 SANTE/10206/2021– rev. 1 20/05/2021
Current MRL regulation	Reg. (EU) 2021/1807
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending (EFSA-Q-2008-513)
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2018a)

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EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	<p>EFSA-Q-2018-00576 Modification of the existing maximum residue levels for clopyralid in various commodities Status: Reasoned opinion available (EFSA Journal 2021;19(1):6389); Reg. (EU) 2021/1807</p> <p>EFSA-Q-2015-00419 (UK) MRLs for clopyralid in spring/green/Welsh onions and leeks Status: Reasoned opinion available (EFSA Journal 2018;16(1):5149)</p> <p>EFSA-Q-2011-00206 Modification of the existing MRLs for clopyralid in various commodities/ Head cabbage, cauliflower, Brocoli, linseeds (and their by-products), swedes and turnips, animal commodities (bovine sheep goat - meat, liver, kidney; milk) Status: Reasoned Opinion available (EFSA Journal 2011;9(10):2418)</p>

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Available data

Three new stability studies has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of this/these studies are presented in Appendix 2.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pasture grass	High water content	17 months	EFSA, 2018a
Maize fodder/forage	High water content	13 months	EFSA, 2018a
Oilseed rape	High oil content	24 months	EFSA, 2018a
Olive (fruit and oil)	High oil content	10 months	EFSA, 2018a
Maize	High starch content	13 months	EFSA, 2018a
Orange	High acid content	10 months	EFSA, 2018a

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Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Orange peel	Other	10 months	EFSA, 2018a
Animal Products			
Ruminant	Muscle	19 months	EFSA, 2018a
Ruminant	Liver	19 months	EFSA, 2018a
Ruminant	Kidney	19 months	EFSA, 2018a
Ruminant	Milk	19 months	EFSA, 2018a
Ruminant	Fat	24 months	EFSA, 2018a
Poultry	Eggs	19 months	EFSA, 2018a
New data			
Dried Navy Beans	High protein content	13 months	Skaggs, C. S., Penning, B. N; 2021; Corteva Study No. 191728
Strawberries	High acid content	24 months	EFSA, R.; 1996; Corteva Study No. GHE-P-4832
Honey/nectar/pollen	pollinator	18 months	Forbes, T.; Cross, M.; 2020; Corteva Study No. 180869

Reference: EFSA, 2018a

“Stability of conjugates was not tested, though clopyralid conjugates are major metabolites comprising up to 50 % of TRR depending on the crop studied. It was assumed that conjugated clopyralid was also stable.”

Conclusion on stability of residues during storage

Clopyralid (free and conjugated) is stable for at least 17 months in high water commodities, 24 months in high oil commodities, 13 months in high starch commodities and 10 months in high acid commodities when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions in the EFSA conclusion 2018a. The additional studies for high protein, and high acid has demonstrated clopyralid is stable across the five commodity categories and therefore is stable in all crop commodities up to 13 months when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

Clopyralid (free and conjugated) is stable for at least 19 months in tissues, milk and eggs and up to 24 months in fat when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

Clopyralid (free and conjugated) is stable for at least 18 months in honey, pollen and nectar when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

zRMS comments:	It was demonstrated that clopyralid was stable for at least 10 months in commodities with high water, high oil, high acid and high starch content. The applicant provided three new studies that are considered acceptable. According to the new studies clopyralid was stable for 13 months in high protein (bean) and high acid (strawberries) content. In bee products it is stable for 18 months.
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7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data are submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

The stability of residues in sample extracts was demonstrated by acceptable procedural recoveries analysed concurrently with residue trial samples.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

New metabolism studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label po- sition	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	¹⁴ C- clopyralid	G, foliar	0.42	1	0, 5, 38	Application at BBCH 31 (8-10 leaf stage)	Finland, 2018a
Root and tuber vegetables	Sugar beet	¹⁴ C- clopyralid	F, foliar	0.30	1	0, 28, 105 (maturity)	Application at BBCH 36	EFSA, 2018a and Finland, 2018a Finland 2018b†
Pulses and oilseeds	Oilseed rape	¹⁴ C- clopyralid	F, foliar	0.30	1	0, 28 (60% fi- nal size), 77 (ma- turity)	Application at BBCH 36	EFSA, 2018a and Finland, 2018a Finland 2018b†
Cereals/grass crops	Pasture grass	¹⁴ C- clopyralid	F, foliar	1.12	1	1, 2, 4, 8, 18 weeks	Non-GLP, non-	Finland, 2018a

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							<i>guideline compliant. Supporting information only.</i>	
Cereals and oilseeds	<i>Oilseed rape and wheat</i>	¹⁴ C-clopyralid	<i>G, Hydroponic</i>	75 µg/L	-	-	<i>Non-guideline compliant. No metabolism data available, only biodistribution. Supporting information only.</i>	Finland, 2018a
New data								
Cereals/grass crops	Cereals	¹⁴ C-clopyralid	F, foliar (last 3 weeks indoors, G)	125 g ae/ha	1	3, 23, and maturity (92)	Application at BBCH 39,	Morton Lloyd, G, 2020, DAS study No. 191200
Root and tuber vegetables	Oilseed rape	¹⁴ C-clopyralid	F	200 g ae/ha	1	23 (forage) and maturity (seeds & trash); pollen	Application at BBCH 30 Trash is not a RAC	Mackenzie, A, 2021, DAS study No. 200928
Pulses and oilseeds								
Pulses and oilseeds	Sugar beet	¹⁴ C-clopyralid	F	314 g ae/ha	1	21 (immature), 110 (roots & foliage)	Application at BBCH 19	DAS Study No. 210071 Ongoing
Root and tuber vegetables								

(a) F:Field, G: greenhouse

DAT: Days after treatment

† The sugar beet and oilseed rape metabolism studies were evaluated in two separate EU processes. The original reports were evaluated during active substance renewal (EFSA 2018a, Finland RAR 2018a) and the amended reports for the existing studies were evaluated in an MRL Evaluation Report (Finland 2018b).

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2018a

“Three Good Laboratory Practice (GLP) and guideline-compliant metabolism studies with foliar application of ¹⁴C-clopyralid are available for root crop, leafy vegetable and pulses/oilseeds.

The extraction with caustic methanol employed in the cabbage study has led to cleavage of the conjugates and resulted in the presence of free clopyralid at maturity up to 92% and 99% total radioactive residue (TRR) in head and wrapper leaves, respectively. In the studies with oilseed rape and sugar beet, a first extraction was performed with acetonitrile/water and followed with a caustic extraction allowing for investigation of the presence of eventual conjugates. In sugar beet, clopyralid was initially the major residue in the plant (97% TRR at day 0 and 85% TRR at day 28). At maturity, it decreased to 51% TRR in the shoot and to 58% TRR in the root. A ‘polar form of clopyralid’ was observed in shoots and roots up to 37% TRR

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and 39% TRR, respectively, but only in the mature plant parts. In oilseed rape clopyralid was present at 63% TRR in immature plant and at 32% and 43% TRR in mature straw and seed, respectively. A ‘polar form of clopyralid’ was reported to 32% and 28% TRR in mature straw and seed, respectively and an unknown metabolite B also referred to as ‘clopyralid conjugates’ to 29% and 18% TRR in mature straw and seed, respectively. From the analytical protocol it can be assumed that the ‘polar clopyralid’ refers to the protonated form (clopyralid acid). However, a confirmation that the observed results in the different metabolism studies are consistent with the analytical conditions (pH) used and an explanation why in mature samples of sugar beet and oilseed rape ‘polar clopyralid’ and clopyralid were observed while ‘polar clopyralid’ was not observed in immature samples as the analytical procedure used was always the same within one study is outstanding (data gap). A clarification is also needed whether the term ‘polar clopyralid’ is referring always to a single structure (and not different polar compounds) and that this structure of ‘polar clopyralid’ is identical across all metabolism studies where it has been identified (data gap).”

To address the EFSA data gap, Dow AgroSciences Ltd (DAS, now Corteva Agriscience) has submitted additional data and argumentation. Further explanation of the applicant’s arguments, additional data and conclusions of EFSA and the RMS may be found in Appendix 4. The applicant believes sufficient data have been provided to conclude that the EFSA-proposed plant residue definition is fully justified and can be adopted (‘sum of clopyralid, its salts and conjugates expressed as clopyralid’) and no further data shall be deemed required. Nonetheless, an oilseed rape metabolism study has been completed, and a sugar beet metabolism study is currently under repetition to confirm the residue definition and thereby fill the data gap.

Summary of new plant metabolism studies

Following a single 125.87 g a.e./ha (104.9% of target) application of [¹⁴C]-clopyralid to wheat, TRR levels in forage, hay, straw and grain ranged from 1.879 – 3.717 mg eq/kg.

For all tissues, accountability, between combustion and extraction data, was 95.4 – 107.6%. When normalised with respect to accountability, aqueous acetonitrile recovered 50.6 – 90.5 %TRR and methanolic base extracts released a further 5.0 – 34.7 %TRR. Further extractions were conducted on all samples using mild aqueous base, mild and stronger acid, which released a further 2.6 – 7.5 %TRR. Non-extractable residues were 1.8 – 7.2 %TRR.

The aqueous acetonitrile contained a resolved clopyralid peak (15.4 – 66.0% TRR, 0.311 – 1.240 mg eq/kg) and a less polar, unresolved region (21.0 – 63.3% TRR, 0.394 – 2.351 mg eq/kg). Upon mild base treatment (similar to analytical method 120610 using methanol:10 N NaOH (100:1, v/v), overnight), primarily clopyralid was detected (*ca.* 98%). The methanol base extract, mild aqueous base and acid further extracts contained only clopyralid (*ca.* 99%). No polar clopyralid was detected in any sample.

Experiments on the apolar unresolved region demonstrated that it was completely converted to clopyralid within an hour of treatment with 5% ammonium hydroxide solution (2:1, v/v, sample:base ratio). Any sort of light manipulation of the sample (SPE, changing the pH etc.) to remove endogenous materials resulted in the elimination of this region, forming clopyralid. This indicates that the unresolved region is a result of weak binding interactions (*e.g.*, electrostatic) between clopyralid and the endogenous plant matrix, which are disrupted by treatment with mild base or removal of endogenous material. The presence of the apolar region in the control sample fortified with clopyralid further adds to the theory that this region is a result of interactions between clopyralid and endogenous materials present in the sample. Overall, it can be strongly hypothesised that this region is the result of chromatographic effects of clopyralid weakly binding/interacting with endogenous material. Therefore, this region can be identified as base-labile clopyralid.

Greater than 90% of the extractable residue was identified as clopyralid. In total, clopyralid accounted for 98.0 %TRR (1.843 mg eq/kg) in forage, 97.2 %TRR (3.608 mg eq/kg) in hay, 92.6 %TRR (1.978 mg eq/kg) in straw and 96.4 %TRR (1.087 mg eq/kg) in grain.

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The metabolism of clopyralid was investigated in spring oilseed rape at a target application rate of 200 g a.e./ha when the plants were at growth stage BBCH 30. Spring oilseed rape anthers (containing pollen), early forage, seeds and trash (including pods) were harvested. Forage (23 d PHI) contained 1.839 mg eq/kg while seed contained 0.069 mg eq/kg.

All samples were subjected to extraction and characterisation. HPLC analysis of the aqueous acetonitrile extracts from forage contained a resolved clopyralid peak (28.8% TRR, 0.530 mg eq/kg) and a broad less polar (apolar), unresolved region (64.0% TRR, 1.178 mg eq/kg). Trash was similar. The equivalent extracts from seeds contained a resolved clopyralid peak (29.0% TRR, 0.020 mg eq/kg) and two minor, more polar regions (2.1 – 3.3% TRR, 0.001 – 0.002 mg eq/kg). Upon mild base treatment (similar to Dow analytical method 120610, using methanol:10 N NaOH (100:1, v/v), overnight) of the neutral organic extracts, only clopyralid was detected (83.8% and 69.4% TRR in forage and trash, respectively). The methanol base extract and further basic extracts from each sample contained only clopyralid and were therefore characterized as base-labile clopyralid. In total, clopyralid (free and base-labile) accounted for 101.6% TRR (1.871 mg eq/kg) in forage, 95.2% TRR (0.213 mg eq/kg) in trash and 70.3% TRR (0.049 mg eq/kg) in seeds. Only clopyralid was detected in the extracts from the analytical method for all three commodities.

The anthers containing pollen were washed with water and centrifuged to separate the pollen. The isolated pollen was then extracted with methanolic base. Both the water washes and the pollen extract were characterized by HPLC. The majority (63.4%) of the water wash eluted with clopyralid, while the remainder of the water wash eluted in the same apolar region as the forage and trash samples and is therefore characterized as base-labile clopyralid. The majority of the pollen residue was extractable (>85%) and eluted with clopyralid, and is therefore characterized as base-labile clopyralid.

Extensive experiments on the apolar unresolved region demonstrated that this region was readily converted to clopyralid in the presence of dilute base. Any light manipulation readily converted the apolar region to clopyralid, which strongly supports the hypothesis that the apolar region is a result of weak electrostatic interactions with endogenous plant matrix and/or chelation of clopyralid to metal ions in the plant. Although extensive attempts were made, no LC-MS mass or fragment ion related to clopyralid could be found in the apolar region, despite optimization of the mass spectrometer for clopyralid.

In total, clopyralid (free and base-labile) accounted for >70% of the TRR in all samples, including seed, forage, trash, and pollen/anthers. Furthermore, the amount of total clopyralid detected by Dow analytical method 120610 was in excellent agreement with the exhaustive methods used in a metabolism study, at greater than 90%.

Conclusion on metabolism in primary crops

The metabolism of clopyralid in three representative crops from three crop groups was re-evaluated during the EU renewal (cabbage, oilseed rape and sugar beet). In addition, a wheat metabolism study (cereals group) was also completed.

Based on the crop metabolism studies re-evaluated during the EU renewal, EFSA proposed the following residue definitions for plant commodities (EFSA, 2018a):

Residue definition for monitoring (plant): Sum of clopyralid, its salts and conjugates expressed as clopyralid

Residue definition for risk assessment (plant): Sum of clopyralid, its salts and conjugates expressed as clopyralid

On the basis of the additional data submitted by the applicant, to the RMS and EFSA in 2019-2020 in the framework of the MRL application, the applicant believes the EFSA-proposed plant residue definition is fully justified and can be adopted ('sum of clopyralid, its salts and conjugates expressed as clopyralid') and no further data shall be deemed required. Nonetheless, the oilseed rape NOR was repeated which

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confirms the residue definition above, and sugar beet metabolism studies is currently under repetition to confirm the residue definition, and thereby address the data gaps noted by EFSA. Further explanation may be found in Appendix 4.

zRMS comments:	<p>The metabolism of clopyralid in primary crops belonging to the group of root crops (sugar beets), leafy crops (head cabbage), pulses/oilseeds (oilseed rape) has been investigated in the framework of the active substance peer review (2018). In the context of the peer review, a data gap was identified for the clarification of the unknown polar compound observed in mature samples of rape seed and sugar beet.</p> <p>EFSA (2021) concluded that for the intended uses in grass and cereals, the metabolic behavior of clopyralid was addressed, and the residue definitions only apply for the crop groups cereals and grass.</p> <p>The applicant provided three new studies on metabolism of clopyralid in following crops: wheat, including forage and mature crop and oilseed rape. The studies should be evaluated at EU level.</p> <p>Therefore, the application on oilseed rape is not acceptable until this condition is fulfilled. The third study on sugar beet is on-going and no study report was available for the current evaluation. Thus, the use on sugar beet is also not acceptable.</p> <p>Revision of previous evaluation:</p> <p>The Applicant provided new studies on metabolism of clopyralid in primary crops to address the data gap regarding the unknown polar compound: in oilseed rape and on sugar beet. The first study indicates that only clopyralid was identified in all rape seed commodities. The second one on sugar beet was on-going at the time of submission and therefore not available for the current evaluation.</p> <p>zRMS is of the opinion that it is indispensable that new data are assessed at EU level (by EFSA) to come to a harmonised decision.</p> <p>zRMS accepts the proposed use in oilseed rape and beet, however once the results of the studies evaluated at EU level are published, a review of the evaluation performed will be necessary.</p>
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7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details						Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals		Remarks	
						DAT	DAP		
EU data									
Leafy vegetables	Cabbage, lettuce	¹⁴ C-2-pyridine-carboxylic acid	F, Bare soil application	0.28-0.30	30 (cabbage), 125, 319 (lettuce)	Cabbage: 78 (immature), 128	Lettuce: 38, 60, 81 and 49, 71	30 DAT mature cabbage was harvested at	Finland, 2018a

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						(mature)		128 days (9+ leaves/head; heads failed to fully close due to heat, BBCH 53)	
Root and tuber vegetables	Turnip, radish	¹⁴ C-2-pyridine-carboxylic acid	F, Bare soil application	0.28-0.30	30 (radish), 125, 319 (turnip)	Radish: 78 (BBCH 53) Turnip: 219, 390	Turnip: 71, 94	-	Finland, 2018a
Cereals	Wheat	¹⁴ C-2-pyridine-carboxylic acid	F, Bare soil application	0.28-0.30	30, 125, 319	Study 1: 244 Study 3: 62 (forage), 78 (hay), 107 (straw and grain)	Study 1: 119 Study 2: 71 (immature), 98 (grain, chaff, straw)	-	Finland, 2018a
Other	Soybean (beans and plant)	¹⁴ C-2-pyridine-carboxylic acid	F, Bare soil application	0.28	125	251	126	-	Finland, 2018a
	Green beans (beans and plant)	¹⁴ C-2-pyridine-carboxylic acid	F, Bare soil application	0.28	319	382, 390	63-71	-	Finland, 2018a

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

DAP: Days after planting

DAT: Days after treatment

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2018a

“Three nature of residues studies in three rotational crops covering the plant-back intervals (PBI) of *ca.* 30, 120 and 365 days are available. Only in the most recent study covering PBI of 30 days, identification of residues was performed and besides the parent only conjugated clopyralid is found in wheat, cabbage and radish. As residues in rotational crops cannot be excluded based on the available data, rotational crop field trials according to current guidelines should be submitted (data gap).”

The confined rotational crop studies were conducted at an exaggerated rate compared to the intended GAPs (1.4N), however when applied at the intended maximum use rate, residues above the LOQ (0.01 mg/kg) in rotated crops may occur at 30 days after treatment (Hall, 2015: max. of 0.549 mg/kg identified as clopyralid free and conjugated in wheat grain).

Total radioactive residues (TRR) in rotated crops 125 days after treatment (Yackovich, 1989, GH-C 2277) were a maximum of 0.015 mg/kg in soybean and wheat straw. TRR values in lettuce, turnip roots and tops and in wheat grain were <0.01 mg/kg. The wheat straw, soybean and soybean trash fractions were extracted with dilute aqueous sodium hydroxide and methanol (4 times) followed by concentration, acidification and partitioning residues into diethyl ether. This method has been proven to quantitatively measure clopyralid,

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free and conjugated. However, for these 125-d PBI samples, 57-65% of the TRR was extracted, with HPLC revealing that the only extracted component was clopyralid, at levels <0.01 mg/kg. The un-extracted residue was <0.01 mg/kg and therefore was not analysed further, but should not be considered to be clopyralid. Therefore, residues of clopyralid in the 125-d PBI samples were all <0.01 mg/kg and a label restriction of 125-d should be acceptable. The Yackovich study was conducted with application to bare soil at 280 g as/ha, therefore supporting uses up to 280 g as/ha and a 125-d Plant Back Interval (“PBI”). TRR values in lettuce, turnip roots and tops and in wheat grain were <0.01 mg/kg.

The metabolism in rotational crops is considered comparable to that in primary crops, therefore the same residue definitions apply.

Conclusion on metabolism in rotational crops

EFSA concluded that even if “*the metabolism studies are not performed with crop groups covering the representative uses in cereals and grass, they are sufficient to derive a general residue definition for primary and rotational crops for risk assessment and monitoring as ‘clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)’ – pending the outstanding clarification on the nature of ‘polar clopyralid’*”.

The rotational crop residue definition for monitoring and risk assessment is: *clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)’ – pending the outstanding clarification on the nature of ‘polar clopyralid’*”.

For the clarification on the nature of “polar clopyralid”, refer to the section on metabolism in primary crop and to Appendix 4 for further details.

The 30-d CRC data indicate residues will be similar or lower than the primary crop residue levels, and if no further application of clopyralid is allowed to the succeeding crops, the MRLs would not be exceeded in the succeeding crops or the current MRL of 0.5 mg/kg set for majority of crops. These data do not include the reduction expected from the primary crop intercept as this could vary depending upon the primary crop and growth stage at application.

For root vegetables, plant back interval of 30-125 days can be accepted without further restriction on the succeeding crops based on the 30-day confined rotational crop study.

In light of results from the field rotational crop study recently performed and submitted in this dossier, the following label restrictions are suggested:

“No mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid.”

zRMS comments:	Due to identified data gap for the submission of rotational crop field trials according to current guidelines EFSA suggests to risk managers as risk mitigation measure to label clopyralid containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (EFSA, 2021). According to Commission Implementing Regulation (EU) 2021/1191 the following Specific provision is listed: “In this overall assessment Member States shall pay particular attention to: possible presence of clopyralid residues in rotational crops”. However the applicant submitted new rotational crop study (2021) which demonstrated that no residues are expected in succeeding at the shorter PBI.
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	Based on the rotational study result provided by the Applicant, no residues are expected in succeeding leafy crops or oilseed seeds even at the shortest PBI of 30 days. In root and tuber crops, no significant residues in roots are expected at the PBI of 90 days or longer, while in tops, no significant residues are expected at PBI of 125 days and longer. In cereal grain and straw, significant residues are not expected at all PBIs. The residue levels in did not exceed the current MRLs for any of the crops in respective crop groups
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7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Clopyralid (99.3)	Finland, 2018a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Clopyralid (96.9)	
Sterilisation (20 minutes, 120°C, pH 6)	Clopyralid (97.1)	

Reference: EFSA, 2018a

“Clopyralid proved to be stable under pasteurisation, baking, brewing, boiling and sterilisation conditions.”

Conclusion on nature of residues in processed commodities

Clopyralid is stable under pasteurisation, baking, brewing, boiling and sterilisation conditions. Specific residue definitions for processed commodities are not required.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (Sugar beet) Leafy crops (Cabbage) Pulses/oilseeds (Oilseed rape) Cereals (wheat)
Rotational crops covered	Radish/turnip, cabbage/lettuce, wheat, soybean (green plant and beans)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (EFSA, 2018a)
Processed commodities	Clopyralid is stable under standard hydrolysis conditions (EFSA, 2018a)

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Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	<p>Clopyralid (Regulation n°2018/1514) Regulation (EU) 2021/1807 of 13 October 2021</p> <p>Applicable only for cereals/grass: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2018d)</p> <p>Existing residue definition of Regulation (EC) No 396/2005: clopyralid</p>
Plant residue definition for risk assessment	<p>Sum of clopyralid, its salts and conjugates, expressed as clopyralid (EFSA, 2018a)*</p> <p>Applicable only for cereals/grass: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2018d)</p>
Conversion factor from enforcement to RA	Not required

* Identified by EFSA as pending clarification on the nature of ‘polar clopyralid’. The applicant has since provided sufficient information to address the data gap (Finland, 2018b), therefore these residue definitions should no longer be considered ‘pending’. Further explanation may be found in Appendix 4.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label po- sition	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of samp- ling	
EU data								
Lactating ruminants	Goat	Clopyralid- 2,6- ¹⁴ C	1	0.484 (50.9 mg as/kg dry feed/day)	5	Milk	Twice daily	Finland, 2018a EFSA, 2018a
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry	Hen	Clopyralid- 2,6- ¹⁴ C	10	0.56-0.65 (11.4 mg as/kg feed/day)	7	Eggs	Twice daily	Finland, 2018a EFSA, 2018a
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of animal metabolism studies reported in the EU

Reference: EFSA, 2018a

“Metabolism studies both for ruminants and poultry are submitted indicating that conjugation is the major pathway; however, significant amounts of glycine conjugates were only found in milk. The conversion factor of 1.3 for monitoring to risk assessment is only relevant for milk and is based on the new ruminant metabolism study.

The residue definition in products of animal origin for risk assessment is proposed as ‘clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)’ and ‘clopyralid and its salts’ for monitoring. The plateau in eggs was reached at *ca.* 7 days and in milk at day 1.”

In milk over 21% of TRR (corresponding to 0.002 mg eq/kg) was found as clopyralid-glycine conjugate (X36538). Clopyralid comprised from 54% to over 70% of the TRR in milk, urine and faeces. In the tissues unchanged clopyralid was the major residue along with minor amounts of conjugate X36538.

Conclusion on metabolism in livestock

Metabolism in animals has been thoroughly characterised in rats, poultry and lactating ruminants. Metabolism is similar in the animals tested, and a pig metabolism study is not required.

A fish metabolism study is not required, as clopyralid is not expected to bioaccumulate in animal tissues as indicated by a Log P_{ow} of -2.63 and a fish bioconcentration factor of < 1.

Based on the goat and hen metabolism studies submitted and evaluated during the EU renewal, EFSA proposed the following residue definitions for animal commodities (EFSA, 2018a):

Residue definition for monitoring (animal): Clopyralid and its salts

Residue definition for risk assessment (animal): Sum of clopyralid, its salts and glycine conjugates, expressed as clopyralid

The conversion factor monitoring / risk assessment is only relevant for milk and is based on the new ruminant metabolism study as 1.3.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1 day in milk
	7 days in eggs
Animal residue definition for monitoring	Clopyralid (Regulation n°2018/1514) Regulation (EU) 2021/1807 During the renewal assessment EFSA proposed a residue definition of: clopyralid and its salts or clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) (EFSA, 2021) (EFSA, 2018a).

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Animal residue definition for risk assessment	Sum of clopyralid, its salts and glycine conjugates, expressed as clopyralid (EFSA, 2018a)
Conversion factor	Milk only: 1.3 (EFSA, 2018a)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

In accordance with the draft fish guidance (SANCO/11187/2013), metabolism in fish is not required, as the Log Pow for clopyralid is < 3 and it is not considered fat soluble.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Studies on cereals that were submitted and evaluated during the EU renewal of clopyralid (Finland 2018a, EFSA 2018a) are also relied upon. EFSA (EFSA, 2018a) concluded that “*the reporting of the trials in the RAR in an inconsistent manner renders a transparent risk assessment not feasible (data gap).*”

Studies that were submitted and evaluated during the original EU peer review of clopyralid (EFSA, 2005) and subsequent MRL evaluations (Finland, 2008 and 2011; EFSA, 2011) are also relied upon. Due to the aforementioned data gap, the relevant magnitude of residue studies have been fully summarized for all uses in Appendix 2.

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Table 7.2-9: Summary of EU reported and new data supporting the intended uses of EF-243 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA†	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugar beet, roots→ Fodder beet, Red beet, Mangels Zonal cGAP: 1 x 150-200 g ae/ha, BBCH 31-39, PHI 42d	New trials (Study No. 200809)	N-EU	Trials GAP: 1 x 125 g ae/ha, BBCH 35, PHI 42d E/RA: 0.10, 0.13, 0.14, 0.16, 0.17, 0.19, 2 x 0.20	N/A				
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 90-120 g ae/ha, BBCH 12-39, PHI 42d, outdoor E/RA: 0.10, 0.13, 0.14, 0.16, 0.17, 0.19, 2 x 0.20	0.165	0.20	0.484	1 (Sugar beet)	Yes
Sugar beet, tops	New trials (Study No. 200809)	N-EU	Trials GAP: 1 x 125 g ae/ha, BBCH 35, PHI 42d E/RA: 2 x 0.12, 0.14, 2 x 0.17, 0.19, 0.20, 0.22	N/A				
	Overall supporting data for cGAP	N-EU	Intended GAP: 1 x 90-120 g ae/ha, BBCH 12-39, PHI 42d, outdoor E/RA: 2 x 0.12, 0.14, 2 x 0.17, 0.19, 0.20, 0.22	0.17	0.22	0.499	Not relevant to animal feed commodities	
Oilseed rape	New trials (Study No. 150534)	N-EU	Trials GAP: 1 x 120 g ae/ha, BBCH 50, outdoor E/RA: <0.01, 3 x 0.02, 2 x 0.03, 0.05, 2 x 0.06, 0.10, 0.30	N/A				
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 120 g ae/ha, BBCH 30-51, PHI N/A, outdoor E/RA: <0.01, 3 x 0.02, 2 x 0.03, 0.05, 2 x 0.06, 0.10, 0.30	0.03	0.30	0.394	0.5	Yes

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) $E = RA^{\dagger}$	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley, grain Zonal cGAP: 1 x 122.4 g ae/ha, up to BBCH 39, PHI N/A	EFSA, 2021; Finland 2018b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 122.4 g ae/ha, BBCH 39 ^[1] , outdoor E/RA: 0.11, 0.17, 0.19, 0.22, 0.26, 0.26, 0.29, 0.290, 0.33, 0.34, 0.35, 0.39	N/A				
	Finland 2018a	N-EU	Trials GAP: 1 x 116–133 g ae/ha BBCH 39 ^[1] , outdoor E/RA: 0.17, 0.29, 0.29, 0.33, 0.34 Residues scaled to intended cGAP, mean scaling factor 0.72: E/RA: 0.116, 0.207, 0.209, 0.230, 0.252					
	Finland 2018b	N-EU	Trials GAP: 1 x 121–133 g ae/ha BBCH 39, outdoor E/RA: 0.11, 0.19, 0.22, 2 x 0.26, 0.35 ^[2] , 0.39 Residues scaled to intended cGAP, mean scaling factor 0.70: E/RA: 0.077, 0.136, 0.149, 0.183, 0.187, 0.250, 0.268					
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 90 g ae/ha, BBCH 30-39, PHI N/A, outdoor E/RA: 0.11, 0.17, 0.19, 0.22, 0.26, 0.26, 0.29, 0.290, 0.33, 0.34, 0.35, 0.39 Residues scaled to intended cGAP E/RA: 0.077, 0.116, 0.136, 0.149, 0.183, 0.187, 0.207, 0.209, 0.230, 0.250, 0.252, 0.268	0.197	0.268	0.566	2	Yes

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA†	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley, straw	EFSA, 2021; Finland 2018b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 122.4 g ae/ha, BBCH 39 ^[1] , outdoor E/RA: 0.24, 0.36, 0.44, 0.48, 0.80, 0.88, 0.94, 1.20, 1.29, 1.70, 1.71, 1.86	N/A				
	Finland 2018a	N-EU	Trials GAP: 1 x 116–133 g ae/ha BBCH 39 ^[1] , outdoor E/RA: 0.24, 0.48, 0.80, 1.71, 1.86 Residues scaled to intended cGAP, mean scaling factor 0.72: E/RA: 0.161, 0.344, 0.550, 1.327, 1.350					
	Finland 2018b	N-EU	Trials GAP: 1 x 121–133 g ae/ha BBCH 39, outdoor E/RA: 0.36, 0.44, 0.88, 0.94, 1.20, 1.29, 1.70 Residues scaled to intended cGAP, mean scaling factor 0.70: E/RA: 0.259, 0.309, 0.629, 0.671, 0.812, 0.886, 1.195					
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 90 g ae/ha, BBCH 30-39, PHI N/A, outdoor E/RA: 0.24, 0.36, 0.44, 0.48, 0.80, 0.88, 0.94 ^[2] , 1.20, 1.29, 1.70, 1.71, 1.86 Residues scaled to intended cGAP E/RA: 0.161, 0.259, 0.309, 0.344, 0.550, 0.629, 0.671, 0.812, 0.886, 1.195, 1.327, 1.350	0.65	1.35	2.370	Not relevant for animal feed items	

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) $E = RA^{\dagger}$	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat, grain→ Oat, Rye, Triticale grain Zonal cGAP: 1 x 122.4 g ae/ha, up to BBCH 39, PHI N/A	EFSA, 2021; Finland 2018b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 122.4 g ae/ha, BBCH 39 ^[1] , outdoor E/RA: 0.31, 0.36, 0.40, 0.44, 0.45, 0.52, 0.65, 0.96, 1.06, 1.26 Residues scaled to EU cGAP: E/RA: 0.46, 0.52, 0.58, 0.66, 0.66, 0.77, 0.87, 1.01, 1.01, 1.47	N/A				
	EFSA, 2005; EFSA, 2021	N-EU	Trials GAP: 1 x 149-152 g ae/ha, BBCH 49 E/RA: 1.06, 1.26 Residues scaled to intended cGAP, mean scaling factor 0.60: E/RA: 0.640, 0.746					
	Finland, 2018b; EFSA, 2021	N-EU	Trials GAP: 1 x 79-85 g ae/ha, BBCH 37-39 E/RA: 0.31, 0.36, 0.40, 0.44, 0.45, 0.52, 0.65, 0.96 Residues scaled to intended cGAP, mean scaling factor 1.09: E/RA: 0.340, 0.381, 0.429, 0.483, 0.488, 0.564, 0.741, 1.08					

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) $E = RA^{\dagger}$	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 90 g ae/ha, BBCH 30-39, PHI N/A, outdoor Residues scaled to intended cGAP: E/RA: 0.340, 0.381, 0.429, 0.483, 0.488, 0.564, 0.64, 0.741, 0.746, 1.08	0.526	1.08	1.767	3 (Wheat, Oat) 5 (Rye)	Yes
Wheat, straw→ Oat, Rye, Triticale straw	EFSA, 2021; Finland 2018b	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 122.4 g ae/ha, BBCH 39, outdoor E/RA: 2 x 0.26, 0.33, 0.37, 0.38, 0.41, 0.43, 0.58, 0.81, 1.40 Residues scaled to EU cGAP: E/RA: 0.39, 0.40, 0.48, 0.49, 0.55, 0.55, 0.61, 0.63, 0.65, 2.17	N/A				
	EFSA, 2005; EFSA, 2021	N-EU	Trials GAP: 1 x 149-152 g ae/ha, BBCH 49 E/RA: 0.58, 0.81 Residues scaled to intended cGAP, mean scaling factor 0.86: E/RA: 0.35, 0.48	N/A				
	Finland, 2018b; EFSA, 2021	N-EU	Trials GAP: 1 x 79-85 g ae/ha, BBCH 37-39 E/RA: 2 x 0.26, 0.33, 0.37, 0.38, 0.41, 0.43, 1.40 Residues scaled to intended cGAP, mean scaling factor 1.09: E/RA: 0.285, 0.293, 0.358, 0.402, 0.406, 0.445, 0.461, 1.595	N/A				

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) $E = RA^{\dagger}$	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 90 g ae/ha, BBCH 30-39, PHI N/A, outdoor Residues scaled to intended cGAP: E/RA: 0.285, 0.293, 0.35, 0.358, 0.402, 0.406, 0.445, 0.461, 0.480, 1.595	0.404	1.595	2.059	Not relevant for animal feed items	
Maize, grain	New trials (Study No. 201513 and GHE-P-10534)	N-EU	Trials GAP: 1 x 125 g ae/ha, BBCH 32, PHI 90d, outdoor E/RA: 0.04, 0.16, 0.17, 0.24, 0.25, 0.32, 0.34, 0.38, 0.41 Residues scaled to intended cGAP, mean scaling factor 0.82 E/RA: 0.03, 0.13, 0.14, 0.20, 0.21, 0.26, 0.27, 0.32, 0.33	N/A				
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 102 g ae/ha, BBCH 30-32, PHI 90d, outdoor Residues scaled to intended cGAP: E/RA: 0.029, 0.13, 0.138, 0.201, 0.212, 0.264, 0.274, 0.323, 0.328	0.212	0.328	0.633	2	Yes
Maize, silage (forage)	New trials (Study No. 201513 and GHE-P-10534)	N-EU	Trials GAP: 1 x 125 g ae/ha, BBCH 32, PHI 60d, outdoor E/RA: 0.27, 0.33, 0.49, 0.91 Residues scaled to intended cGAP, mean scaling factor 0.83: E/RA: 0.231, 0.275, 0.376, 0.78	N/A				

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) $E = RA^{\dagger}$	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 102 g ae/ha, BBCH 30-32, PHI 60d, outdoor Residues scaled to intended cGAP: E/RA: 0.231, 0.275, 0.376, 0.78	0.326	0.78	1.417	Not relevant for animal feed items	
Maize, stover (straw)	New trials (Study No. 201513 and GHE-P-10534)	N-EU	Trials GAP: 1 x 125 g ae/ha, BBCH 32, PHI 90d, outdoor E/RA: 0.12, 0.22, 0.53, 0.67, 0.69, 0.72, 0.93, 1.03, 1.25 Residues scaled to intended cGAP, mean scaling factor 0.82: E/RA: 0.107, 0.179, 0.454, 0.531, 0.550, 0.552, 0.789, 0.817, 1.055	N/A				
	Overall supporting data for cGAP	N-EU	Intended cGAP: 1 x 102 g ae/ha, BBCH 30-32, PHI 90d, outdoor Residues scaled to intended cGAP: E/RA: 0.107, 0.179, 0.454, 0.531, 0.550, 0.552, 0.789, 0.817, 1.055	0.55	1.055	1.764	Not relevant for animal feed items	
Onion	Finland, 2008	N-EU	GAP on which MRL/EU a.s. assessment is based: 100 + 200 g ae/ha ^[3] , BBCH 13-16, PHI 42-66d, outdoor E/RA: <0.01, 2 x 0.02, 0.04, 0.05, 0.17	N/A				

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Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA†	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials (Study No. GHE-P-12680)	N-EU	Trials GAP: 100 + 200 g ae/ha ^[3] , BBCH 13-16, PHI 44d, outdoor E/RA: 0.025, 0.03					
	New trials (Study GHE-P-7289)	N-EU	Trials GAP: 147-150 g ae/ha, BBCH 14-15, PHI 62d, outdoor E/RA: 0.08, 0.14					
	Overall supporting data for cGAP	N-EU	Intended GAP: 1 x 120.24 g ae/ha, BBCH 11-16, PHI 42d, outdoor E/RA: <0.01, 2 x 0.02, 0.025, 0.03, 0.04, 0.05, 0.08, 0.14, 0.17 Residues scaled, mean scaling factor of 0.60-0.65 E/RA: <0.01, 2 x 0.012, 0.014, 0.018, 0.022, 0.033, 0.060, 0.10, 0.114	0.016 0.022	0.10 0.114	0.148 0.2	0.5	Yes

N/A: not applicable

* Source of EU MRL: Reg. (EU) 2021/1807

† Residue definition for risk assessment and monitoring: Sum of clopyralid, its salts and conjugates, expressed as clopyralid.

[1] The RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since cereal grain is not yet formed, only the stems are elongating between these growth stages. Therefore trials conducted at BBCH 39-45 can be considered to support the cGAP.

[2] Application occurred at BBCH 45 and the RMS considered it to be belong in the same cereals residue population with the applications that occurred at BBCH 39.

[3] Although 2 applications were made in the onion residue trials, the applications were ca. 1 month apart and it is generally accepted that it is the final application that determines the final residue, therefore these data are suitable to support the intended 1 application GAP.

7.2.3.2 Conclusion on the magnitude of residues in plants

Sugar beet is a major crop in the N-EU (central/northern regulatory zone) and **Sugar beet, tops** are an animal feed item. The critical GAP is for one application at 90-120 g ae/ha, at BBCH 12-39, PHI 42 days, which is less critical than the zonal cGAP (one application 150-200 g ae/ha, at BBCH 31-39, and 42 day PHI) for product GF-2000 in the central regulatory zone. To support the intended cGAP, eight trials on sugar beet are available (1 x 125 g ae/ha, BBCH 39, PHI 100-134). The data submitted show that no exceedance of the current EU MRL will occur. An EU MRL is not relevant for animal feed items. In accordance with SANTE/2019/12752, data on sugar beet may be extrapolated to support fodder beet, red beet, and mangels, which is the case here. The uses are considered acceptable.

Oilseed rape is a major crop in northern Europe (central/northern regulatory zone). The intended critical GAP is for one application at 120 g ae/ha, at BBCH 30-51. To support the zonal cGAP, twelve trials on oilseed rape are available at the cGAP. One trial was not relied upon, as the residue was identified as an outlier according to the Dixon's Q-test. This approach was previously accepted by member states using the same dataset (GF-3488 dRRs). The data submitted show that no exceedance of the current EU MRLs will occur. The uses are considered acceptable..

Barley grain is a major crop in northern Europe (central/northern regulatory zone) and **Barley, straw** is an animal feed item. The critical GAP in the northern residues zone is for one application at 120 g ae/ha, at BBCH 30-32. The EF-243 GAP is within this zonal cGAP. Twelve trials on barley are available. To support the intended cGAP for EF-243, all residues have been scaled to the intended cGAP rate (90 g ae/ha). Although the trials were conducted at BBCH 39-45, during the EU evaluation the RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since grain is not formed, only the stems are elongating between these growth stages. Therefore trials conducted at BBCH 39 can be considered to support the cGAP. The single trial that applied clopyralid at BBCH 45 is relied upon as application is at a worst-case later growth stage, yet the residues are comparable to those observed when application was at BBCH 39. The barley data is not combined with the wheat data, as the datasets arise from different populations (Mann-Whitney U-Test). The data submitted show that no exceedance of the current EU MRL will occur. An EU MRL is not relevant for straw. The use is considered acceptable.

Wheat grain is a major crop in northern Europe (central/northern regulatory zone) and **Wheat, straw** is an animal feed item. The critical GAP in the northern residues zone is for one application at 120 g ae/ha, at BBCH 30-32. The EF-243 GAP is within this zonal cGAP. Ten trials on wheat are available. To support the intended cGAP for EF-243, all residues have been scaled to the intended cGAP rate (90 g ae/ha). Although some trials were conducted at BBCH 37-39, during the EU evaluation the RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since grain is not yet formed and only the stems are elongating between these growth stages. Therefore trials conducted at BBCH 37-39 can be considered to support the cGAP. The wheat data is not combined with the barley data, as the datasets arise from different populations (Mann-Whitney U-Test). The wheat dataset is more critical and is therefore used for extrapolation to oat, rye, and triticale in accordance with SANTE/2019/12752. The data submitted show that no exceedance of the current EU MRL will occur. An EU MRL is not relevant for straw. The use is considered acceptable.

Maize (grain) is a major crop in northern Europe (central/northern regulatory zone), and **Maize, forage** and **Maize, stover** are animal feed items. The intended critical GAP is for one application at 102 g ae/ha, at BBCH 30-32, PHI 90 days. To support the cGAP, nine trials on maize, grain and stover are available and four trials on maize, forage are available. All residues have been scaled to the intended cGAP. The data submitted show that no exceedance of the current EU MRL will occur. An EU MRL is not relevant for animal feed items. The use is considered acceptable.

Onions are a major crop in northern Europe (central/northern regulatory zone). The critical GAP is for one application at 120.24 g ae/ha, at BBCH 11-16, PHI 42 days. To support the cGAP, eight trials on onions are available at a more critical GAP (1 x 100 + 1 x 200 g ae/ha, BBCH 13-16, PHI 42-66 days). The interval

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between applications was *ca.* 1 month, and it is recognised that the final application generally determines residues in samples at harvest. Thus, the trials with two applications may be used to support the proposed GAP with a single application. All residues have been scaled to the cGAP rate. The PHIs in the supervised residue trials ranged from 42 to 66 days, but all trials were conducted at matching growth stages to the intended GAP. Therefore, all trials are considered suitable to support the intended GAP. The data submitted show that no exceedance of the current EU MRL will occur. Even if the dataset is used unscaled, the data submitted show that the unscaled residues do not exceed the current MRL (HR<MRL). Therefore it can confidently be asserted that residues arising from the intended cGAP will not exceed the current MRL. The use is considered acceptable.

zRMS comments:	<p>The zRMS agrees with the conclusions for the intended uses, except for the oilseed rape and sugar beet due to the reasons set out in point 7.2.2.1.</p> <p>Residue trials on barley, wheat, oat, triticale, rye, maize, oilseed rape, sugar beet and onion were evaluated at EU level. The proposed GAP is within the evaluated EU GAP.</p> <p>For maize and onion the additional trials were provided by the applicant.</p> <p>There were no exceedances of residues above the current MRLs for these crops.</p> <p>The proposed application on barley, wheat, oat, triticale, rye, maize oilseed rape, sugar beet and onion is acceptable.</p>
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7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The inputs for the dietary burden are listed below. All uses in the Article 43 procedure have been included at their worst-case residue endpoints across both residue zones (NEU/SEU). In addition, and in line with the approach in EFSA 2021, all other feed crops on which the use of clopyralid is authorized according to Regulation (EC) No 396/2005, e.g., for which the existing EU MRL is set above the LOQ, have been included. Input values for Article 43 uses that i) were not considered or ii) are more critical than those evaluated as part of EFSA 2021 have been summarized at the top of the table for clarity. As risk assessment values could not be retrieved for all uses listed, the MRL value was used. EFSA have previously noted that this can lead to a possible overestimation of the actual livestock dietary exposure to clopyralid residues. Input values can be found in Table 7.2-10.

To avoid over conservative calculations, the potato MRL (0.5 mg/kg) was not included in this assessment. There is currently no registered GAP for potatoes, and it is unlikely that other register holders would have a registration on potatoes because clopyralid is highly phytotoxic to potatoes. DAS (now Corteva Agriscience) has a label recommendation to kill volunteer potatoes.

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Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized within the Art. 43 procedure and all other feed crops on which the use of clopyralid is authorized according to Regulation (EC) No 396/2005, for which the existing EU MRL is set above the LOQ)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Feed items related to the Article 43 product renewal process				
Corn, field, forage/silage	0.60	STMR (GF-2895 NEU)	1.41	HR (GF-2895 NEU)
Corn, field, stover (fodder)	0.81	STMR (GF-2895 NEU)	1.95	HR (GF-2895 NEU)
Corn, pop (stover)	0.81	STMR (GF-2895 NEU)	1.95	HR (GF-2895 NEU)
Millet, straw	0.57	STMR (GF-2895 SEU)	1.86	HR (GF-2895 SEU)
Sorghum, forage	0.70	STMR (GF-2895 SEU)	0.83	HR (GF-2895 SEU)
Sorghum, grain, stover	0.57	STMR (GF-2895 SEU)	1.86	HR (GF-2895 SEU)
Sorghum, silage	0.42	STMR x PF (0.6) ^(a) (GF-2895 SEU)	0.5	HR x PF (0.6) ^(a) (GF-2895 SEU)
Millet, grain	0.11	STMR (GF-2895 SEU)		
Sorghum, grain	0.11	STMR (GF-2895 SEU)		
Corn, field (Maize)	0.30	STMR (GF-2895 NEU)		
Corn, pop	0.30	STMR (GF-2895 NEU)		
Corn, field, milled by-products	0.30	STMR (GF-2895 NEU) x PF(1) ^(a)		
Corn, field, hominy meal	1.80	STMR (GF-2895 NEU) x PF(6) ^(a)		
Corn, field, gluten feed	0.75	STMR (GF-2895 NEU) x PF(2.5) ^(a)		
Corn, field, gluten meal	0.65	STMR (GF-2895 NEU) x PF(1) ^(a)		
Feed items related to EFSA Journal 2021;19(1):6389 https://doi.org/10.2903/j.efsa.2021.6389				
Barley, straw	0.91	STMR (Barley, NEU)	1.86	HR (Barley, NEU)
Grass, forage (fresh)	7.08	STMR (NEU)	15.16	HR (NEU)
Grass, hay	24.78	STMR (NEU) x PF (3.5) ^(a)	53.2	HR (NEU) x PF (3.5) ^(a)
Grass, silage	11.33	STMR (NEU) x PF (1.6) ^(a)	24.32	HR (NEU) x PF (1.6) ^(a)
Oat, straw ^(b)	0.58	STMR (Wheat, SEU)	2.17	HR (Wheat, NEU)
Rye, straw ^(b)	0.58	STMR (Wheat, SEU)	2.17	HR (Wheat, NEU)
Triticale, straw ^(b)	0.58	STMR (Wheat, SEU)	2.17	HR (Wheat, NEU)
Wheat, straw ^(b)	0.58	STMR (Wheat, SEU)	2.17	HR (Wheat, NEU)
Barley, grain	0.33	STMR (Barley, SEU)		
Oat, grain ^(b)	0.72	STMR (Wheat, NEU)		
Rye, grain ^(b)	0.72	STMR (Wheat, NEU)		
Triticale, grain ^(b)	0.72	STMR (Wheat, NEU)		
Wheat, grain ^(b)	0.72	STMR (Wheat, NEU)		
Brewer's grain, dried	1.09	STMR (Barley, SEU) x PF (3.3) ^(a)		

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Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Distiller grain, dried	2.38	STMR (Wheat, NEU) x PF (3.3) ^(a)		
Wheat gluten, meal	1.3	STMR (Wheat, NEU) x PF (1.8) ^(a)		
Wheat, milled by products	5.04	STMR (Wheat, NEU) x PF (7) ^(a)		
Feed items related to the previous evaluations (as considered in the evaluation report by the EMS (Finland, 2018b))				
Beet mangel, fodder	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Beet, sugar (tops)	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Cabbage, heads (leaves)	0.23	STMR (EFSA, 2011)	1.52	HR (EFSA, 2011)
Corn, field (stover)^(e)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Corn, pop (stover)^(e)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Kale	1	MRL	1	MRL
Turnip, tops (leaves)	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Swede, roots	0.35	STMR (EFSA, 2011)	0.80	HR (EFSA, 2011)
Turnip, roots	0.35	STMR (EFSA, 2011)	0.80	HR (EFSA, 2011)
Maize, field (grain)^(e)	0.06	STMR (Finland, 2008)		
Maize, pop (grain)^(e)	0.06	STMR (Finland, 2008)		
Cotton	0.5	MRL		
Pea, seed (dry)	0.5	MRL		
Soybean seed	0.5	MRL		
Apple, pomace (wet)	0.05	STMR (EFSA, 2005) x PF (5) ^(a)		
Beet, sugar (dried pulp)	6.30	STMR (EFSA, 2005) x PF (18) ^(a)		
Beet, sugar (ensiled pulp)	1.05	STMR (EFSA, 2005) x PF (3) ^(a)		
Beet, sugar (molasses)	9.80	STMR (EFSA, 2005) x PF (28) ^(a)		
Canola (Rape seed), meal	0.06	STMR (Finland, 2018b) x PF (2) ^(a)		
Citrus, dried pulp	5.00	MRL x PF (10) ^(a)		
Corn, field, milled by products	0.06	STMR (Finland, 2008) x PF (1)^(a)		
Corn, field, hominy meal	0.36	STMR (Finland, 2008) x PF (6)^(a)		
Corn, field, gluten feed	0.15	STMR (Finland, 2008) x PF (2.5)^(a)		
Corn, field, gluten meal	0.06	STMR (Finland, 2008) x PF (1)^(a)		
Cotton, meal	0.65	MRL x PF (1.3) ^(a)		
Flaxseed/Linseed, meal	8.92	STMR (EFSA, 2011) x PF (2) ^(a)		
Peanut, meal	2.00	MRL x PF (2) ^(a)		
Rape, meal	0.06	STMR x PF (2) ^(a,d)		
Soybean, meal	0.65	MRL x PF (1.3) ^(a)		

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Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Soybean, hulls	6.50	MRL x PF (13) ^(a)		
Sunflower, meal	1.00	MRL x PF (2) ^(a)		

(a): Default processing factors as inserted in the Animal model 2017 were used.

(b): Wheat grain and straw data are extrapolated to oats and rye.

(c): Corn, field (stover) and corn, pop (stover) as well as grain are replaced with more critical data from the submitted maize study 201513.

(d): EFSA 2021 indicates an MRL was used as the input value. However, based on the burden calculation results and the fact that the EU cGAP for canola/rape seed is known, the input value was almost certainly an STMR.

The results of the dietary burden calculations are summarised in the following table.

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Table 7.2-11: Results of the dietary burden calculation (without consideration of residues associated with rotational crops)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.761	1.521	19.79	39.55	Dairy cattle	Grass	forage (fresh)	Yes
Cattle (dairy only)	0.761	1.521	19.79	39.55	Dairy cattle	Grass	forage (fresh)	Yes
Sheep (all diets)	0.914	1.934	27.41	58.01	Ram/Ewe	Grass	forage (fresh)	Yes
Sheep (ewe only)	0.914	1.934	27.41	58.01	Ram/Ewe	Grass	forage (fresh)	Yes
Swine (all diets)	0.221	0.407	9.58	17.62	Swine (breeding)	Grass	forage (fresh)	Yes
Poultry (all diets)	0.149	0.204	2.18	2.98	Poultry layer	Cabbage, heads	leaves	Yes
Poultry (layer only)	0.149	0.204	2.18	2.98	Poultry layer	Cabbage, heads	leaves	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

At the time of submission, the dietary burden intakes are within those calculated in the EFSA MRL Reasoned Opinion (EFSA, 2021), which set the animal MRLs in Reg. (EU) 2021/1807. Therefore the new animal MRLs will accommodate the Article 43 uses presented in this submission.

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To account for residues in rotational crops, residues associated with study 190557 have been considered as part of an additional dietary burden calculation. Rotational STMR and HR values have been calculated based on the worse case values across different treatment rates at the 30-day PBI (*e.g.*, residues in OSR whole plant were higher in the 80 g a.e./ha plot than the 125 g a.e./ha plot at the 30-day PBI; therefore, the former values were used). These rotational input values have been extrapolated to similar crops (*e.g.*, residues in wheat/barley whole plant have been extrapolated to other cereal forage items). Input values, extrapolations, and overall data selection are detailed in Table 7.2-12.

Calculated rotational STMR and HR values at the 30-day PBI have been summed with any inputs arising from residues associated with primary uses, thereby giving a worse case dietary burden calculation (*i.e.*, an additive scenario). Where the rotational STMR or HR was <0.01 mg/kg (<LOQ), the rotational residue value was not added to the primary crop input value, assuming a primary use existed. Where rotational residues were present and no primary use exists, input values in the dietary burden contain only residues associated with the crop rotation study. Input values used for the dietary burden calculation can be found in Table 7.2-13, which is effectively an extension of Table 7.2-10 to account for rotational residues.

Table 7.2-12: Rotational residue input values, applicability and data source.

Crop	Rate g ae/ha	PBI days	Residue mg/kg	STMR	HR
Radish root → Carrot, Cassava, Swede, Turnips, and Potato	125	30	4x <0.01*, 0.027, 0.042	<0.01	0.042
Radish tops with leaves → Beet, mangel fodder, Beet, sugar tops, and Turnip tops	125	30	3x <0.01, 0.017**, 0.541, 0.627	<0.01	0.627
Oilseed, whole plant → Rape forage	80	30	4x <0.01, 0.113, 0.212	<0.01	0.212
Cereals, whole plant → Barley, Wheat, Maize, Millet, Sorghum, Rye, Triticale, Oat and Sugar canes forage	125	30	2x <0.01, 0.034, 0.195, 0.515, 0.583	0.115	0.583
Cereals, grain → Barley, Wheat, Maize, Millet, Sorghum, Rye, Triticale, and Oat grain	125	30	2x <0.01, 0.035, 0.053, 0.134, 0.167	0.044	0.167
Cereals, straw → Barley, Wheat, Maize, Millet, Sorghum, Rye, Triticale, Oat, and Rice straw	125	30	2x <0.01, 0.10, 0.159, 0.183, 0.279	0.130	0.279

* One residue value of <0.01 is excluded from the evaluation due to exceedance of FSS.

** Residue value 0.017 is excluded from the evaluation due to exceedance of FSS.

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Table 7.2-13: Input values for the dietary burden calculation (considering residues in rotation, the uses authorized within the Art. 43 procedure and all other feed crops on which the use of clopyralid is authorized according to Regulation (EC) No 396/2005, for which the existing EU MRL is set above the LOQ)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Feed items related to residues in rotated commodities without primary clopyralid uses. Values taken from study 190557				
Barley, forage	0.12	STMR _{rot}	0.583	HR _{rot}
Barley, silage	0.15	STMR _{rot} x PF (1.3) ^(a)	0.76	HR _{rot} x PF (1.3) ^(a)
Millet, forage	0.12	STMR _{rot}	0.583	HR _{rot}
Oat, forage	0.12	STMR _{rot}	0.58	HR _{rot}
Oat, hay	0.35	STMR _{rot} x PF (3) ^(a)	1.75	HR _{rot} x PF (3) ^(a)
Rape, forage	0.01	STMR _{rot}	0.212	HR _{rot}
Rice, straw	0.13	STMR _{rot}	0.279	HR _{rot}
Rye, forage	0.12	STMR _{rot}	0.583	HR _{rot}
Triticale, forage	0.12	STMR _{rot}	0.583	HR _{rot}
Triticale, hay	0.12	STMR _{rot}	0.583	HR _{rot}
Wheat, forage	0.12	STMR _{rot}	0.58	HR _{rot}
Wheat, hay	0.40	STMR _{rot} x PF (3.5) ^(a)	2.04	HR _{rot} x PF (3.5) ^(a)
Carrot, culls	0.01	STMR _{rot}	0.042	HR _{rot}
Cassava/tapioca	0.01	STMR _{rot}	0.042	HR _{rot}
Potato	0.01	STMR _{rot}	0.042	HR _{rot}
Potato, process waste	0.01	STMR _{rot} x PF (1)		
Potato, dried pulp	0.01	STMR _{rot} x PF (1)		
Sugarcane, molasses	3.68	STMR _{rot} x PF (32) ^(a)		
Feed items related to the Article 43 product renewal process				
Corn, field, forage/silage	0.72	STMR (GF-2895 NEU) + STMR _{rot}	1.99	HR (GF-2895 NEU) + HR _{rot}
Corn, field, stover (fodder)	0.94	STMR (GF-2895 NEU) + STMR _{rot}	2.23	HR (GF-2895 NEU) + HR _{rot}
Corn, pop (stover)	0.94	STMR (GF-2895 NEU) + STMR _{rot}	2.23	HR (GF-2895 NEU) + HR _{rot}
Millet, straw	0.70	STMR (GF-2895 NEU) + STMR _{rot}	2.14	HR (GF-2895 NEU) + HR _{rot}
Sorghum, forage	0.82	STMR (GF-2895 NEU) + STMR _{rot}	1.41	HR (GF-2895 NEU) + HR _{rot}
Sorghum, grain, stover	0.70	STMR (GF-2895 NEU) + STMR _{rot}	2.14	HR (GF-2895 NEU) + HR _{rot}
Sorghum, silage	0.49	STMR x PF (0.6) ^(a) (GF-2895 SEU) + STMR _{rot}	0.85	HR x PF (0.6) ^(a) (GF-2895 SEU) + HR _{rot}
Millet, grain	0.154	STMR (GF-2895 NEU) + STMR _{rot}		
Sorghum, grain	0.154	STMR (GF-2895 NEU) + STMR _{rot}		
Corn, field (Maize)	0.30	STMR (GF-2895 NEU) + STMR _{rot}		
Corn, pop	0.30	STMR (GF-2895 NEU) + STMR _{rot}		

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Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Corn, field, milled by-products	0.34	STMR (GF-2895 NEU) + STMR _{rot} x PF(1) ^(a)		
Corn, field, hominy meal	2.06	STMR (GF-2895 NEU) + STMR _{rot} x PF(6) ^(a)		
Corn, field, gluten feed	0.86	STMR (GF-2895 NEU) + STMR _{rot} x PF(2.5) ^(a)		
Corn, field, gluten meal	0.34	STMR (GF-2895 NEU) + STMR _{rot} x PF(1) ^(a)		
Feed items related to EFSA Journal 2021;19(1):6389 https://doi.org/10.2903/j.efsa.2021.6389				
Barley, straw	1.04	STMR (Barley, NEU) + STMR _{rot}	2.14	HR (Barley, NEU) + HR _{rot}
Grass, forage (fresh)	7.08	STMR (NEU)	15.16	HR (NEU)
Grass, hay	24.78	STMR (NEU) x PF (3.5) ^(a)	53.2	HR (NEU) x PF (3.5) ^(a)
Grass, silage	11.33	STMR (NEU) x PF (1.6) ^(a)	24.32	HR (NEU) x PF (1.6) ^(a)
Oat, straw ^(b)	0.71	STMR (Wheat, SEU) + STMR _{rot}	2.45	HR (Wheat, NEU) + HR _{rot}
Rye, straw ^(b)	0.71	STMR (Wheat, SEU) + STMR _{rot}	2.45	HR (Wheat, NEU) + HR _{rot}
Triticale, straw ^(b)	0.71	STMR (Wheat, SEU) + STMR _{rot}	2.45	HR (Wheat, NEU) + HR _{rot}
Wheat, straw ^(b)	0.71	STMR (Wheat, SEU) + STMR _{rot}	2.45	HR (Wheat, NEU) + HR _{rot}
Barley, grain	0.37	STMR (Barley, SEU) + STMR _{rot}		
Oat, grain ^(b)	0.76	STMR (Wheat, NEU) + STMR _{rot}		
Rye, grain ^(b)	0.76	STMR (Wheat, NEU) + STMR _{rot}		
Triticale, grain ^(b)	0.76	STMR (Wheat, NEU) + STMR _{rot}		
Wheat, grain ^(b)	0.76	STMR (Wheat, NEU) + STMR _{rot}		
Brewer's grain, dried	1.23	STMR (Barley, SEU) + STMR _{rot} x PF (3.3) ^(a)		
Distiller grain, dried	2.52	STMR (Wheat, NEU) + STMR _{rot} x PF (3.3) ^(a)		
Wheat gluten, meal	1.38	STMR (Wheat, NEU) + STMR _{rot} x PF (1.8) ^(a)		
Wheat, milled by products	5.35	STMR (Wheat, NEU) + STMR _{rot} x PF (7) ^(a)		
Feed items related to the previous evaluations (as considered in the evaluation report by the EMS (Finland, 2018b))				
Beet mangel, fodder	0.47	STMR (EFSA, 2005)	1.68	HR (EFSA, 2005) + HR _{rot}
Beet, sugar (tops)	0.47	STMR (EFSA, 2005)	1.68	HR (EFSA, 2005) + HR _{rot}
Cabbage, heads (leaves)	0.23	STMR (EFSA, 2011)	1.52	HR (EFSA, 2011)
Corn, field (stover) ^(c)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Corn, pop (stover) ^(c)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Kale	1	MRL	1	MRL
Turnip, tops (leaves)	0.47	STMR (EFSA, 2005)	1.08	HR (EFSA, 2005) + HR _{rot}
Swede, roots	0.35	STMR (EFSA, 2011)	0.842	HR (EFSA, 2011) + HR _{rot}

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Feed commodity	Median dietary burden		Maximum dietary burden	
	Input Value (mg/kg)	Comment	Input Value (mg/kg)	Comment
Turnip, roots	0.35	STMR (EFSA, 2011)	0.842	HR (EFSA, 2011) + HR _{rot}
Maize, field (grain)	0.09	STMR (Finland, 2008) + STMR _{rot}		
Maize, pop (grain)	0.09	STMR (Finland, 2008) + STMR _{rot}		
Cotton	0.5	MRL		
Pea, seed (dry)	0.5	MRL		
Soybean seed	0.5	MRL		
Apple, pomace (wet)	0.05	STMR (EFSA, 2005) x PF (5) ^(a)		
Beet, sugar (dried pulp)	6.30	STMR (EFSA, 2005) x PF (18) ^(a)		
Beet, sugar (ensiled pulp)	1.05	STMR (EFSA, 2005) x PF (3) ^(a)		
Beet, sugar (molasses)	9.80	STMR (EFSA, 2005) x PF (28) ^(a)		
Canola (Rape seed), meal	0.06	STMR (Finland, 2018b) x PF (2) ^(a)		
Citrus, dried pulp	5.00	MRL x PF (10) ^(a)		
Corn, field, milled by-products	0.30	STMR (Finland, 2008) + STMR _{rot} x PF(1) ^(a)		
Corn, field, hominy meal	1.80	STMR (Finland, 2008) + STMR _{rot} x PF(6) ^(a)		
Corn, field, gluten feed	0.75	STMR (Finland, 2008) + STMR _{rot} x PF(2.5) ^(a)		
Corn, field, gluten meal	0.65	STMR (Finland, 2008) + STMR _{rot} x PF(1) ^(a)		
Cotton, meal	0.65	MRL x PF (1.3) ^(a)		
Flaxseed/Linseed, meal	8.92	STMR (EFSA, 2011) x PF (2) ^(a)		
Peanut, meal	2.00	MRL x PF (2) ^(a)		
Rape, meal	0.06	STMR x PF (2) ^(a,d)		
Soybean, meal	0.65	MRL x PF (1.3) ^(a)		
Soybean, hulls	6.50	MRL x PF (13) ^(a)		
Sunflower, meal	1.00	MRL x PF (2) ^(a)		

STMR_{rot}: STMR calculated from rotation crop residue data at the 30d plant-back interval or worst case value at a later plant back.

HR_{rot}: HR calculated from rotation crop residue data at the 30d plant-back interval or worst case value at a later plant back.

(a): Default processing factors as inserted in the Animal model 2017 were used.

(b): Wheat grain and straw data are extrapolated to oats and rye.

(c): Corn, field (stover) and corn, pop (stover) as well as grain are replaced with more critical data from the submitted maize study 201513.

(d): EFSA 2021 indicates an MRL was used as the input value. However, based on the burden calculation results and the fact that the EU cGAP for canola/rape seed is known, the input value was almost certainly an STMR.

The results of the dietary burden containing inputs for rotational residues is presented in Table 7.2-14.

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Table 7.2-14: Results of the dietary burden calculation (with consideration of residues associated with crop rotation at the 30d plant-back interval)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.761	1.524	19.79	39.63	Dairy cattle	Grass	forage (fresh)	Yes
Cattle (dairy only)	0.761	1.524	19.79	39.63	Dairy cattle	Grass	forage (fresh)	Yes
Sheep (all diets)	0.914	1.934	27.41	58.03	Ram/Ewe	Grass	forage (fresh)	Yes
Sheep (ewe only)	0.914	1.934	27.41	58.03	Ram/Ewe	Grass	forage (fresh)	Yes
Swine (all diets)	0.225	0.414	9.75	17.93	Swine (breeding)	Grass	forage (fresh)	Yes
Poultry (all diets)	0.158	0.214	2.31	3.12	Poultry layer	Cabbage, heads	leaves	Yes
Poultry (layer only)	0.158	0.214	2.31	3.12	Poultry layer	Cabbage, heads	leaves	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

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A comparison between the dietary burdens with and without consideration of rotational inputs is presented in Table 7.2-15. For ruminants and swine, consideration of rotational residues results in a maximum burden increase of 1.8%, which illustrates that primary crop residues are driving the dietary burden calculation (principally, grass forage). For poultry, the maximum burden increase is 6.1%, again indicating that primary crop residues are driving the dietary burden calculation (principally, cabbage).

Table 7.2-15: Comparison of dietary burden calculation with consideration of rotated residues expressed as % increase in burden relative to values presented in Table 7.2-11

Relevant groups	Dietary burden expressed in			
	mg/kg bw per day		mg/kg DM	
	Median % Increase	Maximum % Increase	Median % Increase	Maximum % Increase
Cattle (all diets)	0.0	0.2	0.0	0.2
Cattle (dairy only)	0.0	0.2	0.0	0.2
Sheep (all diets)	0.0	0.0	0.0	0.0
Sheep (ewe only)	0.0	0.0	0.0	0.0
Swine (all diets)	1.8	1.7	1.8	1.7
Poultry (all diets)	6.1	4.8	6.1	4.8
Poultry (layer only)	6.1	4.8	6.1	4.8

(%): percent increase when considering rotated residues VS primary crop inputs alone.

For the livestock assessed, the increase in dietary burden results in estimated residues in animal commodities that are within the new EU MRLs (Reg. (EU) 2021/1807). Furthermore, no dietary risk assessment concerns are noted. A minimum 30-day PBI for the livestock feed uses assessed within the dietary burden calculation is supported.

zRMS comment: new dietary burden calculations were performed, taking into account STMR and HR values from residues trials for proposed uses.

New data requirements (Regulation (EU) No 283/2013)

Animals	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Above 0.004 mg/kg bw	Maximum burden (mg/kg DM)	Highest contributing commodities
Beef cattle	0,019	0,043	Yes	1,81	Corn, field forage/silage
Dairy cattle	0,028	0,064	Yes	1,66	Corn, field forage/silage
Ram/Ewe	0,023	0,047	Yes	1,40	Barley straw
Lamb	0,029	0,060	Yes	1,40	Barley straw
Pig (breeding)	0,013	0,029	Yes	1,25	Corn, field forage/silage
Pig (finishing)	0,013	0,026	Yes	0,86	Rye grain
Poultry broiler	0,030	0,061	Yes	0,86	Rye grain
Poultry layer	0,034	0,071	Yes	1,04	Corn, field forage/silage
Turkey	0,026	0,053	Yes	0,74	Rye grain

7.2.4.1 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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No new data were submitted in the framework of this application. As the dietary burden intakes are within those calculated in the EFSA MRL Reasoned Opinion (EFSA, 2021), the existing animal MRLs accommodate the Article 43 uses presented in this submission (including consideration of rotational residues) and no further evaluation is warranted.

Livestock feeding studies were evaluated during renewal of clopyralid and are summarised below.

Reference: EFSA, 2018a

“GLP- and guideline-compliant feeding studies with poultry and cattle analysing for all compounds covered by the residue definition for risk assessment and within a time period covered by storage stability data were presented. Residues in poultry matrices at the highest dose group at sampling day 28 were highest in eggs (up to 0.046 mg/kg), followed by liver (up to 0.034 mg/kg) and muscle (up to 0.017 mg/kg), whereas very little residue were quantified in fat (0.005 mg/kg). Residues in cow’s milk were in the highest dosing group already at day 2 (up to 0.0175 mg/kg) and remained at this level. Residue levels at the highest dose group were observed also in all other organs (up to 0.484 mg/kg in muscle, up to 1.962 g/kg in liver, up to 25.3 mg/kg in kidney and up to 2.131 mg/kg in average fat).”

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

zRMS comments:	According to the residue data from livestock feeding studies presented in EFSA Journal (2021), no exceedance of MRL was observed in any animal commodity.
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7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

Clopyralid is stable under pasteurisation, baking, brewing, boiling and sterilisation conditions (EFSA, 2018a).

New data are submitted in the framework of this application.

Table 7.2-16: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Sum of clopyralid, its salts and conjugates, expressed as clopyralid					
Wheat / bran	4	5.7	N/A	-	EFSA, 2021
Wheat / white flour	4	0.25	N/A	-	EFSA, 2021
Wheat / wholemeal flour	2	1	N/A	-	EFSA, 2021
Wheat / germ	2	3.3	N/A	-	EFSA, 2021
Wheat / white bread	2	0.1	N/A	-	EFSA, 2021
Wheat / wholemeal bread	2	0.6	N/A	-	EFSA, 2021

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Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Barley / malt sprouts	2	0.2	N/A	-	EFSA, 2021
Barley / brewing malt	2	0.7	N/A	-	EFSA, 2021
Barley / spent grains and flocs	2	0.2	N/A	-	EFSA, 2021
Barley / brewer's yeast	2	0.1	N/A	-	EFSA, 2021
Barley / beer	2	0.1	N/A	-	EFSA, 2021
Oilseed rape / oil	15	0.1	NA		EFSA, 2005
New data					
Sugar beet / pulp	3	0.7	N/A	-	Report GH-C 3305 and Report No. 181493
Sugar beet / molasses	3	4.4	N/A	-	
Sugar beet / brown sugar	2	0.9	N/A	-	
Sugar beet / sugar juice	2	0.5	N/A	-	
Sugar beet / non-refined sugar	2	4.1	N/A	-	
Sugar beet / white sugar	3	0.3	N/A	-	

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

Residues on the intended uses do exceed the trigger value for processing studies (0.1 mg/kg). Data on sugar beet and wheat processed commodities summarised above are used to refine dietary burden and consumer intakes where necessary. Default processing factors can be used for all other commodities.

zRMS comments:	Processing data were evaluated in the EU review for clopyralid and shows the stability of clopyralid in different processing condition. Additional study is not required.
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7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation. Three nature of residues studies in three rotational crops covering the plant-back interval (PBI) of *ca* 30, 120 and 365 days are available. According to the results of the confined rotational crop studies submitted in the framework of clopyralid's renewal process, residues above the LOQ may be expected in rotational crops. Therefore, EFSA recommended the submission of rotational field crop studies to either confirm the proposed MRLs or to modify the proposed MRLs if necessary (EFSA, 2018a).

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

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7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

A new study for residues in succeeding crops has been submitted by the applicant in the framework of this application. The study is summarized in the table below. The detailed results are presented in Appendix 2.

Table 7.2-17: Summary of available studies in field rotational crops

Primary crop	Rate (g ae/ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
New data					
Bare soil	3 rates: 60, 80, 125 (1 application to achieve targeted plantback intervals)	Leafy and Brassica vegetables	Head cabbage	30, 90, 125, 270-365	Devine, C., 2021, Study No. 190557
		Root and tuber vegetables	Radish		
		Oilseeds	Oilseed rape, Sunflower		
		Cereals	Barley, Wheat		

Radish root and radish tops with leaves samples from three sites in Northern France, Poland and Southern France were stored for longer than 443 days and were excluded from further evaluations to determine plantback intervals and the impact of rotational crops on livestock dietary burdens.

Residues of clopyralid in head cabbage were <0.01 mg/kg at all application rates and at all plantback intervals (PBI). Residues of clopyralid in radish roots ranged from <0.01 to 0.042 mg/kg at all application rates at the shortest PBI of 30 days and were < 0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in oilseed rape and sunflower seeds were <0.01 mg/kg at all application rates and at all PBI. Residues of clopyralid in barley and wheat grain ranged from <0.01 to 0.17 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.037 mg/kg at all application rates at a 90-day or longer PBI.

The residues of clopyralid in rotational crops representative of food commodities are all well below the established EU MRLs which, for most food crop commodities, are 0.5 mg/kg or higher (Table 7.2-18).

Further, the EU MRL for chicory roots is set at a lower (default) value of 0.05 mg/kg, which is still higher than the maximum residue value that was observed for the representative root crop (*i.e.*, 0.042 mg/kg for radish roots at 30-day PBI at 125 g ae/ha treatment rate).

Table 7.2-18: Summary of Clopyralid Residues in Representative Food Commodities at Treatment Rate 125 g ae/ha and 30-day PBI and EU MRL Compliance

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Representative Food Commodity → Crop Group	Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD cal- culator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL com- pliance
Head cabbage → Leafy and Brassica vegetables	6x <0.01	0.01	0.01	0.010	0.5 (Leafy vegetables) 1 (Leafy brassicas) 3 (Head cabbage cauliflower)	Yes
Radish root → Root and tuber vegetables	4 x <0.01*, 0.027, 0.042	0.01	0.042	0.072	0.5 (Potato, carrot, radish) 1 (Beetroots, sugarbeets) 1.5 (Turnips, swedes)	Yes
Oilseed rape, Sun- flower seed → Oilseeds	6x <0.01	0.01	0.01	0.010	0.5 (Oilseeds) 20 (Linseed)	Yes
Barley, Wheat grain → Cereals grain	2x <0.01, 0.035, 0.053, 0.13, 0.17	0.044	0.17	0.335	2 (Barley, maize, rice) 3 (Wheat, oat) 5 (Rye)	Yes

* One residue value of <0.01 mg/kg is excluded from the evaluation due to exceedance of frozen storage stability.

~~For livestock feed commodities, residues of clopyralid in radish tops with leaves ranged from <0.01 to 0.54 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.025 mg/kg at all application rates at a 90-day or longer PBI.~~ Residues of clopyralid in oilseed rape and sunflower whole plant (forage commodity) ranged from <0.01 to 0.21 mg/kg at all application rates at the shortest PBI of 30 days and were <0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in the rest of the oilseed rape and sunflower plants after seed harvest ranged from <0.01 to 0.089 mg/kg at all application rates at the shortest PBI of 30 days and were <0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in barley and wheat whole plant (forage commodity) ranged from <0.01 to 0.58 mg/kg at all application rates at the shortest PBI of 30 days, ranged from <0.01 to 0.084 mg/kg at all application rates at the 90-day PBI, and ranged from <0.01 to 0.017 at all application rates at a 125-day or longer PBI. Residues of clopyralid in the rest of the barley and wheat plants after seed harvest ranged from <0.01 to 0.28 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.036 mg/kg at all application rates at a 90-day or longer PBI.

The EU MRL for sugar canes, which can be represented by cereal forages, is 0.05 mg/kg (default). Based on the available whole plant data, it is recommended that sugar canes not be planted for 125 days after application of clopyralid.

EU MRLs are not currently set on livestock feed commodities; however, the potential clopyralid residues in rotational crops were considered when estimating livestock dietary burdens. The potential clopyralid residues in rotational crops do not significantly increase livestock dietary burdens, which are driven by

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registered uses on cereals and pasture. For the livestock assessed, the small increases in dietary burdens result in estimated residues in animal commodities that are within the new EU MRLs under Reg. (EU) 2021/1807. Therefore, a minimum 30-day PBI for the livestock feed uses assessed within the dietary burden calculation is supported.

Conclusion on rotational crops studies

Residues of clopyralid in rotational crop food commodities are anticipated to be less than the established EU MRLs. Residues in rotational crop livestock feed commodities were taken into consideration when estimating the livestock dietary burdens. No mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid.

zRMS comments:	The study demonstrated that no residues are expected in succeeding leafy, root and tuber crops or oilseed seeds and cereal grain. The residue levels did not exceed the current MRLs for any of the crops in respective crop groups.
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7.2.7 Other / special studies (KCA6.10, 6.10.1)

In accordance with SANTE/11956/2016 rev. 9, crops included in this submission are considered melliferous, application of clopyralid is close to flowering and the active substance is systemic, therefore data are required. A honey study was completed in 2021 and will be submitted with a new MRL application in 2022.

zRMS comments:	<p>The only melliferous crop requested is rapeseed, which is not accepted due to the reasons provided in point 7.2.2.1. Beet, maize, cereals and onion from seeds are not melliferous crops. Only oilseed rape is a melliferous plant.</p> <p>When available, the results of residue studies on rapeseed honey should be submitted for the evaluation.</p>
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A study was conducted to determine residue levels of clopyralid in nectar, pollen, plants, and honey after one application of a clopyralid-containing formulation, GF-1966, under semi-field conditions to winter oilseed rape plants (Study ID DAS 200098).

The study was conducted in 2020 as six separate field trials, with four trials located in N-EU (Northern and Southern Germany, Romania, and The Netherlands) and two trials located in S-EU (Southern France and Spain). The study consisted of two treatment groups per trial: the test item group T (two replicates- Ta and Tb) and an untreated control C (one replicate). There was one application of GF-1966 (720 g a.e./kg SG) in the test item treatment group at a target rate of 125 g a.e./ha in water spray volume of 200-300L/ha at BBCH 55 for trials -02, -03, -05, -06 and -07 and BBCH 57 for trial -04. Winter oilseed rape plants were collected six times after application (up to 25 days after application [DAA]), pollen and forager bees for nectar preparation were collected six times after application (up to 34 DAA) and honey was collected once in all trials (17-49 DAA) for subsequent residue analysis. The maximum period of frozen storage from the day of sampling until extraction was 313 days for matrices honey, pollen, nectar, and plant.

The study supports a proposed MRL of 0.15 mg/kg for clopyralid in honey and was submitted to EMS Finland in 2022 (EFSA-Q-2022-00622).

A summary of the study is presented in Appendix 2.

zRMS	The applicant provided the honey study report. The zRMS evaluated the study and found the study acceptable. The application rate used in the study was comparable to the proposed use rate for oilseed rape. The residues in honey were 4x <0.01, 0.0274 and 0.0695 mg/kg. Calculated
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com-ments :

STMR is 0.014 mg/kg and unrounded MRL 0.117 mg/kg (rounded 0.15 mg/kg). Current MRL for clopyralid in honey is 0.05 mg/kg and it is potentially exceeded.
EFSA (2024): The Applicant submitted a request to the competent national authority in Finland to modify the existing MRLs for clopyralid in honey.
To accommodate clopyralid residues in honey from the authorised use on oilseed rape (identified as the critical GAP for residues in honey), it is proposed to raise the existing MRLs in honey from the limit of quantification of 0.05 to 0.15 mg/kg. The data submitted in support of the request were found to be sufficient to derive new MRL for honey.

B.5 | RECOMMENDED MRLS

Code ^a	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Existing residue definition: Clopyralid				
Proposed enforcement residue definition: Sum of clopyralid, its salts and conjugates, expressed as clopyralid				
1040000	Honey and other apiculture products ^b	0.05*	0.15	MRL proposal based on a single honey residue study conducted by Applicant. The proposal is supported by sufficient data to show that consumer risks are identified.

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.
^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.
^bAccording to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed with group.
*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

EFSA (2024) concluded the short-term and long-term intake of clopyralid residues in honey, resulting from the authorised use of clopyralid on oilseed rape notified in the MRL assessment, is unlikely to present a risk to consumer health.

ARfD	0.17 mg/kg bw (European Commission, 2021b)
Highest IESTI, according to EFSA PRIMo	Honey: 0.1% of ARfD

ADI	0.15 mg/kg bw per day (European Commission, 2021b)
Highest IEDI, according to EFSA PRIMo	29% ADI (NL toddler)
	Contribution of crops assessed: Honey: <0.001% of ADI (DE child)

Taking into account national harmonisation arrangements, the use of Lontrel 300 in oilseed rape is accepted conditionally, until a new MRL value for honey is published. Once the new MRLs for honey are published in the Regulation, the report should be revised.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

The input values in the following table were used to estimate consumer risk using the EFSA PRIMo Rev 3.1. The chronic dietary risk assessment is based on current MRLs from Reg. 2018/1514-2021/1807, including STMR and HR for honey. apart from indicated animal products, wheat, and oat which considered

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MRLs adopted in the Article 6 MRL Evaluation Report (EFSA Journal 2021; 19(1):6389).

The acute dietary assessments are performed based on MRL inputs only for the commodities for which GAPs are notified in the clopyralid Article 43 process.

Table 7.2-19: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Clopyralid common moiety (sum of clopyralid, its salts and conjugates, expressed as clopyralid)				
Onion, Garlic, Shallot	0.5	EU MRL/Reg. 2021/1807	0.5	EU MRL/Reg. 2021/1807
Spring onions	0.7		0.7	
Broccoli	1.5	STMR (NEU) flowering brassica, section 7.2.3.1 of this submission EFSA(2011)	0.85-0.73	HR (NEU) flowering brassica, section 7.2.3.1 of this submission EFSA(2011)
	0.27-0.3			
Cauliflower	3.0	EU MRL/Reg. 2021/1807	0.85-1.42	EU MRL/Reg. 2021/1807
	0.27-0.29	STMR (NEU) flowering brassica, section 7.2.3.1 of this submission EFSA(2011)		
Other Flowering brassica	0.5	EU MRL/Reg. 2021/1807	0.85-0.5	EU MRL/Reg. 2021/1807
	0.27	STMR (NEU) flowering brassica, section 7.2.3.1 of this submission		
Head cabbage	3.0	EU MRL/Reg. 2021/1807	0.91-1.52	HR (NEU) flowering brassica, section 7.2.3.1 of this submission EFSA(2011)
	0.21-0.23	STMR (NEU) flowering brassica, section 7.2.3.1 of this submission EFSA(2011)		
Brussel sprouts	0.5	EU MRL/Reg. 2021/1807	0.5	EU MRL/Reg. 2021/1807
Spinach, Chard/beet leaves	1.0		1.0	

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Oilseed rape, Mustard seed, Borage seed	0.5		0.5	
Linseed	20		20	
Barley, Maize	2.0		2.0	
Rye	5.0		5.0	
Oat, Wheat	3.0	EU MRL/Reg. 2021/1807	3.0	EU MRL/Reg. 2021/1807
Sugar beet	1.0	EU MRL/Reg. 2021/1807	1.0	EU MRL/Reg. 2021/1807
Red beet	1.0		1.0	
Swede	1.5		1.5	
Turnips	1.5		1.5	
All other plant commodities	EU MRL/Reg. 2021/1807		Not relevant for an acute risk assessment	
Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)				
Swine, muscle	0.05*	EU MRL/Reg. 2021/1807	0.05*	EU MRL/Reg. 2021/1807
Swine, fat	0.05		0.05	
Swine, liver	0.05		0.05	
Swine, kidney	0.6		0.6	
Swine, edible offals	0.05		0.05	
Swine, Others	0.05		0.05	
Bovine, muscle	0.05		0.05	
Bovine, fat	0.15		0.15	
Bovine, liver	0.15		0.15	
Bovine, kidney	1.5		1.5	
Bovine, edible offals	0.05*		0.05*	
Bovine, Others	0.05*		0.05*	
Sheep, muscle	0.05		0.05	
Sheep, fat	0.2		0.2	
Sheep, liver	0.2		0.2	
Sheep, kidney	2.0		2.0	
Sheep, edible offals	0.05*		0.05*	
Sheep, Others	0.05*		0.05*	
Goat, muscle	0.05		0.05	

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat, fat	0.2		0.2	
Goat, liver	0.2		0.2	
Goat, kidney	2.0		2.0	
Goat, edible offals	0.05*		0.05*	
Goat, Others	0.05*		0.05*	
Equine	0.05*		0.05*	
Poultry, muscle	0.05*		0.05*	
Poultry, fat	0.05*		0.05*	
Poultry, liver	0.05		0.05	
Poultry, kidney	0.05*		0.05*	
Poultry, edible offals	0.05*		0.05*	
Poultry, others	0.05*		0.05*	
Milk	0.05 CF of 1.3 (EFSA, 2018a)		0.05 CF of 1.3 (EFSA, 2018a)	
Eggs	0.05*		0.05*	
Honey	0.014	STM _R (this application)	0.0695	HR (this application)

7.2.8.2 Conclusion on consumer risk assessment

The highest Theoretical Maximum Daily Intake (TMDI) is 42% of the ADI (based on NL toddler). The acute risk assessment was undertaken only for the crops under consideration. Children have the highest International Estimated Short-Term Intake (IESTI) for unprocessed commodities at 34% of the ARfD (NL toddler) based on the consumption of beetroots, and for processed commodities at 65% of the ARfD (NL child) from the consumption of sugar beets (root)/sugar.

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-20: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	42% (based on NL toddlers)
IEDI (% ADI) according to EFSA PRIMo	Not necessary
IESTI (% ARfD) according to EFSA PRIMo*	MRL inputs only for the commodities for which GAPs are notified in the Article 43 submission: <u>Unprocessed Commodities</u>

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	<p>34% — Beetroots (based on NL toddlers)</p> <p>25% — Wheat (based on UK 4-6 year olds)</p> <p>15% — Wheat (based on UK 15-18 yr)</p> <p>14% — Beetroots (based on NL general)</p> <p>13% — Linseeds (based on DE child)</p> <p>11% — Chards/beet leaves (based on NL general)</p> <p>11% — Rye (based on UK infant)</p> <p>48.39% Cauliflowers (based on UK infants)</p> <p>45.64% Swedes/rutabagas (based on UK infants)</p> <p>39.56% Head cabbages (based on BE toddlers)</p> <p>33.57% Beetroots (based on NL toddler)</p> <p>31.70% Turnips (based on UK 4-6 years)</p> <p>25.50% Wheat (based on UK 4-6 years)</p> <p>18.90% Chinese cabbages/pe-tsai (based on BE toddlers)</p> <p>18.59% Rye (based on UK infant)</p> <p>17.86% Broccoli (based on BE toddlers)</p> <p>13.29% Spinaches (based on BE toddlers)</p> <p>12.60% Linseeds (based on DE child)</p> <p>11.12% Chards/beet leaves (based on NL general)</p> <p>All others commodities ≤10% ARfD</p> <p><u>Processed commodities</u></p> <p>65% — Sugar beets (root) / sugar (based on NL child)</p> <p>27% — Maize / oil (based on NL toddlers)</p> <p>26% — Beetroots / boiled (based on NL toddlers)</p> <p>26% — Sugar beets (root) / sugar (based on FR adult)</p> <p>23% — Beetroots / boiled (based on NL general)</p> <p>21% — Wheat / milling (flour) (based on DE child)</p> <p>18% — Chards/beet leaves / boiled (based on NL child)</p> <p>15% — Maize / oil (based on NL general)</p> <p>64.8% Sugar beets (root) / sugar (based on NL child)</p> <p>58.1% Cauliflowers / boiled (based on NL toddler)</p> <p>44.7% Turnips / boiled (based on NL child)</p> <p>33.8% Broccoli / boiled (based on NL toddler)</p> <p>27.4% Maize / oil (based on NL toddler)</p> <p>26.1% Beetroots / boiled (based on NL toddler)</p> <p>21.3% Wheat / milling (flour) (based on DE child)</p> <p>18.3% Chards/beet leaves / boiled (based on NL child)</p> <p>10.7% Rye / boiled ((based on NL child)</p> <p>10.3% Rye / milling (wholemeal)-baking (based on NL child)</p> <p>All others processed commodities ≤10% ARfD</p>
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not relevant

* include raw and processed commodities if both values are required for PRIMO

** National risk assessment calculators

The proposed uses of clopyralid in the formulation EF-243 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2005. Conclusion regarding the peer review of the pesticide risk assessment of the active substance clopyralid. Finalised: 14 December 2005. EFSA Scientific Report (2005) 50, 1-65. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2011. Modification of the existing MRLs for clopyralid in various commodities. EFSA Journal 2011;9(10):2418. [doi:10.2903/j.efsa.2011.2418](https://doi.org/10.2903/j.efsa.2011.2418). Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2018a. Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, Ctverackova L, De Lentdecker C, Egsmose M, Erdos Z, Fait G, Ferreira L, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans JO, Medina P, Mineo D, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Van Dijk J and Villamar-Bouza L, 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(8):5389, 21 pp. <https://doi.org/10.2903/j.efsa.2018.5389>

EFSA (European Food Safety Authority), 2018b. Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018. Reasoned Opinion on the modification of the existing maximum residue levels for clopyralid in spring/green/Welsh onions and leeks. EFSA Journal 2018;16 (1):5149, 19 pp. <https://doi.org/10.2903/j.efsa.2018.5149>

European Food Safety Authority (EFSA), 2021. Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the modification of the existing maximum residue levels for clopyralid in various commodities. EFSA Journal 2021;19(1):6389, 46 pp. <https://doi.org/10.2903/j.efsa.2018.5149>

Finland, 2005. Revised Draft Assessment Report (DAR) on clopyralid prepared by the rapporteur Member State Finland under Directive 91/414/EEC, September 2005.

Finland, 2008. Evaluation Report on the modification of MRLs for clopyralid in brassica vegetables, linseed, swedes and turnips prepared by the evaluating Member State Finland under Article 8 of Regulation (EC) No 396/2005, 15 December 2008.

Finland, 2018a. Revised Renewal Assessment Report (RAR) on clopyralid prepared by the rapporteur Member State Finland in the framework of Commission Implementing Regulation (EU) 844/2012, May 2018. Available online: <http://www.efsa.europa.eu>

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Finland, 2018b. Evaluation Report, prepared under Article 8 of Regulation (EC) No 396/2005. MRL application on the setting of MRL(s) in various commodities. 31 May 2018. Ongoing EFSA evaluation. EFSA-Q-2018-00576. Updated in January 2019 and July 2020.

European Food Safety Authority (EFSA), 2024. Giulia Bellisai | Giovanni Bernasconi | Luis Carrasco Cabrera | Irene Castellan | Monica del Aguila | Lucien Ferreira | German Giner Santonja | Luna Greco | Samira Jarrah | Renata Leuschner | Andrea Mioč | Stefanie Nave | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Alessia Pia Scarlato | Marta Szot | Anne Theobald | Manuela Tiramani | Alessia Verani-Modification of the existing maximum residue level for clopyralid in honey. EFSA Journal. 2024;22:e8546. <https://doi.org/10.2903/j.efsa.2024.8546>.

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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Skaggs, C.S., Penning, B.N.	2021	Storage Stability of Clopyralid for One Year in Dried Beans Corteva Report No. 191728 Study No. SGS-19-01-08 SGS North America, Inc GLP Unpublished	N	Corteva Agriscience
KCA 6.1	Teasdale, R.	1996	Frozen Storage Stability of Clopyralid Residues in Strawberries Corteva Report No. GHE-P-4832 Study No. CEMS-235 CEM Analytical Services Ltd. GLP Unpublished	N	Corteva Agriscience
KCA 6.1	Forbes, T., Cross, M	2021	Frozen Storage Stability of Clopyralid in Pollinator Matrices Corteva Report No. 180869 Study No. CEMS-8756 CEM Analytical Services (CEMAS)	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.2.1/01	Morton Lloyd, G.	2020	The Metabolism of [14C]-Clopyralid in Wheat DAS Study No. 191200 Study No. 229882 Charles River Laboratories GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1/02	MacKenzie, A.	2021	The Metabolism of [14C]-Clopyralid in Spring Oilseed Rape DAS Study No. 200928 Study No. 231101 Charles River Laboratories GLP Unpublished	N	Corteva Agriscience
KCA 6.3.1/01	Delmotte, R.	2017	Magnitude of the Residues of Halauxifen-methyl and Clopyralid in Oilseed rape (RAC Whole Plant, Seed and Straw), following One Application of GF-3488, Northern Europe - 2015 DAS Report No. 150534 Study No. RDE-15-20400 Staphyt GLP Unpublished	N	Corteva Agriscience
KCA 6.3.3/01	Devine, C.	2021	Residues of Clopyralid in Maize at Intervals at Harvest Follow-ing a Single Application of GF-1966 – Northern Europe – 2020 Corteva Report No. 201513 Study No. CEMS-9387 CEM Analytical Services Ltd (CEMAS) GLP	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			UnpublishedUnpublished		
KCA 6.3.3/02	Devine, H.C.	2003	Residues of Clopyralid in Maize at Intervals and At Harvest Following One or Two Applications of LONTREL 100 (EF-1136), Northern and Southern Europe – 2002 Study No. CEMS-1786; DAS Report No. GHE-P-10534 CEM Analytical Services Ltd GLP Unpublished	N	Corteva Agriscience
KCA 6.3.4/01	Pirie, D.	2021	Magnitude and Decline of Residues of Clopyralid in Sugar Beet Following Applications of GF-1966 in Northern Europe and the UK, Initiated in 2020. DAS Study No. 200809 Study No. 684083 Charles River Laboratories Edinburgh Ltd. GLP Unpublished	N	Corteva Agriscience
KCA 6.3.5/01	Devine, H.C.	2004	Residues of Clopyralid in Onions at Harvest and at Intervals Following Two Application of Lontrel 100 (EF-1136), UK - 2003 Study No. CEMS-2030 DAS Report No. GHE-P-10805 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
KCA 6.3.5/02	Devine, H.C.	2005	Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe - 2004 Study No. CEMS-2346 DAS Report No. GHE-P-11080 CEM Analytical Services Ltd (CEMAS) GLP	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.3.5/03	Devine, H.C.	2006	Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe-2005 Study No. CEMS-2696 DAS Report No. GHE-P-11272 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
KCA 6.3.5/04	Rawle, N. W.	2012	Residues of Clopyralid in Bulb Onions following Two Applications of EF-1136-Northern Europe-2011; Study No. CEMS-4969 DAS Report No. GHE-P-12680 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
KCA 6.3.5/05	Butler, R.E. and Reynens, P.	1998	Determination of Residues of Clopyralid in Onions following a single application of Lontrel 100 (EF-1136), Belgium, 1997; Study No. R97-030 DAS Report No. GHE-P-7289 GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3/01	Phillips, A.M.	1994	Determination of residues of clopyralid in sugar beet processed fractions DAS Report No. GH-C 3305 North American Environmental Chemistry Laboratory GLP Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.3/02	Devine, H.C.	2020	Residues of Clopyralid in Sugar Beet and Process Fractions Following Multiple Applications of GF-1966 – Northern Europe – 2019 DAS Report No. 181493 Study No. CEMS-8908 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
KCA 6.6.2/01	Devine, C.	2021	Determination of Residues of Clopyralid after One Application of GF-1966 (EC Formulation) on Bare Soil in Rotational Crops at 3 Sites in Northern Europe and 3 Sites in Southern Europe 2019-2020 Corteva Study No. 190557 Study No. CEMS-9009 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
Point 7.2.1	Appeltauer A.	2021	Determination of Residues of Clopyralid in Nectar, Pollen, Plants and Honey of Winter Oilseed Rape after One Application of GF-1966 in a Semi-Field Residue Study in Germany, Romania, The Netherlands, Southern France and Spain in 2020. Study code S20-00871 Study number DAS-200098 Eurofins Agrosience Services Ecotox GmbH GLP Unpublished	N	Corteva Agriscience

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List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 (CA 6.1.1/1)	Allen, L.	2013	Frozen Storage Stability of Residues of Clopyralid in Crop Matrices DAS Study No. 120939 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP Unpublished	N	Corteva Agriscience
KCA 6.1 (CA 6.1.1/2)	Foster, D.R., Blakeslee, B.A., Rutherford, B.S.	1996	Frozen Storage Stability of Clopyralid, 2,4-D in Corn Grain, Straw and Fodder DAS Study No. RES93050.01 DowElanco, Indianapolis, Indiana, US GLP Unpublished	N	Corteva Agriscience
KCA 6.1 (CA 6.1.1/3)	Clements, B., Bolton, A.	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Study No. GHE-P-5350 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP Unpublished	N	Corteva Agriscience
KCA 6.1 (CA 6.1.2/1)	[REDACTED]	2015	Frozen Storage Stability of Clopyralid in Bovine Fat [REDACTED] GLP Unpublished	Y	Corteva Agriscience
KCA 6.1 (CA 6.1.2/2)	[REDACTED]	2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg [REDACTED] GLP Unpublished	Y	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1 (CA 6.2.1/1)	Chapleo, S.; Caley, C. Y.	2002, revised 2019 †	The Metabolism of [14C]-Clopyralid in Sugar Beet DAS Study No. GHE-P-9939 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1 (CA 6.2.1/2)	Guo, C.	1996	Metabolism of 14C -Clopyralid in Cabbage DAS Study No. RES95095 DAS Report No. GH-C-4289 ABC Laboratories Inc, Columbia, Missouri, USA GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1 (CA 6.2.1/3)	Chapleo, S., Caley, C. Y., White, D. E.	2002, revised 2019†	The Metabolism of (14C)-Clopyralid in Oilseed Rape DAS Study No. GHE-P 9938 Inveresk Research International, Tranent, East Lothian, UK GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1	Bauriedel, WR, Miller, JH	1981	A Field Metabolism Study of 14C-Labeled 3,6-Dichloropicolinic acid Applied to Pasture Grass DAS Study ID GH-C 1424 Dow Chemical USA Non-GLP (pre-GLP) Unpublished	N	Corteva Agriscience
KCA 6.2.1 (CA 6.2.1/4)	Gourlay, V.	2015	Plant uptake of 14C -labelled clopyralid in wheat and oilseed rape under greenhouse conditions DAS Study No. 150297 RLP AgroScience GmbH, 67435 Neustadt a.d. Weinstraße, Germany GLP Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.2 (CA 6.2.2/1)	[REDACTED]	2014	A Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid [REDACTED] GLP Unpublished	Y	Corteva Agriscience
KCA 6.2.3 (CA 6.2.3/1)	[REDACTED]	2015	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid [REDACTED] GLP Unpublished	Y	Corteva Agriscience
KCA 6.3.2/01 (CA 6.3.2/1)	Boissinot, J.C.	2015	Magnitude of the residues of clopyralid in spring barley (RAC whole plant, grain and straw), following one application of GF-1966, Northern and Southern Europe – 2014 DAS Study No. 140655 STAPHYT GLP Unpublished	N	Corteva Agriscience
KCA 6.3.2/02	Grall, E.	2016	Magnitude of the Residues of Clopyralid in Winter Barley (RAC Whole Plant, Grain and Straw), Following One Application of GF-1966, Northern and Southern Europe (France, Poland, UK and Spain) - 2015 Study No. EGL-15-22231 DAS Report No. 150644 STAPHYT GLP Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.2/03	Peterek, S.	2017	Magnitude of the Residues of Clopyralid in Winter and Spring Wheat (RAC Whole Plants, Straw and Grain), Following One Application of GF-1374, Northern Europe (France, Germany, United Kingdom and Hungary) - 2016 Study Report Code SPK-16-26573 DAS Report No. 160618 STAPHYT GLP Unpublished	N	Corteva Agriscience
KCA 6.3.2/04 (CA 6.3.3/10)	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in wheat at intervals following a single application of LONTREL 100 (EF-1136), EU Northern Zone – 2001 Study No. CEMS-1544 / GHE-P-9385 CEM Analytical Services Ltd GLP Unpublished	N	Corteva Agriscience
KCA 6.4.1 (CA 6.4.1/1)	[REDACTED]	1974	Dowco 290 and 2,4-D Chicken Feeding Study [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience
KCA 6.4.1 (CA 6.4.1/2)	[REDACTED]	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Chickens Fed the Herbicide [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.1 (CA 6.4.1/3)	[REDACTED]	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens [REDACTED] GLP Unpublished	Y	Corteva Agriscience
KCA 6.4.2 (CA 6.4.2/1)	[REDACTED]	1974	Milk Residue Study with Dairy Cows Fed Lontrel Herbicide, Nellite Nematocide and 2,4-D Herbicide: Animal Care, Sampling and Production Records [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience
KCA 6.4.2 (CA 6.4.2/2)	[REDACTED]	1974	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Milk and Cream from Cows Fed the Herbicide [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience
KCA 6.4.2 (CA 6.4.2/3)	[REDACTED]	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Bovine Tissues from Calves Fed the Herbicide [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.2 (CA 6.4.2/4)	[REDACTED]	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle [REDACTED] GLP Unpublished	Y	Corteva Agriscience
KCA 6.4.3 (CA 6.4.3/1)	[REDACTED]	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Swine Fed the Herbicide [REDACTED] Non-GLP Unpublished	Y	Corteva Agriscience
KCA 6.5.1 (CA 6.5.1/1)	Adusumilli, H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (CA 6.5.3/2)	Devine, H.C.	2006	Residues of clopyralid in wheat and process fractions at harvest following a single application of EF-1498, Northern France - 2005 DAS Study No. GHE-P-11274 CEM Analytical Services - UK GLP Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.3 (IIA 6.5.2/06)	Day, SR	1987	Clopyralid Residues in Rape Plant, Straw, Seed and Oil, Following Application of LONTREL 100, Germany 1985 and 1986 Study No. GHE-P-1740 Non-GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (CA 6.5.3/2)	Devine, H.C.	2006	Residues of clopyralid in wheat and process fractions at harvest following a single application of EF-1498, Northern France - 2005 DAS Study No. GHE-P-11274 CEM Analytical Services - UK GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (CA 6.5.3/3)	Devine, H.C.	2008	Residues of clopyralid in spring barley and process fractions at harvest and at intervals following a single application of Lontrel 100 (EF-1136), Southern Europe 2006 DAS Study No. GHE-P-11684 CEM Analytical Services - UK GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (IIA 6.5.2/01)	Jones EM and Yuill MM	1976	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed, Oil, Cake and Straw from a 1974-5 Trial Carried Out by Dow Personnel Study No. GHE-P-324 Non-GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (IIA 6.5.2/02)	Jones EM and Yuill MM	1976	Determination of Residues of 3,6 dichloropicolinic Acid (DOWCO 290) in Rape Seed, Oil and Cake from 1975 Trials Carried Out by the Boots Company Limited Study No. GHE-P-325 Non-GLP Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.3 (IIA 6.5.2/03)	Jones EM and Yuill MM	1976	Determination of Residues of 3,6 dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake, Oil and Straw from a Trial Carried Out in 1975 in Sweden by BT KEMI Study No. GHE-P-337 Non-GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (IIA 6.5.2/04)	Jones EM and Yuill MM	1976	Determination of Residues of 3,6 dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake and Oil from Five Trial Locations in Sweden, 1975. Cooperator – Astra Ewos Study No. GHE-P-350 Non-GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3 (IIA 6.5.2/05)	Jones EM and Yuill MM	1976	Determination of Residues of 3,6 dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake, Oil and Straw from a Trial Carried Out in Germany, 1975. Cooperator – Schreing AG Study No. GHE-P-395 Non-GLP Unpublished	N	Corteva Agriscience
KCA 6.6.1 (CA 6.6.1/1)	Yackovich, P. R. ; Lardie, T. S. ; Brink, D. L.	1993	A 10-1/2 Month Rotational Crops Study With 14C -Labeled Clopyralid - MET90080 DAS Study No. GH-C 2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP Unpublished	N	Corteva Agriscience
KCA 6.6.1 (CA 6.6.1/2)	Yackovich, P.R.; Lardie T.S.; Miller J.H.	1989	A 125-Day Rotational Crops Study with 14C Labelled Clopyralid DAS Study No. GH-C 2277 DowElanco, Midland, Michigan, USA Unpublished	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.6.1 (CA 6.6.1/3)	Hall, L. R.	2015 revised 2018	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP Unpublished	N	Corteva Agriscience

† The amended reports (2019) have been evaluated as part of the Article 6 MRL evaluation (Finland 2018b; EFSA, 2021).

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Clopyralid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	Study performed according to guideline and GLP requirements. Storage stability of clopyralid was demonstrated for up to 13 months in dried navy beans stored under frozen conditions. The study is acceptable.
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Reference:	KCA 6.1
Report	Skaggs, C. S., Penning, B. N; 2021; Storage Stability of Clopyralid for One Year in Dried Beans; SGS North America, Inc., 1405 32nd Avenue, Brookings, SD 57006, USA.; Lab Study No.SGS-19-01-08; Corteva Study No. 191728 ; 27 October 2021
Guideline(s):	Yes, SANCO 825/00 Rev. 8.1, SANCO 3029/99 Rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

Test Item(s)

Test item (common name):	Clopyralid
Purity:	95.9%
Description (physical state):	Off-white powder
Lot/batch no.:	910905 5P [TSN100167]

Method Scope

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This method is applicable for the quantitative determination of residues of clopyralid in dried navy beans (high protein). The method was validated in dried navy beans over the concentration range of 0.01-0.10 mg/kg with a validated limit of quantitation of 0.01 mg/kg.

Method Principle

Residues of clopyralid are extracted from crop samples with 100:1 methanol:10N NaOH by blending for approximately 1 minute and shaking for 1 hour on a reciprocal shaker. The extracts are allowed to set ambient overnight. An aliquot of the extract is submitted to a nitrogen stream to remove the methanol and then brought back to volume with 1N sodium hydroxide. The clean up for crops is affected by partitioning the basic extract with DCM. An aliquot of the extract is acidified with HCl and submitted to a polymeric reversed-phase solid phase extraction column (Waters, HLB SPE) cleanup and elution with DCM. After removal of the DCM using nitrogen blow down, the sample is reconstituted in 10:90, methanol:0.1% formic acid. The final extract is filtered through a 0.2-µm PTFE syringe filter and then analyzed by liquid chromatography coupled with negative-ion electrospray ionization tandem mass spectrometry (ESI LC/MS/MS).

Linearity

For each analyte, the linearity of detector response was evaluated using solvent standard solutions with calibration range 0.1 – 25 ng/mL (sample equivalence of 0.002 – 0.5 mg/kg). Calibration curves were calculated by linear regression analysis with 1/x weighting.

RESULTS AND DISCUSSION

Method Performance

The validated method performance was further demonstrated by concurrent recovery samples analyzed in this study. Mean concurrent recovery values were 70-110%; RSD ≤ 20%. The storage stability sample concentrations were corrected for the mean recovery values of the procedural samples. The results obtained are summarised in the following tables.

Table: 1 *Summary of quantitative recovery of clopyralid (m/z 189.8/146.0Q)*

Matrix group	Matrix	LOQ	Fortification level	Recovery (%)		SD (%)	RSD (%)	n
			mg/kg	mean	range			
High protein	Dried navy beans	0.01	0.01	90	82-105	5.9	6.5	21
High protein	Dried navy beans	0.01	0.10	83	70-99	7.3	8.7	21

Stability

Storage stability of clopyralid was demonstrated for up to 13 months in dried navy beans.

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Table: 2 *Results of frozen storage stability samples for clopyralid residues – dried navy beans*

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0824	82	83	0.6	0.8	0.0988	99	99	0.6	0.6
0	0.10	0.0820	82				0.0988	99			
0	0.10	0.0832	83				0.1000	100			
31	0.10	0.0736	74	74	1.6	2.2	0.0860	86	86	1.5	1.8
31	0.10	0.0763	76				0.0884	88			
31	0.10	0.0733	73				0.0849	85			
62	0.10	0.0679	68	73	5.6	7.7	0.0861	86	93	7.0	7.6
62	0.10	0.0728	73				0.0924	92			
62	0.10	0.0791	79				0.1000	100			
90	0.10	0.0737	74	74	0.5	0.7	0.0914	91	92	1.2	1.3
90	0.10	0.0740	74				0.0914	91			
90	0.10	0.0747	75				0.0926	93			
182	0.10	0.0775	77	83	6.5	7.9	0.0846	85	91	7.2	7.9
182	0.10	0.0901	90				0.0989	99			
182	0.10	0.0810	81				0.0890	89			
273	0.10	0.0939	94	89	4.8	5.4	0.1044	104	98	5.1	5.2
273	0.10	0.0873	87				0.0967	97			
273	0.10	0.0846	85				0.0944	94			
395	0.10	0.1053	105	99	5.2	5.2	0.1458	146	138	7.0	5.1
395	0.10	0.0970	97				0.1347	135			
395	0.10	0.0957	96				0.1333	133			

CONCLUSION

The data indicates that residues of clopyralid are stable for at least 395 days (13 months) in dried navy beans stored under frozen conditions. These conditions are consistent with the storage of actual field samples.

A 2.1.1.1.1.2 Study 2

Comments of zRMS:	Study performed according to method similar to OECD guideline 506 and GLP requirements. The minor deviation was identified – one fortification level instead of two as is recommended in OECD guideline was used. However, the method can be considered to be fit for purpose. The data indicates that residues of clopyralid are stable for at least 24 months in strawberries stored under frozen conditions.
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Reference:

KCA 6.1

Report

Teasdale, R.; 1996; Frozen Storage Stability of Clopyralid Residues in

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	Strawberries; CEM Analytical Services, North Ascot, Berkshire, UK; Lab Study No. CEMS-235; Sponsor Study No. GHE-P-4832 ; 17 June 1996
Guideline(s):	Similar to OECD Guideline 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

Test Item(s)	
Test item (common name):	Clopyralid
Purity:	N/A
Description (physical state):	Solid
Lot/batch no.:	N/A (TSN100042)

Method Scope

This method is applicable for the quantitative determination of residues of clopyralid in agricultural commodities (acidic crop). The method was independently validated in strawberries over the concentration range of 0.10 mg/kg with a validated limit of quantitation of 0.1 mg/kg.

Method Principle

Residues of clopyralid are extracted from samples by homogenising and shaking with caustic methanol. After centrifugation, an aliquot of the supernatant was acidified and the fluroxypyr partitioned into dichloromethane. The dichloromethane layer was then partitioned into aqueous sodium bicarbonate and, after acidification, into diethyl ether. After removal of the diethyl ether by evaporation, the residue was treated with butylation reagent. The clopyralid (as the butyl ester) was partitioned into hexane in the presence of water prior to a silica Bond Elut clean-up procedure. Analysis was by capillary gas chromatography with electron capture and the external standardisation technique.

Linearity

For each analyte, the linearity of detector response was evaluated using solvent standard solutions with calibration standards range of 1-50 ng/mL (sample equivalence of 0.0125 – 0.625 mg/kg). Calibration curves were calculated by linear regression analysis with 1/x weighting, with a correlation coefficient > 0.995.

RESULTS AND DISCUSSION

Method Performance

The validated method performance was further demonstrated by virtue of concurrent recovery samples analyzed in this study. Mean concurrent recovery values were 70-110%; RSD ≤ 20%. The storage stability sample concentrations were corrected for the mean recovery values of the procedural samples. The results obtained are summarised in the following tables.

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Table 1: *Summary of quantitative recovery of Clopyralid*

Matrix group	Matrix	LOQ	Fortification level	Recovery (%)		SD	RSD	n
			mg/kg	mean	range	(%)	(%)	
Acidic Crop	Strawberries	0.1	0.10	80	68-89	-	9.7	7

Stability

Storage stability of clopyralid was demonstrated for up to 24 months in strawberries.

Table 2: *Results of frozen storage stability samples for Clopyralid residues – Strawberries*

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0872	93	80	8.0	10.0	0.093	107	91	9.3	10.1
0	0.10	0.0740	78				0.078	90			
0	0.10	0.0666	70				0.070	80			
0	0.10	0.0746	79				0.079	91			
0	0.10	0.0703	74				0.074	85			
0	0.10	0.0782	83				0.083	95			
32	0.10	0.0732	78	73	-	-	0.078	107	100		
32	0.10	0.0641	68				0.068	93			
124	0.10	0.0730	77	73	-	-	0.077	113	107		
124	0.10	0.0653	69				0.069	100			
250	0.10	0.0773	81	89	-	-	0.081	91	100		
250	0.10	0.0911	96				0.096	108			
370	0.10	0.0745	78	78	-	-	0.078	98	98		
370	0.10	0.0746	78				0.078	98			
549	0.10	0.0666	72	73	-	-	0.072	94	95		
549	0.10	0.0673	73				0.073	95			
725	0.10	0.0645	68	66	12.8	19.5	0.068	80	77	15.2	19.5
725	0.10	0.0802	85				0.085	100			
725	0.10	0.0460	48				0.048	56			
725	0.10	0.0690	73				0.073	86			
725	0.10	0.0556	58				0.058	68			
725	0.10	0.0586	62				0.062	73			

CONCLUSION

The data indicates that residues of clopyralid are stable for at least 24 months in strawberries stored under frozen conditions. These conditions are consistent with the storage of actual field samples.

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A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1

Comments of zRMS:	Study performed according to OECD guideline 506 and GLP requirements. The data indicates that residues of clopyralid are stable for 18 months in pollen, nectar or honey stored under frozen conditions. Study is acceptable.
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Reference:	KCA 6.1
Report	Forbes, T.; Cross, M.; 2020; Frozen Storage Stability of Clopyralid in Pollinator Matrices; CEM Analytical Services (CEMAS), Imperial House, Oaklands Business Centre Oaklands Park, Wokingham, Berkshire, RG41 2FD, UK; Lab Study No. CEMS-8756; Corteva Study No. 180869 ; 09 April 2020
Guideline(s):	OECD Guideline 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

Test Item(s)

Test item (Common name):	Clopyralid
Purity:	99.9 (% , w/w)
Description (physical state):	White solid
Lot/batch no.:	YC2-106153-68 (TSN301194)

Method Scope

The analytical method used for the determination of clopyralid was Dow AgroSciences Method study ID 171332, "Validation of an Analytical Method for the Determination of Clopyralid in Pollinator Matrices." This method is applicable for the quantitative determination of residues of clopyralid in pollinator matrices (pollen, nectar and honey). The method was validated over the concentration range of 0.001-0.01 mg/kg with a validated limit of quantitation of 0.001 mg/kg.

Method Principle

Residues of clopyralid are extracted from samples by shaking with a mixture of methanol containing 10 N sodium hydroxide. The final sample extracts are analyzed for clopyralid by gas chromatography with negative ion electrospray ionization mass spectrometry (GC/NCI-MS).

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Linearity

The linearity of detector response was evaluated using solvent standard solutions for nectar and honey, but matrix-matched standard solutions for pollen. Calibration curves were calculated by linear regression analysis with 1/x weighting.

RESULTS AND DISCUSSION

Method Performance

The validated method performance was further demonstrated by virtue of concurrent recovery samples analyzed in this study. Mean concurrent recovery values were 70-110%; $RSD \leq 20\%$. Recoveries of the stored samples were presented as both uncorrected and corrected for the mean procedural recoveries in each analytical batch. The results obtained are summarised in the following tables.

Table 1: *Summary of quantitative ion recovery of Clopyralid (m/z 233.0)*

Matrix group	Matrix	Fortification level (mg/kg)	Recovery (%)		SD (%)	RSD (%)	n
			mean	range			
Pollinator	Pollen	0.001	86	67 – 120	11.1	13.0	18
		0.01	83	73 – 95	6.1	7.4	18
	Nectar	0.001	97	82 – 110	8.8	9.1	18
		0.01	90	79 – 99	5.2	5.8	18
	Honey	0.001	90	76 – 100	6.3	7.0	18
		0.01	90	76 – 99	5.6	6.2	18

Stability

Storage stability of clopyralid was demonstrated for 550 – 557 days (18 months) in pollen, nectar or honey.

Table 2: *Results of frozen storage stability samples for Clopyralid in Pollen*

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0085	85	94	8.1	8.6	0.0103	103	114	9.3	8.2
0	0.10	0.0098	98				0.0118	118			
0	0.10	0.0100	100				0.0120	120			
33	0.10	0.0097	97	91	5.1	5.6	0.0103	103	97	5.1	5.3
33	0.10	0.0090	90				0.0096	96			
33	0.10	0.0087	87				0.0093	93			
91	0.10	0.0097	97	93	3.2	3.4	0.0115	115	111	3.6	3.2
91	0.10	0.0091	91				0.0108	108			
91	0.10	0.0092	92				0.0110	110			

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187	0.10	0.0079	79	77	2.0	2.6	0.0098	98	96	2.1	2.2
187	0.10	0.0077	77				0.0097	97			
187	0.10	0.0075	75				0.0094	94			
364	0.10	0.0102	102	98	5.1	5.3	0.0123	123	118	6.2	5.3
364	0.10	0.0092	92				0.0111	111			
364	0.10	0.0099	99				0.0120	120			
557	0.10	0.0094	94	90	9.3	10.4	0.0114	114	108	10.7	9.9
557	0.10	0.0096	96				0.0115	115			
557	0.10	0.0079	79				0.0096	96			

Table 3: Results of frozen storage stability samples for Clopyralid in Nectar

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0089	89	91	2.7	3.0	0.0090	90	92	2.8	3.0
0	0.10	0.0094	94				0.0095	95			
0	0.10	0.0089	89				0.0090	90			
28	0.10	0.0091	91	97	5.3	5.5	0.0093	93	99	5.3	5.3
28	0.10	0.0099	99				0.0101	101			
28	0.10	0.0101	101				0.0103	103			
89	0.10	0.0106	106	99	6.1	6.1	0.0116	116	109	6.1	5.6
89	0.10	0.0095	95				0.0105	105			
89	0.10	0.0096	96				0.0106	106			
187	0.10	0.0095	95	96	4.2	4.3	0.0102	102	103	4.2	4.0
187	0.10	0.0093	93				0.0100	100			
187	0.10	0.0101	101				0.0108	108			
364	0.10	0.0101	101	106	5.0	4.7	0.0107	107	113	5.5	4.9
364	0.10	0.0111	111				0.0118	118			
364	0.10	0.0106	106				0.0113	113			
550	0.10	0.0102	102	102	3.5	3.5	0.0116	116	116	3.5	3.0
550	0.10	0.0098	98				0.0112	112			
550	0.10	0.0105	105				0.0119	119			

Table 4: Results of frozen storage stability samples for Clopyralid in Honey

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0086	86	89	4.4	5.0	0.0099	99	102	5.1	5.0
0	0.10	0.0094	94				0.0108	108			
0	0.10	0.0087	87				0.0100	100			
33	0.10	0.0089	89	93	4.7	5.1	0.0101	101	105	5.1	4.9
33	0.10	0.0091	91				0.0104	104			
33	0.10	0.0098	98				0.0111	111			
91	0.10	0.0106	106				0.0115	115			

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91	0.10	0.0102	102				0.0111	111			
91	0.10	0.0096	96	101	5.0	5.0	0.0104	104	110	5.6	5.1
187	0.10	0.0101	101				0.0111	111			
187	0.10	0.0099	99	100	1.2	1.2	0.0109	109	110	1.0	0.9
187	0.10	0.0101	101				0.0110	110			
364	0.10	0.0118	118				0.0123	123			
364	0.10	0.0104	104	112	7.2	6.4	0.0109	109	117	7.2	6.2
364	0.10	0.0114	114				0.0119	119			
557	0.10	0.0105	105				0.0122	122			
557	0.10	0.0106	106	106	0.6	0.5	0.0124	124	123	1.0	0.8
557	0.10	0.0106	106				0.0123	123			

CONCLUSION

The data indicates that residues of clopyralid are stable for 550 – 557 days (18 months) in pollen, nectar or honey stored under frozen conditions. These conditions are consistent with the storage of actual field samples.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

A 2.1.2.1.1.1 Study 1, wheat

Comments of zRMS:	The study was performed according to current guidelines and GLP requirements. The study was already evaluated and considered acceptable (EFSA, 2021). Only parent clopyralid was identified in all tested samples, constituting 93-98% of TRR while not other significant metabolites were identified.
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Reference: KCA 6.2.1/01

Report: Morton Lloyd, G.; 2020; The Metabolism of [¹⁴C]-Clopyralid in Wheat; Charles River Laboratories Edinburg Ltd., Tranent, UK; Lab Study No. 229882; DAS Study No. 191200; 19 June 2020; Unpublished

Guidelines: OECD 501, OPPTS 860.1300

Deviations: none

GLP: Yes

BACKGROUND INFORMATION

Clopyralid (3,6-dichloropyridine-2-carboxylic acid) is a selective herbicide developed for use on a variety of agricultural crops including wheat.

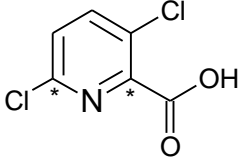
MATERIALS AND METHODS

Test Item(s)

Non-radiolabelled test item #1

Test item (Common name):	Clopyralid
Purity:	99.9%
Description (physical state):	Solid
Lot/batch no.:	YC2-106153-68 (TSN301194)

Radiolabelled test item #1

Test item (Common name):	[¹⁴ C]-Clopyralid
Name:	3,6-Dichloropicolinic acid-2,6- ¹⁴ C, X755015
Structural Formula:	
Position of labelling (*)	
Lot/batch no.:	INV306082
Radiochemical purity:	99.0%
Specific radioactivity:	35.0 mCi/mmol

Methods

Test Site Information

Testing environment:	outdoor test plots - F, glasshouse when outdoor conditions were unfavourable (early October 2019) - G
Container description:	Plastic, internal dimensions: 0.755 x 0.555 m, 4 used
Soil type:	sandy loam (UK and USDA)
Soil characteristics:	1.70% OC pH 6.8 (in water) CEC 10.2 meq/100 g 67% Sand (UK) 20% Silt (UK) 13% Clay (UK)
Any adverse weather conditions:	No

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Any adverse insect or disease problems: No

Study Use Pattern

Application method: Foliar
 Formulation type: DMA salt, GF-2895
 Application rate: 120 g ae/ha (target), actual 126 g ae/ha
 Number of applications: 1
 Timing of applications: 23 July 2019, BBCH 39
 PHI (Days after Treatment): 3 (forage), 23 (hay), 92 (mature straw & grain)

Test System

Organism (*Species*): Spring Wheat (*Triticum*)
 Variety: Mulika
 Crop group: Cereal & forage/pulses
 Growth stage at application: BBCH 39
 Harvested RAC: forage, hay, grain & straw
 Growth stage at harvest: Forage: BBCH 43 (26 Jul 2019), hay: BBCH 71 (15 Aug 2019), mature: BBCH 89 (23 Oct 2019)
 Harvesting procedure: Approximately $\frac{1}{4}$ plants randomly selected for forage sampling, cut at soil surface. Approximately $\frac{1}{3}$ remaining plants cut at soil surface for hay; hay was air-dried in a glasshouse for 5 days. Remaining plants were harvested at maturity. The heads were removed by hand and grain threshed; the chaff was combined with the straw. After weighing, the samples were stored frozen (-20 °C).

Sample Handling and Preparation

Each frozen plant fraction was homogenised with excess carbon dioxide chips using a Waring PB20 or a Hobart VCB61 blender. The carbon dioxide was then allowed to sublime while frozen prior to removal of sub-samples for combustion.

Sub-samples (five each, *ca.* 0.1 – 0.3 g) of the milled tissue were analysed by oxidative combustion to determine the total radioactive residues in the sample.

Extraction of Sample Residues

Aqueous Acetonitrile Extraction (E1-2)

Approximately 25 g of homogenized tissue was extracted with approx. 125 – 250 mL of 1:1 acetonitrile:water (v/v). The mixture was blended using a Silverson SL2 TopDrive homogenizer for approximately 5 minutes. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the extraction was repeated once more using *ca.* 62.5 – 125 mL solvent, after which the extracts were pooled and volume measured. Triplicate aliquots of each pooled extract were analysed by liquid scintillation counting.

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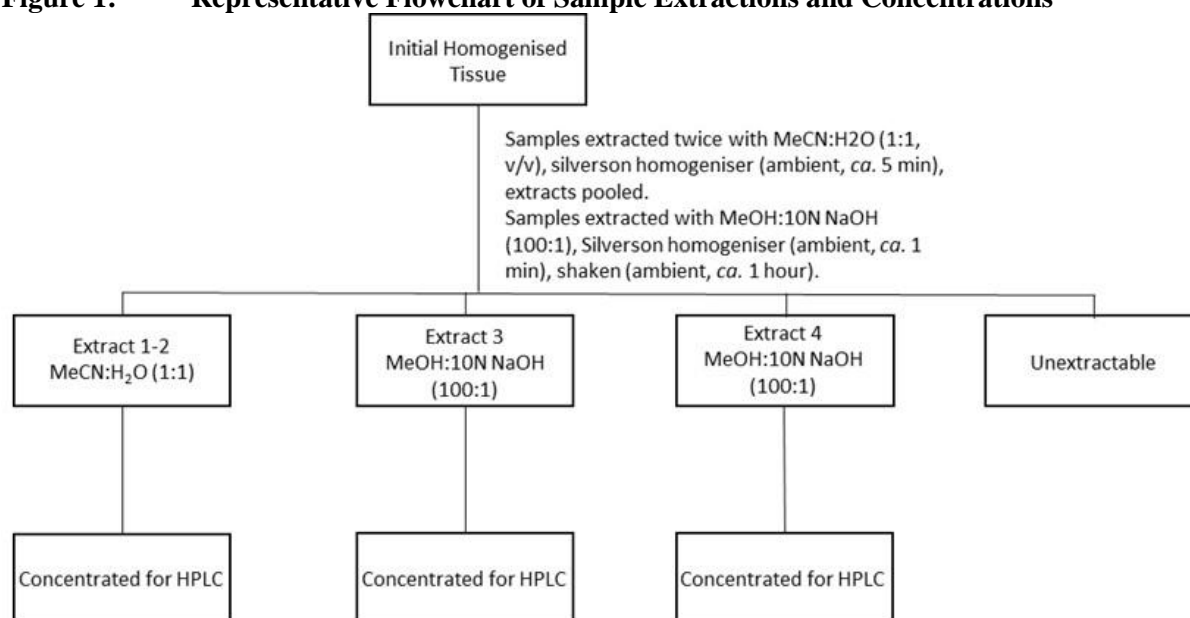
For “dry” samples (hay, straw and grain), the extraction tissue was soaked in the first extract solvent for *ca.* 30 minutes prior to blending.

The remaining solid for each sample was further extracted as described below.

Methanolic Base Extraction (E3 and E4)

Following neutral organic solvent extraction, all samples were subjected to base extraction. The entire remaining residue sample following neutral organic extraction was homogenised in the presence of *ca.* 62.5 – 125 mL methanol:10 N sodium hydroxide (100:1, v/v) for *ca.* 1 minute using a Silverson SL2 TopDrive homogeniser, before being shaken on a reciprocal shaker for *ca.* 1 hour. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the extract volume measured. For wheat straw and grain, the extraction was repeated once more using the same volume of solvent (E4). Triplicate aliquots of each extract were analysed by liquid scintillation counting. The post extracted tissue for all samples was dried and aliquots combusted.

Figure 1: Representative Flowchart of Sample Extractions and Concentrations



Note: Above flowchart is a generic overview of sample processing. Selected samples have not had all extractions conducted.

Further Extraction

Aqueous Base Further Extractions (FE1)

Aliquots of dried forage, hay, straw and grain post extraction solids were subjected to further base extraction. Approximately 1.5 – 10 g of post extraction solids was extracted with 30 - 100 mL of 0.1 M NaOH (20:1, v/w for forage solvent:PES, 10:1, v/w for hay, straw and grain solvent:PES). The mixture was shaken on a reciprocal shaker for *ca.* 1 hour, at ambient, before the solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes). The extract volume for forage, hay and straw was measured and triplicate aliquots of each extract were analysed by liquid scintillation counting. Due to the viscous nature of the grain extract, this was diluted to 100 mL with the addition of Milli-Q water prior to analysis by liquid scintillation counting. The forage post extracted tissue was dried and aliquots combusted.

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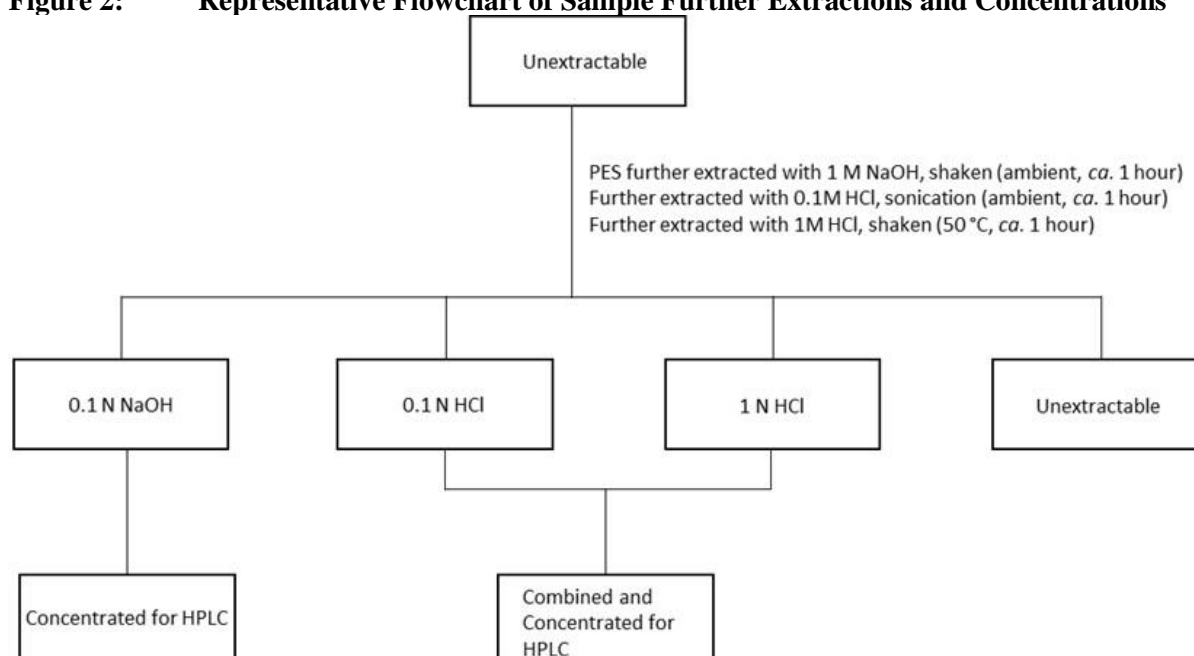
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Acid Extraction (FE2 and FE3)

Following extraction with base (FE1), hay, grain and straw post extraction solids were subjected to acid extraction. The entire remaining residue was extracted with 50 mL of 0.1 M HCl (5:1, v/w solvent:PES) with ultrasonication at ambient for *ca.* 1 hour. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes) and the extract volume measured. Triplicate aliquots of each extract (FE2) were analysed by liquid scintillation counting. The grain post extracted tissue was dried and aliquots combusted.

Remaining hay and straw residue were further extracted with 50 mL of 1 M HCl (5:1, v/w solvent:PES). Samples were shaken by hand for *ca.* 1 minute, before shaking in a water bath at *ca.* 50 °C for *ca.* 1 hour. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes) and the extract volume measured. Triplicate aliquots of each extract (FE3) were analysed by liquid scintillation counting. The post extracted tissue was dried and aliquots combusted.

Figure 2: Representative Flowchart of Sample Further Extractions and Concentrations



Note: Above flowchart is a generic overview of sample processing. Selected samples have not had all extractions conducted.

Base Treatment of Suspected Conjugate Fractions

Neutral Organic Extract Base Treatment

To further characterise the neutral-organic sample extracts, aliquots of forage, hay, straw and grain pooled extract 1-2 were subjected to base treatment, using methodology similar to the field trial analytical method (analytical method 120610). The solvent was removed under nitrogen until dryness (ambient temperature) and the sample reconstituted in an equal volume (amount of initial neutral-organic extract aliquot) of methanol:10 N NaOH (100:1, v/v). Samples were homogenised for *ca.* 1 minute using a Silverson SL2 TopDrive homogeniser, shaken for *ca.* 1 hour on a reciprocal shaker and left at ambient overnight. Samples were centrifuged and the supernatants analysed by LSC. Where recoveries were low, a wash of the pellet after centrifuging was conducted using water:acetonitrile, 1:1 (v/v). The wash was centrifuged prior to analysis by LSC. Base treatment samples were combined with the respective wash prior to HPLC analysis.

Separate aliquots of forage, hay, straw and grain pooled extract 1-2 were processed using the same procedure with methanol:water (100:1, v/v), no caustic, to act as control samples.

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Control Fortification

Homogenised control wheat grain was fortified with [^{14}C]-clopyralid radiodiluted stock solution prior to extraction with aqueous acetonitrile, as described above. The extract was concentrated and analysed by HPLC, as described above for the treated tissue.

Metabolite Isolation and Identification

Non-radiolabeled clopyralid was used as a reference standard for chromatographical comparison. HPLC retention time comparisons were made between this reference standard and the radioactive peaks in the chromatograms in order to provide initial tentative identifications.

Based on the initial HPLC analyses, clopyralid fractions were targeted for isolation and structure confirmation. This was accomplished using a grain aqueous acetonitrile SPE sample and a straw methanolic base SPE sample which were submitted for radio LC-MS and LC-MS/MS analyses. A bulk grain aqueous acetonitrile extract was submitted for MRM-MS analyses.

Analytical Methodology

Total ^{14}C measurement

Oxidative Combustion:

Approximately 0.1-0.3 g sub-samples of each sample were weighed in 3 to 5 replicates into Combustorcones® (Packard Bioscience) and combusted using a Perkin Elmer Tri-Carb 307 Automatic Sample Oxidiser. The resultant $^{14}\text{CO}_2$ was absorbed in Carbo-Sorb® (Packard Bioscience), mixed automatically with Permafluor® scintillation fluid (Packard Bioscience) and the radioactivity determined by LSC.

The efficiency of the oxidiser was determined daily, and at regular intervals throughout each batch of analyses. Carbon-14 standards were combusted at the beginning of each batch of analyses. Combustion efficiencies were in excess of 97.1%. Combustion values were not corrected for the oxidizer efficiencies.

Liquid Scintillation Counting:

The liquid scintillation counters automatically converted the radioactivity counting rate in counts per minute (cpm) to disintegrations per minute (dpm) using an external standard to correct for sample quenching. The instrument was calibrated approximately every three months with a set of ten quenched standards. Each day of use, the instrument was normalized and its performance was checked with respect to background cpm value, unquenched standard cpm value, and quenched standard dpm value for a range of quenched standards. The scintillation counters used were a Packard 2100TR Tri-Carb (Packard Instrument Co.). The dpm value for the liquid samples was determined by LSC after diluting an appropriate aliquot of the sample with Aquasafe 500 Plus scintillation cocktail (Zinsser Analytic, Maidenhead, UK) and counting for at least five minutes.

Sample Concentration

The general sample processing procedure for the aqueous acetonitrile pooled extract 1-2 was to concentrate aliquots either under nitrogen or by rotary evaporation (at ambient), to a reduced volume or dryness before reconstitution to a known volume in a suitable solvent (water, water:acetonitrile or water:methanol). Samples were centrifuged (*ca.* 13,000 rpm for *ca.* 10 minutes) and the supernatant analysed by LSC and HPLC.

Aliquots of base extracts (extract 3 and 4) were neutralised to *ca.* pH 7 using hydrochloric acid solution before concentration in a similar manner to the neutral organic extracts (E1-2).

Where required, aliquots of base treatment and associated control samples were combined with the respective wash prior to concentration. Base treated samples were processed in a similar manner to the base extracts (*e.g.*, neutralized). Control samples were processed in a similar manner to the neutral organic extracts.

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Aliquots of mild base further extracts (FE1) were neutralized to *ca.* pH 7 using hydrochloric acid solution prior to centrifuging (*ca.* 13,000 rpm for *ca.* 10 minutes). The resulting supernatants were concentrated in a similar manner to the neutral organic extracts.

For hay and straw samples, equal proportion of the mild acid (FE2) and stronger acid (FE3) further extracts were combined and neutralised to *ca.* pH 7 using sodium hydroxide solution prior to centrifuging (*ca.* 13,000 rpm for *ca.* 10 minutes). The resulting supernatants were concentrated in a similar manner to the neutral organic extracts.

For grain, pH analysis of the mild acid further extract (FE2) determined it to be basic. This was due to carry-over from the mild base further extraction (FE1). The sample was neutralized to *ca.* pH 7 using hydrochloric acid solution prior to centrifuging (*ca.* 13,000 rpm for *ca.* 10 minutes). The resulting supernatants were concentrated in a similar manner to the neutral organic extracts.

Solid phase extraction (SPE)

In order to remove endogenous material from samples prior to mass spec analysis, selected samples were subjected to solid phase extraction (SPE).

Aliquots of forage concentrated extract 3 (methanolic base), straw concentrated extract 3 (methanolic base), and grain concentrated extract 1-2 (neutral organic) were loaded onto pre-conditioned C18 SPE cartridges (Varian, 6cc, 1 g) and the radioactivity washed off with acetonitrile:water (3:7, v/v). The organic solvent of each sample was removed under nitrogen before each was pre-treated with 5% NH₄OH (250 – 500 µL) prior to loading on to a MAX cartridge (Oasis, 6cc, 500 mg). Where required, samples were split across multiple MAX cartridges and eluates combined. MAX cartridges washed with 5% NH₄OH and eluted sequentially with methanol, 2% formic acid in organic (methanol or methanol:acetonitrile, 40:60) and 2% TFA in methanol. The volume of each eluate was measured and aliquots were removed for LSC analysis. Fractions which contained radioactivity were neutralised, concentrated and reconstituted in a suitable solvent prior to HPLC and MS analysis.

High performance liquid chromatography (HPLC) for quantitation

HPLC analyses of all sample extracts were accomplished using a Waters SPHERISORB ODS 2 column (150 x 4.6 mm, 5 µm particle size; 1.0 mL/min; UV detection at 280 nm) and a 1 step, non-linear gradient.

Mass spectral analysis (LC/MS) for identification of transformation products

A forage methanolic base, straw methanolic base and grain neutral-organic samples were cleaned-up by SPE to aid confirmation of clopyralid by mass spectral analysis. Mass spectral analysis was also conducted on bulk treated wheat grain and fortified wheat grain samples.

RESULTS AND DISCUSSION

Results of In-Life Phase

The [¹⁴C]-clopyralid plot received 21.095 mg, equivalent to 125.87 g a.e./ha (104.9% of target of 120 g a.e./ha). Radiochemical purity and stability of the formulated application solution pre- and post-application were ≥97.7%, indicating the stability of the radiolabelled test item throughout the formulation and application process.

Total Radioactive Residue (TRR) Levels

TRR levels in all samples, expressed as mg/kg of parent equivalents are shown below.

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Table 21: Total radioactive residues (TRRs) in Plant Samples Collected for Clopyralid Nature of Residue in Wheat Study

Matrix	Days after Application	TRR (mg eq./kg)
Wheat Forage	3	1.879
Wheat Hay	23	3.717
Wheat Straw	92	2.134
Wheat Grain	92	1.128

¹ = mg eq/kg = mg parent equivalents per kg of tissue**Distribution of Residues Following Extraction**Forage

Accountability, between combustion and extraction data, was 103.0% for forage. When normalised with respect to accountability, aqueous acetonitrile recovered 90.5 % TRR (1.700 mg eq/kg) and methanolic base extracted 5.0 % TRR (0.095 mg eq/kg). The level of non-extractable radioactivity following initial extractions accounted for 3.2 % TRR (0.060 mg eq/kg) and therefore was subjected to further extraction. A further aqueous mild base extraction released 2.6 % TRR (0.050 mg eq/kg). Final unextracted residues accounted for 1.8 % TRR (0.035 mg eq/kg).

Hay

Accountability, between combustion and extraction data, was 107.6% for hay. When normalised with respect to accountability, aqueous acetonitrile recovered 78.6 % TRR (2.923 mg eq/kg) and methanolic base extracted 13.2 % TRR (0.491 mg eq/kg). The level of non-extractable radioactivity following initial extractions accounted for 8.6 % TRR (0.318 mg eq/kg) and therefore was subjected to further extraction. Further aqueous mild base, mild acid and stronger acid extractions (FE1, FE2 and FE3) released a total of 5.3 % TRR (0.197 mg eq/kg). Final unextracted residues accounted for 2.9 % TRR (0.107 mg eq/kg).

Straw

Accountability, between combustion and extraction data, was 101.5% for straw. When normalised with respect to accountability, aqueous acetonitrile recovered 50.6 % TRR (1.081 mg eq/kg) and methanolic base extracts released a further 34.7 % TRR (0.739 mg eq/kg). The level of non-extractable radioactivity following initial extractions accounted for 13.7 % TRR (0.293 mg eq/kg) and therefore was subjected to further extraction. Further mild base, mild acid and stronger acid extractions (FE1, FE2 and FE3) released a total of 7.5 % TRR (0.160 mg eq/kg). Final unextracted residues accounted for 7.2 % TRR (0.154 mg eq/kg).

Grain

Accountability, between combustion and extraction data, was 95.4% for grain. When normalised with respect to accountability, aqueous acetonitrile recovered 72.6% TRR (0.820 mg eq/kg) and methanolic base extracts released a further 20.4 % TRR (0.229 mg eq/kg). The level of non-extractable radioactivity following initial extractions accounted for 7.2 % TRR (0.082 mg eq/kg) and therefore was subject to further extractions. Further mild base and mild acid extractions released 3.4 % TRR (0.038 mg eq/kg). Final unextracted residues accounted for 3.7 % TRR (0.041 mg eq/kg).

The distribution of the residues in the wheat samples among the fractions generated following the extractions, expressed both as a percentage of the total sample residue and as mg/kg of clopyralid equivalents is shown below.

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Table 22: Normalised Characterisation of Residues in Wheat Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Wheat							
	Forage		Hay		Straw		Grain	
	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg
TRR ¹	100.0	1.879	100.0	3.171	100.0	2.134	100.0	1.128
Pooled Extract 1-2 Acetonitrile:water (1/1, v/v)	90.5	1.700	78.6	2.923	50.6	1.081	72.6	0.820
Extract 3 Methanol:10 N NaOH (100/1, v/v)	5.0	0.095	13.2	0.491	26.8	0.571	14.2	0.159
Extract 4 Methanol:10 N NaOH (100/1, v/v)	NC		NC		7.9	0.168	6.2	0.070
Sum of initial extracts (1-4)	95.5	1.795	91.8	3.414	85.3	1.820	93.0	1.049
Further Extract 1 0.1 M NaOH	2.6	0.050	3.3	0.125	4.5	0.097	2.0	0.022
Further Extract 2 0.1 M HCl	NC		1.3	0.048	2.1	0.044	1.4	0.016
Further Extract 3 1 M HCl	NC		0.7	0.024	0.9	0.019	NC	
Sum of further extracts (FE1-3)	2.6	0.050	5.3	0.197	7.5	0.160	3.4	0.038
Sum of neutral and further extracts	98.1	1.845	97.1	3.611	92.8	1.980	96.4	1.087
Characterised by HPLC	98.1	1.845	97.1	3.611	92.8	1.980	96.4	1.087
Unextracted	1.8	0.035	2.9	0.107	7.2	0.154	3.7	0.041
Accountability (%) ²	99.9		100.0		100.0		100.1	

¹ = TRR determined by initial extractions² = Accountability = %TRR total extractable + %TRR unextractable

NC = Not Conducted

Characterization and Identification of Residues

Forage:

The main component in the aqueous acetonitrile extract was clopyralid, accounting for 66.0 %TRR, 1.240 mg eq/kg (E1-2). A number of less polar components (maximum individual component 5.4 %TRR) were also detected, with the entire region accounting for 21.0 %TRR (0.394 mg eq/kg). Upon mild base treatment, primarily clopyralid was detected (98.7 %ROI). Therefore, the less polar components are identified as base-labile clopyralid. Two more polar components, accounting for 3.4 %TRR (0.064 mg eq/kg) were also detected. These components were also reduced to clopyralid under base treatment, and therefore, are identified as base-labile clopyralid.

Base-labile clopyralid was the only component detected in the organic mild base extract (E3), accounting for 5.0 %TRR, 0.095 mg eq/kg.

Base-labile clopyralid was the only component detected in the aqueous mild base further extract (FE1), accounting for 2.6 %TRR, 0.050 mg eq/kg.

Overall, 98.1% of the radioactivity was extractable and 94.6 %TRR (1.779 mg eq/kg) was shown to be clopyralid. Of this, 66.0 %TRR (1.240 mg eq/kg) was “free” clopyralid and 32.0 %TRR (0.603 mg eq/kg) was base-labile clopyralid.

Hay:

A resolved clopyralid peak accounted for 15.4 %TRR, 0.571 mg eq/kg in the aqueous acetonitrile extracts (E1-2). A large unresolved, less polar, region, accounting for 63.3 %TRR, 2.351 mg eq/kg was also

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detected. Upon mild base treatment, primarily clopyralid was detected (97.7 %ROI) and therefore is identified as base-labile clopyralid.

Base-labile clopyralid was the only component detected in the organic base extract (E3), accounting for 13.2 %TRR, 0.491 mg eq/kg.

Base labile clopyralid was the main component detected in the aqueous mild base (FE1) further extract, accounting for 3.3 %TRR, 0.125 mg eq/kg. Acid-labile clopyralid was the only component present in the combined acidic further extracts (FE2-3), accounting for 2.0 %TRR, 0.072 mg eq/kg.

Overall, 97.1% of the radioactivity was extractable, and 97.2 % TRR (3.608 mg eq/kg) was shown to be clopyralid. Of this, 15.4 %TRR (0.571 mg eq/kg) was “free” clopyralid, 79.8 %TRR (2.965 mg eq/kg) was base-labile clopyralid and 2.0 %TRR (0.072 mg eq/kg) was acid-labile clopyralid.

Straw:

A resolved clopyralid peak accounted for 20.4 %TRR, 0.436 mg eq/kg in the aqueous acetonitrile extracts (E1-2). A large, less polar, unresolved region, accounting for 30.1 %TRR, 0.645 mg eq/kg was also detected. Upon mild base treatment, primarily clopyralid was detected (98.7 %ROI) and therefore is identified as base-labile clopyralid.

Base-labile clopyralid was the major component detected in the organic base extracts (E3 and E4), accounting for 34.6 %TRR, 0.737 mg eq/kg.

Base-labile clopyralid was the only component detected in the mild base further extract (FE1), accounting for 4.5 %TRR, 0.097 mg eq/kg and acid-labile clopyralid was detected in the combined acidic further extracts (FE2-3) 3.0 %TRR, 0.063 mg eq/kg, respectively.

Overall, 92.8% of the radioactivity was extractable, and 92.6 %TRR (1.978 mg eq/kg) was shown to be clopyralid. Of this, 20.4 %TRR (0.436 mg eq/kg) was “free” clopyralid, 69.2 %TRR (1.479 mg eq/kg) was base-labile clopyralid and 3.0 %TRR (0.063 mg eq/kg) was acid-labile clopyralid.

Grain:

A resolved clopyralid peak accounted for 27.5 %TRR, 0.311 mg eq/kg in the aqueous acetonitrile extracts (E1-2). A large, less polar, unresolved region, accounting for 45.1 %TRR, 0.509 mg eq/kg was also detected. Upon mild base treatment, primarily clopyralid was detected (98.2 %ROI) and therefore is identified as base-labile clopyralid.

Base-labile clopyralid was the only component detected in the organic base extracts, accounting for 20.4 %TRR, 0.229 mg eq/kg.

Base-labile clopyralid was the only component detected in the mild base further extract (FE1) accounting for 2.0 %TRR, 0.022 mg eq/kg. As the mild acidic further extract (FE2) remained basic, the clopyralid released in this extraction is determined to be base-labile clopyralid, which accounted for 1.4 %TRR, 0.016 mg eq/kg.

Overall, 96.4% of the radioactivity was extractable, and 96.4 %TRR (1.087 mg eq/kg) was shown to be clopyralid. Of this, 27.5 %TRR (0.311 mg eq/kg) was “free” clopyralid and 68.9 %TRR (0.776 mg eq/kg) was base-labile clopyralid.

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Table 23: Clopyralid Levels in Wheat Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Wheat							
	Forage		Hay		Straw		Grain	
	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg
TRR ¹	100	1.879	100.0	3.171	100.0	2.134	100.0	1.128
Total Extractable	98.1	1.845	97.1	3.611	92.8	1.980	96.4	1.087
Total Analysed by HPLC ²	98.1	1.845	97.1	3.611	92.8	1.980	96.4	1.087
Clopyralid ³	66.0	1.240	15.4	0.571	20.4	0.436	27.5	0.311
Base-Labile Clopyralid ⁴	32.0	0.603	79.8	2.965	69.2	1.479	68.9 ⁶	0.776 ⁶
Acid-Labile Clopyralid ⁵	-	-	2.0	0.072	3.0	0.063	- ⁶	- ⁶
Total Identified as Clopyralid (HPLC/MS)	98.0	1.843	97.2	3.608	92.6	1.978	96.4	1.087
Total Characterised by HPLC	-	-	<0.1	0.002	0.1	0.002	-	-
Unextracted	1.8	0.035	2.9	0.107	7.2	0.154	3.7	0.041
Accountability ⁷	99.9		100.0		100.0		100.1	

¹ = TRR determined by combustion² = Total extracts that were prepared and analysed by HPLC does not include any losses/gains during processing³ = Total free clopyralid detected in aqueous acetonitrile extracts.⁴ = Sum of 'unresolved region' in aqueous acetonitrile extracts and clopyralid in base extracts (E3, E4 and FE1). Extensive investigation work was conducted on the 'unresolved region'. Mild base treatment resulted in >97% clopyralid. Further experiments were conducted and the conclusion of these experiments is that this region is base-labile clopyralid.⁵ = Total clopyralid detected in acidic further extracts.⁶ = As the mild acidic further extract (FE2) was basic, the clopyralid detected in this extract is base-labile clopyralid.⁷ = Accountability = %TRR extractable + %TRR unextractable

Metabolite Identification

Confirmation of Clopyralid

The identity of clopyralid was confirmed in a grain aqueous acetonitrile SPE sample and in a straw methanolic base SPE sample by qualitative mass spectrometry using radio LC-MS and LC-MS/MS. Identification was confirmed by expected isotope pattern and comparison of retention time, accurate mass measurement and fragmentation pathway with an authentic reference standard for clopyralid.

Clopyralid was also confirmed in a bulk treated grain aqueous acetonitrile extract and a fortified grain sample using MRM-MS.

Characterisation of Unresolved Region

A large unresolved region, less polar than clopyralid, was detected in each concentrated aqueous acetonitrile extract, eluting from 14 – 22.5 minutes and accounting for 21.0 - 63.3 %TRR (0.394 – 2.351 mg eq/kg). Multiple experiments were conducted to explore the nature and identity of this region.

Base Treatment of Treated Samples:

Initially the aqueous acetonitrile extracts from forage, hay, straw and grain were treated with mild base (methanol:10 N NaOH, 100:1, v/v, ambient, 24h), and subsequent HPLC analysis resulted in >97.7 %ROI clopyralid. The near-complete conversion of the unresolved region after a mild base treatment may be due to hydrolysis and/or a result of the change in sample pH. Therefore, additional investigations into the effect of base on the sample extracts were conducted.

pH Adjustment of Treated Samples:

To investigate the effect of pH on wheat grain extract, the concentrated aqueous acetonitrile extract from the treated grain sample was adjusted to pH 11 with the addition of 5% ammonium hydroxide solution (2:1 ,v/v sample:base ratio). HPLC analysis of the resulting sample was conducted after 1, 2, 4 and 24 hours.

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Analysis showed that after 1 hour, the unresolved region was not detectable. The region was not seen in any of the subsequent analysis.

However, a second peak eluting at 13.8 minutes was detected in analysis of pH adjusted samples after 1, 2 and 4 hours. At the 24-hour analysis, the second peak was not well resolved but was still present.

To investigate the second peak, an aliquot of the clopyralid standard was analysed by HPLC following addition of 5% ammonium hydroxide. This analysis also showed two peaks, which suggests that the second peak is clopyralid in an altered ionization form. A split clopyralid peak was also detected during MS analysis. The peaks at 10.75 and 11.50 minutes can be tentatively identified as clopyralid, indicating a split peak. The sample was re-prepared for MS and no split peak was detected in that analysis, which was subsequently used for confirmation of clopyralid.

The complete removal of the unresolved region seen through this analysis demonstrates that a significant amount of clopyralid is rapidly released by adjustment of the sample pH. This indicates that the unresolved region is a result of weak binding interactions between clopyralid and the endogenous plant matrix, which are disrupted by treatment with mild base. The use of mild base and the speed of conversion to clopyralid suggests that clopyralid is not covalently bonded to the plant matrix (*e.g.*, sugars, amino acids etc) but binds *via* weak interactions (*e.g.*, electrostatic) which can be easily disrupted. This was further confirmed by the fortification of control tissue.

Fortification of Control Tissue:

To investigate this hypothesis further, homogenised control grain tissue was fortified with [¹⁴C]-clopyralid. The fortified sample was extracted, concentrated and analysed by HPLC following the same procedure as the treated grain sample. The resulting HPLC analysis showed an unresolved region accounting for 11.1% ROI. As the control tissue had been homogenised and stored frozen it is highly improbable that 'conjugates' were formed during the fortification experiment. Therefore, this supports the results from the pH adjustment experiments which show that the unresolved region is likely a result of interactions between clopyralid and endogenous plant matrix. Furthermore, this supports the conclusion that clopyralid likewise interacted with endogenous plant matrix in the treated wheat matrices, especially hay, straw, and grain.

SPE of Treated Samples:

Attempts were made to remove endogenous material from the concentrated aqueous acetonitrile extract from treated wheat grain using SPE. Removal of this endogenous material through ion exchange SPE resulted in the removal of the unresolved region. This further supports the idea that the unresolved region is linked to the endogenous matrix present in the sample. The reduction in the unresolved region could also be due to the use of mild base (ammonium hydroxide) during the SPE process. Use of mild base (ammonium hydroxide) to change sample pH also reduces the unresolved region. Overall, this SPE procedure shows that the unresolved region can be reduced to clopyralid with only very light manipulation of the sample.

LC-MS:

Initial MS analysis on the treated wheat grain sample, performed on a LUMOS Mass Spectrometer, did not detect clopyralid in the unresolved region. Interference from endogenous plant matrix present in the sample caused a number of effects, including suppression of the ionisation and very low intensity peaks. Limited injection volumes restricted the amount of mass injected on the MS, further reducing the intensity of peaks. Attempts to generate a cleaner sample for LC-MS analysis through SPE resulted in the loss of the unresolved region. To further investigate this initial MS analysis, additional MS work was conducted using an API4000 Mass Spectrometer. Analysis of the treated wheat grain and fortified wheat grain sample did not detect clopyralid in the unresolved region. Due to the low injection volumes used during this analysis, not enough mass was injected to detect clopyralid in the unresolved region.

Conclusion of Experiments on Unresolved Region:

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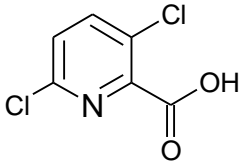
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Although experiments on this apolar unresolved region did not result in a conclusive identification, it can be strongly hypothesised that this region is the result of chromatographic effects of clopyralid weakly binding and interacting with endogenous material. Conversion to clopyralid is rapid under mild base conditions. Furthermore, clopyralid test material created a similar unresolved region when fortified onto control grain. Therefore, this region can be identified as base-labile clopyralid.

The structure, chemical name and the common name used in the study report for clopyralid are shown below.

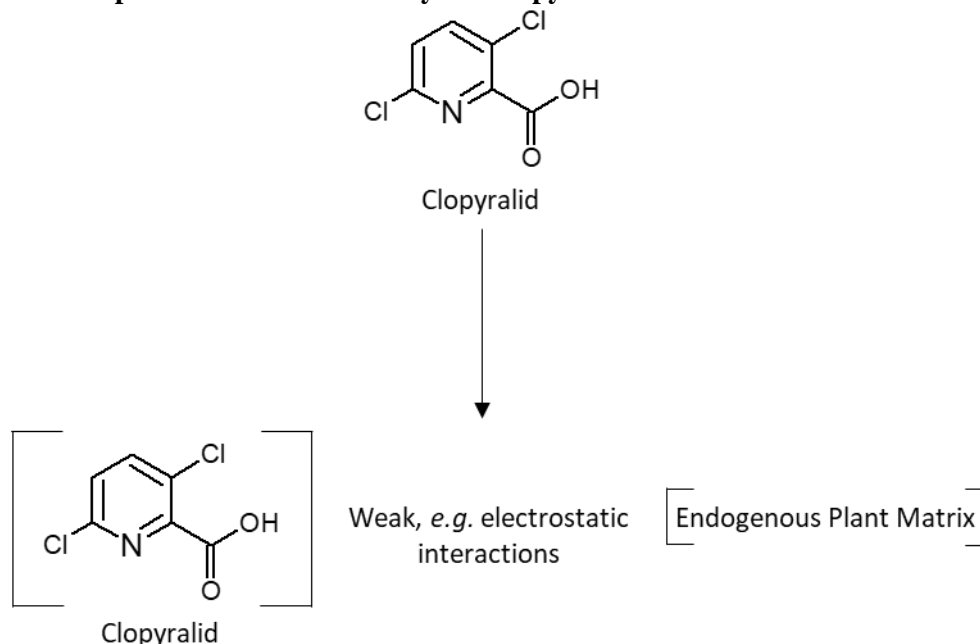
Table 24: Identification of compounds from metabolism study

Common name/code number	Chemical name	Chemical structure
Clopyralid	3,6-Dichloropicolinic Acid	

Metabolic Pathway

A metabolic pathway indicating interactions with endogenous plant material is presented below. No metabolites of clopyralid were detected in this study.

Figure 3: Proposed Metabolic Pathway for Clopyralid in Wheat



Storage Stability

Storage stability data for samples and extracts is provided below. All samples and extracts were stored in a freezer set to maintain -20 °C when not in use. Initial extractions of all samples occurred within 27 days after harvest, while HPLC analyses of initial extracts occurred typically within 49 days of harvest.

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Table 25: Summary of storage stability

Matrix	Storage temp. (°C)	Harvest date	Combustion analysis date	Initial extraction date	Initial chromatography date
Forage	-20 °C	26 Jul 2019	05 Aug 2019 (10 DAH)	22 Aug 2019 (27 DAH)	29 Aug 2019 (34 DAH)
Hay	-20 °C	15 Aug 2019	27 Aug 2019 (12 DAH)	03 Sep 2019 (19 DAH)	03 Oct 2019 (49 DAH)
Straw	-20 °C	23 Oct 2019	25 Oct 2019 (2 DAH)	31 Oct 2019 (8 DAH)	07 Nov 2019 (15 DAH)
Grain	-20 °C	23 Oct 2019	25 Oct 2019 (2 DAH)	31 Oct 2019 (8 DAH)	07 Nov 2019 (15 DAH)

DAH = days after harvest

CONCLUSION

The wheat metabolism study is considered scientifically acceptable. Following a single 125.87 g a.e./ha (104.9% of target) application of [¹⁴C]-clopyralid to wheat, TRR levels in forage, hay, straw and grain ranged from 1.879 – 3.717 mg eq/kg.

For all tissues, accountability, between combustion and extraction data, was 95.4 – 107.6%. When normalised with respect to accountability, aqueous acetonitrile recovered 50.6 – 90.5 %TRR and methanolic base extracts released a further 5.0 – 34.7 %TRR. Further extractions were conducted on all samples using mild aqueous base, mild and stronger acid, which released a further 2.6 – 7.5 %TRR. Non-extractable residues were 1.8 – 7.2 %TRR.

The aqueous acetonitrile contained a resolved clopyralid peak (15.4 – 66.0% TRR, 0.311 – 1.240 mg eq/kg) and a less polar, unresolved region (21.0 – 63.3% TRR, 0.394 – 2.351 mg eq/kg). Upon mild base treatment (similar to analytical method 120610 using methanol:10 N NaOH (100:1, v/v), overnight), primarily clopyralid was detected (*ca.* 98%). The methanol base extract, mild aqueous base and acid further extracts contained only clopyralid (*ca.* 99%). No polar clopyralid was detected in any sample.

Experiments on the apolar unresolved region demonstrated that it was completely converted to clopyralid within an hour of treatment with 5% ammonium hydroxide solution (2:1, v/v, sample:base ratio). Any sort of light manipulation of the sample (SPE, changing the pH etc.) to remove endogenous materials resulted in the elimination of this region, forming clopyralid. This indicates that the unresolved region is a result of weak binding interactions (*e.g.* electrostatic) between clopyralid and the endogenous plant matrix, which are disrupted by treatment with mild base or removal of endogenous material. The presence of the apolar region in the control sample fortified with clopyralid further adds to the theory that this region is a result of interactions between clopyralid and endogenous materials present in the sample. Overall, it can be strongly hypothesised that this region is the result of chromatographic effects of clopyralid weakly binding/interacting with endogenous material. Therefore, this region can be identified as base-labile clopyralid.

Greater than 90% of the extractable residue was identified as clopyralid. In total, clopyralid accounted for 98.0 %TRR (1.843 mg eq/kg) in forage, 97.2 %TRR (3.608 mg eq/kg) in hay, 92.6 %TRR (1.978 mg eq/kg) in straw and 96.4 %TRR (1.087 mg eq/kg) in grain.

A 2.1.2.1.1.2 Study 2 – Oilseed rape

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Comments of zRMS:	The study was performed according to OECD guideline and GLP requirements. In total, clopyralid (free and base-labile) accounted for >70% of the TRR in all samples, including seed, forage, trash, and pollen/anthers. However, the study should be evaluated at EU level.
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Reference: KCA 6.2.1/02

Report: Mackenzie.; 2021; The Metabolism of [¹⁴C]-Clopyralid in Oilseed Rape; Charles River Laboratories Edinburg Ltd., Tranent, UK; Lab Study No. 231101; DAS Study No. 200928; 22 September 2021; Unpublished

Guidelines: OECD 501, OPPTS 860.1300

Deviations: none

GLP: Yes

BACKGROUND INFORMATION

Clopyralid (3,6-dichloropyridine-2-carboxylic acid) is a selective herbicide developed for use on a variety of agricultural crops including oilseed rape.

A previous study had been conducted to investigate the metabolism of clopyralid in oilseed rape. In this study, two regions of unidentified radioactivity were detected in trash and seed. A polar component re-formed clopyralid under modified HPLC conditions or acid hydrolysis; evidence indicated this was an artefact of the HPLC system and it was concluded to represent unchanged clopyralid. An apolar component was entirely converted to clopyralid by hydrolysis and was concluded to be either unchanged clopyralid or clopyralid in conjugated form. The amount of co-injected organic solvent and potentially matrix effects during chromatography appeared to influence the amount of each component. Therefore, the Sponsor initiated an additional oilseed rape study to further investigate the nature of these unknowns.

MATERIALS AND METHODS

Test Item(s)

Non-radiolabelled test item #1

Test item (Common name): Clopyralid
Purity: 99.9%
Description (physical state): Solid
Lot/batch no.: TSN301194 (YC2-106153-68)

Radiolabelled test item #1

Test item (Common name): [¹⁴C]-Clopyralid
Name: 3,6-Dichloropicolinic acid-2,6-¹⁴C, X755015

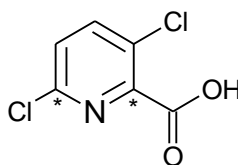
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Structural Formula:

Position of labelling (*)



Lot/batch no.:

INV306082

Radiochemical purity:

99.0%

Specific radioactivity:

35.0 mCi/mmol

Methods

Test Site Information

Testing environment:

F - (outdoors) from application until mature harvest, except one plot moved into glasshouse (25 May 2020) for pollen collection - G

Container description:

Plastic, internal dimensions: 0.755 x 0.555 m, 6 used (5 treated and 1 control)

Soil type:

Sandy Loam (UK and USDA)

Soil characteristics:

2.16% OM
 pH 7.2 (in water)
 CEC 8.9 meq/100 g
 63% Sand (USDA)
 26% Silt (USDA)
 11% Clay (USDA)

Any adverse weather conditions:

No

Any adverse insect or disease problems:

No

Study Use Pattern

Application method:

Foliar

Formulation type:

Monoethanolamine salt, GF-1966

Application rate:

200 g ae/ha (target), actual 199.09 g ae/ha

Number of applications:

1

Timing of applications

19 May 2020, BBCH 30

PHI (Days after Treatment):

23 (forage), 9-31 (pollen/anthers), 94 (mature seed and trash)

Test System

Organism (*Species*):Spring oilseed rape (*Brassica napus*)

Variety:

Click

Crop group:

Oilseed

Growth stage at application:

BBCH 30

Harvested RAC:

Early forage, seeds

Other harvested commodities:

Pollen/anthers, trash

Growth stage at harvest:

Pollen/anthers: BBCH 60-69 (28 May–19 Jun 2020),
 Early forage: BBCH 66 (11 Jun 2020),
 Mature seed and trash: BBCH 89 (21 Aug 2020)

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Harvesting procedure:

Plants were randomly sampled for forage harvest (approximately 1/3 from each of the containers except the container dedicated to pollen/anther harvest), cut at soil surface. Remaining plants were sampled at maturity. Pods were removed and seeds separated from pods by hand. Trash was cut at soil surface and combined with pods.

Forage, trash, and seeds were stored frozen (-20°C).

Anthers (containing pollen) were separated from flowers using tweezers every 1-5 days for *ca.* 3 weeks and stored at 4°C between collections.

Sample Handling, Preparation, and TRR Determination

Each frozen plant fraction (forage, trash and seeds) was homogenised with excess carbon dioxide chips using a Waring PB20 or a Hobart VCB61 blender. The carbon dioxide was then allowed to sublime while frozen prior to removal of sub-samples for combustion. Sub-samples (five each, *ca.* 0.3 g) of the milled tissue were analysed by oxidative combustion to determine the total radioactive residues in the sample.

As part of the extraction sequence, the anther samples were manually separated into anther capsules and pollen using a scalpel blade and washed with water to fully separate the pollen from the anther capsules. This was conducted on the same day following the final anther/pollen harvest and the processed samples stored in a freezer set to maintain -20°C.

Extraction of Sample Residues – Forage, Trash and Seeds**Aqueous Acetonitrile Extraction (E1-2)**

Samples of oilseed rape forage, trash and seed were extracted as follows. Approximately 25 g (forage or trash) or 15 g (seeds repeat) of homogenised tissue was extracted with 1:1 acetonitrile:Milli-Q® water (v/v) at a solvent:sample ratio of 5:1 (mL:g) for forage and seed, and a ratio of 10:1 for trash (included a *ca.* 30 minutes soak prior to blending). The mixture was blended using a Silverson L5T TopDrive homogeniser for approximately 5 minutes at room temperature. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and Extract 1 decanted. The extraction was repeated once more at a solvent:sample ratio of 2.5:1 (mL:g) for forage and seed and 5:1 (mL:g) for trash, and Extract 2 decanted. Extract 1 and Extract 2 were pooled and the volume measured. Where required, extracts were filtered through a 100 µm nylon cell strainer when decanting after centrifuging. Any solid material captured during filtration was returned to the extraction pot. Aliquots of each combined extract (E1-E2) were analyzed by liquid scintillation counting.

For forage aqueous acetonitrile extracts E1-E2 only, where recovery was slightly lower, a flask wash of the associated glassware from concentration including round bottom flask, volumetric flask and centrifuge tube was conducted using acetonitrile. The flask wash was centrifuged (*ca.* 13,000 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) prior to analysis by LSC and direct analysis by HPLC.

Methanolic Base Extraction (E3)

Following neutral organic solvent extraction, the samples were subjected to base extraction. The entire remaining residue sample following neutral organic extraction was homogenised in the presence of methanol:10 N aqueous sodium hydroxide (100:1, v/v) for *ca.* 1 minute at room temperature using a Silverson L5T TopDrive homogeniser before being shaken on a reciprocal shaker for *ca.* 1 hour. Forage and seed samples were extracted at a solvent:sample ratio of 2.5:1 (mL:g) and trash samples were extracted at a

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solvent:sample ratio of 5:1 (mL:g). The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the total extract volume measured. Where required, extracts were filtered through a 100 µM nylon cell strainer when decanting after centrifuging. Any solid material captured during filtration was returned to the extraction pot. Aliquots of Extract 3 were analysed by liquid scintillation.

Methanolic Base Extraction (E4-E6) of Seed Only

For seed samples, the entire remaining residue following extract 3 was extracted with methanolic base (E4-6) as follows. For extract 4 (E4) and extract 5 (E5), the remaining seed residue was homogenised in the presence of methanol:10 N sodium hydroxide (100:1, v/v) for *ca.* 1 minute at room temperature, using a Silverson L5T TopDrive homogeniser, before being shaken on a reciprocal shaker for either *ca.* 1 hour (E4) or overnight (E5). Extractions were performed at a solvent:sample ratio of 4:1(mL:g) and 2.5:1(mL:g) for E4 and E5, respectively. For each extraction, solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the extract volume measured prior to analysis by liquid scintillation counting.

Following E5, the remaining residue was homogenised in the presence of 0.5 N aqueous sodium hydroxide at a solvent:sample ratio of 2.5:1 (mL:g) for *ca.* 5 minutes at room temperature using a Silverson L5T TopDrive homogeniser before being placed in a shaking water bath set to maintain at *ca.* 50°C for *ca.* 4 hours. The sample was allowed to cool prior to separating the solid and liquid phases by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). The remaining solid residue was then rinsed with methanol at a solvent:sample ratio of 1:1 (mL:g), shaken by hand for 30 seconds and the solid and liquid phases separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). The methanol rinse was repeated a second time and both rinses and 0.5 N NaOH extract pooled forming Extract E6. The total extract volume was measured prior to analysis by liquid scintillation counting.

Further Extraction 0.1N Sodium Hydroxide (FE1) of Forage and Trash Only

Following the initial extractions (E3) and initial combustion of the remaining debris the remaining residue from forage and trash samples was further extracted in the presence of 0.1 N NaOH at a solvent:sample ratio of 10:1 (mL:g). Extracts were placed in a water bath set to maintain at *ca.* 50°C for *ca.* 4 hours. The extracts were allowed to cool prior to separating the solid and liquid phases by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). Following Further extract 1 the tissue sample was rinsed with Milli-Q water (5:1 mL/g), and the resulting rinse shaken by hand prior to separation by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). The water rinse was combined with the 0.1 N NaOH extract. The total extract volume was recorded and aliquots of Further Extract 1 were analysed by liquid scintillation.

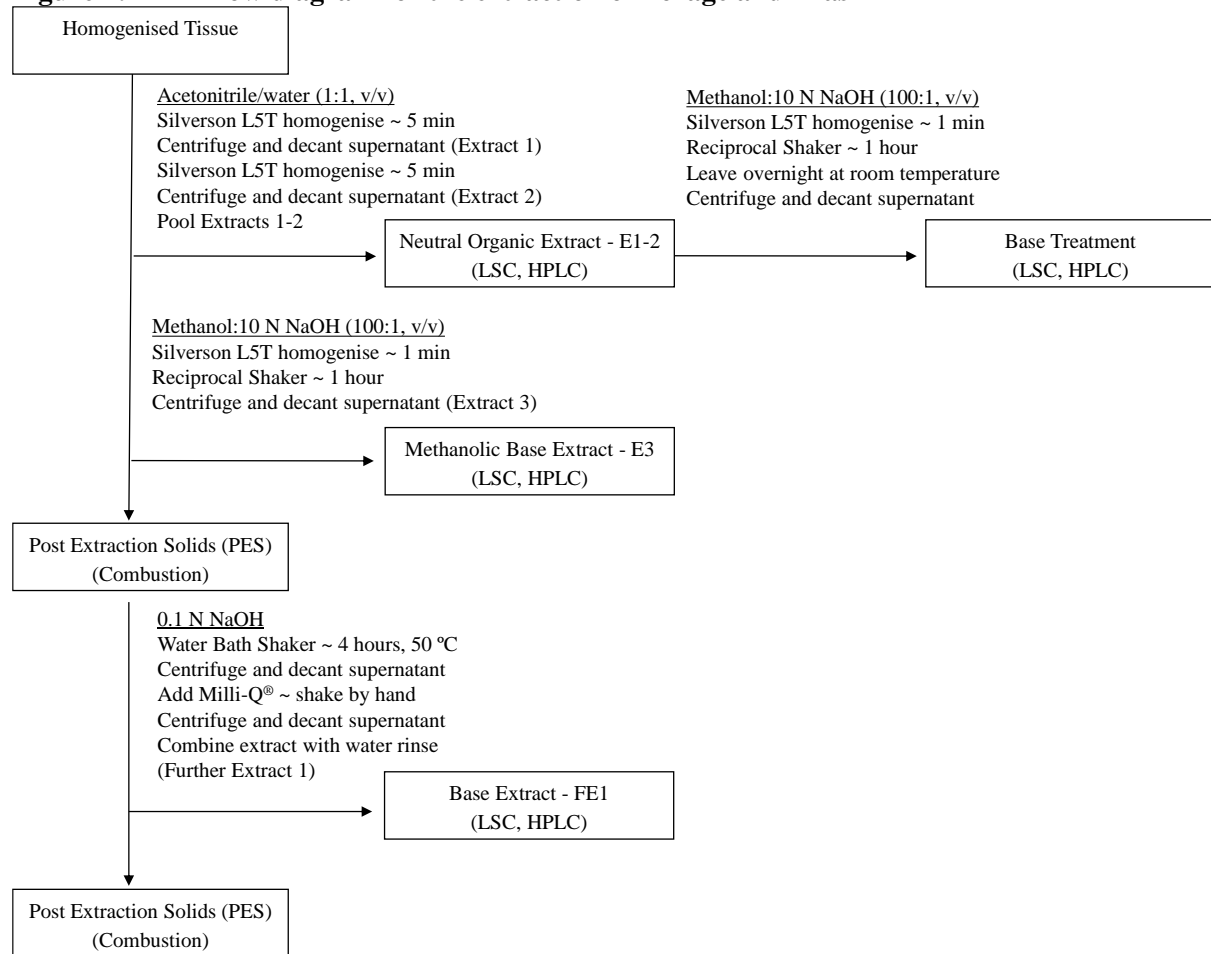
Further Extraction 0.5N Sodium Hydroxide (FE1) of Seed Only

Following the extraction of seeds through E6, the remaining residue was homogenised in the presence of 0.5 N sodium hydroxide at a solvent:sample ratio of 8:1 (mL:g) for *ca.* 5 minutes at room temperature using a silverson SL2 TopDrive homogeniser before being placed in a shaking water bath set to maintain at *ca.* 50°C for *ca.* 4 hours. The sample was allowed to cool prior to separating the solid and liquid phases by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). The remaining solid residue was then rinsed with methanol at a solvent:sample ratio of 1:1 (mL:g), shaken by hand for 30 seconds and the solid and liquid phases separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40). The methanol rinse was repeated a second time. Both rinses and 0.5 N NaOH extract were pooled and total extract volume measured. Aliquots of Further Extract 1 were analysed by liquid scintillation counting.

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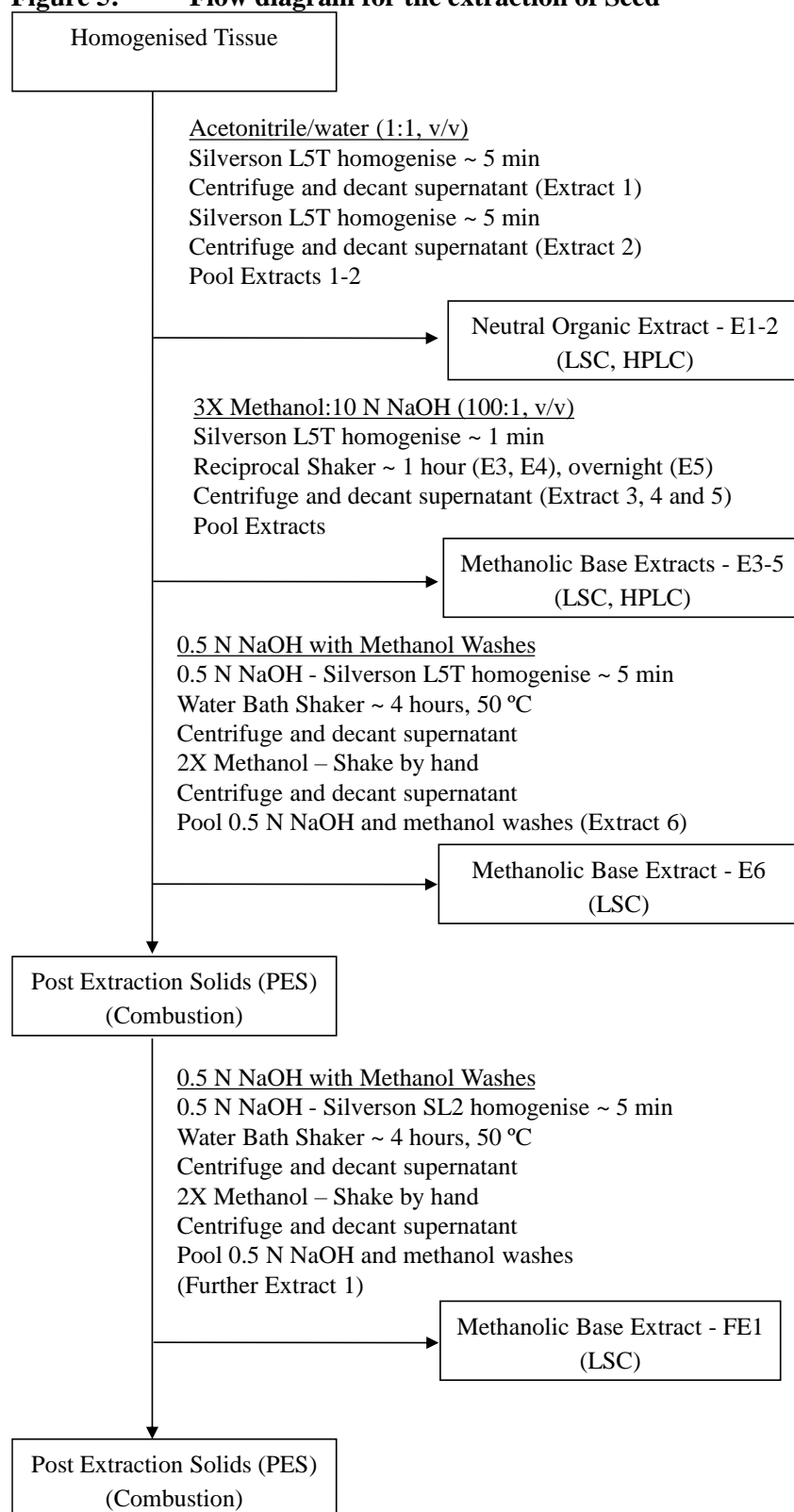
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Figure 4: Flow diagram for the extraction of Forage and Trash

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Figure 5: Flow diagram for the extraction of Seed

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Extraction of Sample Residues – Anthers/Pollen

Anther/Pollen Processing

Once all of the sample collection was complete (after approximately three weeks of sampling every 1-5 days), the anthers (including pollen) were finely chopped with a scalpel blade to open up the anther capsules and release the pollen. Water was used to wash the pollen away from the anther capsules; Milli-Q® water was added to completely cover the sample, still containing the anthers with the pollen, and the mixture was then agitated using a vortex mixer for *ca.* 1 minute and sonicated for *ca.* 5 minutes. The pollen suspension was decanted from the anthers then transferred to a centrifuge tube and centrifuged (*ca.* 13000 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) to separate the pollen from the water wash. The volume of the water wash (Water Wash 1) was measured and transferred to a suitable container. The remaining anthers sample was washed a second time following the same procedure to suspend any remaining pollen. The volume of the water wash (Water Wash 2) was measured and transferred to a suitable container. Water Wash 1 and Water Wash 2 were analysed by LSC. Following the water washes, the individual pollen and anthers fractions were weighed.

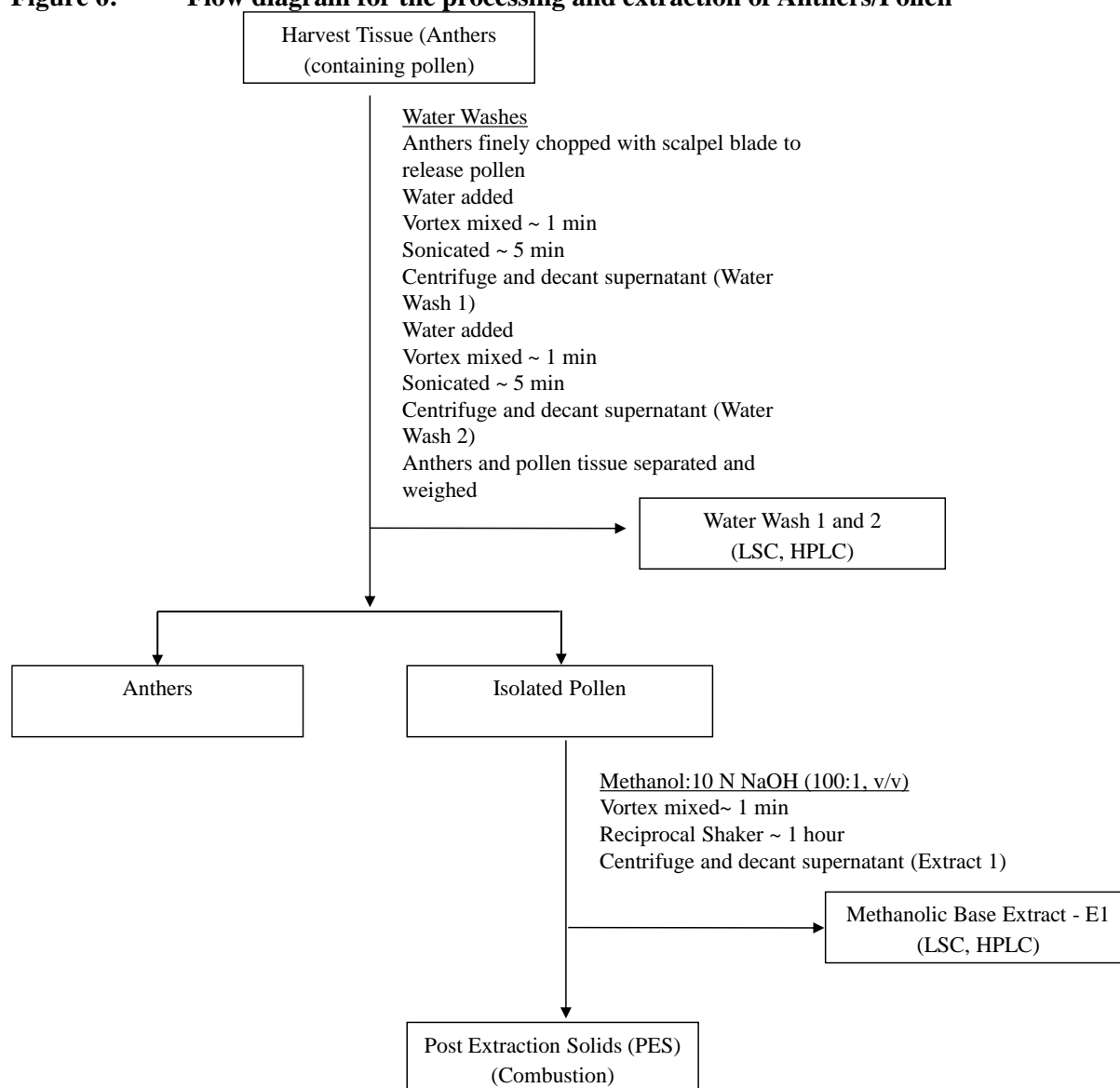
Pollen Extraction

Once isolated from the anthers, pollen was extracted with methanol:10N NaOH (100:1 v/v) at a solvent:sample ratio of 25:1 (mL:g). Note that the mass of isolated pollen allowed for a single extraction, not a sequence, and therefore the MOR analytical method solvent was selected. The mixture was vortex mixed for *ca.* 1 minute and then placed on a reciprocating shaker for *ca.* 1 hour at room temperature. The solid and liquid phases were separated by centrifugation (*ca.* 13000 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the extract decanted and volume measured. The pollen extract was analysed by liquid scintillation counting. The pollen post extraction solid was combusted.

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Figure 6: Flow diagram for the processing and extraction of Anthers/Pollen**Analytical Method Extraction (Radiovalidation)**

To compare the extractability of the analytical method to the metabolism method, aliquots of forage, trash and seeds homogenised tissue were subjected to base treatment, using methodology from the field trial analytical method (Dow 120610). For each commodity 100 mL of methanol:10 N NaOH (100:1, v/v) was added to *ca.* 5 g of homogenised tissue. Samples were homogenised for *ca.* 1 minute using a Silver-son L5T TopDrive homogeniser, shaken for *ca.* 1 hour on a reciprocal shaker and left at ambient temperature overnight. Samples were centrifuged and the supernatants analysed by LSC. One mL (forage) and 5 mL (trash) of extract was neutralized with hydrochloric acid solution prior to concentration under a gentle stream of nitrogen. Samples were reconstituted in 1 mL acetonitrile:water (3:7, v/v) and analysed by LSC prior to HPLC analysis.

For the seeds extracts only, 30 mL of the resulting extract was split between two 50 mL centrifuge tubes (15 mL in each tube) and 3 mL of 1 N NaOH added to each. The samples were then placed under a gentle stream of nitrogen to remove the methanol (*ca.* 3 mL volume remained). The samples were made to

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15 mL each with 1 N NaOH. The samples were then partitioned with an equivalent volume of DCM (15 mL), then vortex mixed and sonicated thoroughly prior to centrifuging at *ca.* 3000 rpm for *ca.* 2 minutes. The aqueous layer was removed and both the aqueous and DCM layers pooled prior to analysis by LSC. Five mL of the aqueous layer was concentrated to *ca.* 0.5 mL then made to 1 mL with acetonitrile:water (3:7 v/v). The sample was neutralized with concentrated hydrochloric acid. The neutralized sample was analysed by LSC prior to HPLC analysis.

Characterisation of Apolar Region

Neutral Organic Extract Base Treatment

To further characterise the neutral organic extracts (E1-2) of forage, trash, and seeds, 10 mL aliquots of pooled extract 1-2 were subjected to base treatment, using methodology similar to the field trial analytical method (Dow 120610). The neutral solvent was evaporated under nitrogen, at ambient temperature, until dryness and the sample reconstituted in 10 mL of methanol:10 N NaOH (100:1, v/v). Samples were homogenised for *ca.* 1 minute using a Silverson SL2 TopDrive homogeniser, shaken for *ca.* 1 hour on a reciprocal shaker and left at ambient temperature overnight. Samples were centrifuged (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and the supernatants analysed by LSC. For forage only, where recoveries were low, a wash of the pellet after centrifuging was conducted using 5 mL water:acetonitrile, 1:1 (v/v). The wash was centrifuged (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) prior to analysis by LSC. Base treatment samples were combined with the respective wash prior to concentration and HPLC analysis.

A separate control sample consisting of an aliquot of forage pooled extract 1-2 was processed using the same procedure with methanol:water (100:1, v/v), containing no sodium hydroxide to confirm that any changes during processing resulted from the presence of base in the samples.

pH Adjustment of Treated Samples

To investigate the effects of pH on oilseed rape, the concentrated aqueous acetonitrile extracts (E1-2) of forage were subjected to a number of experiments:

1. An aliquot of concentrated E1-2 was pH adjusted with the addition of 5% ammonium hydroxide solution (4:1, v/v sample:base ratio). The aliquot at each time point, 0.5 hours and 24 h, was acidified to pH 1 immediately prior to injection on the HPLC to aid chromatography.
2. To investigate the second peak, a number of further investigations were conducted. The solvent ratio in the initial pH adjustment experiments described above was acetonitrile:water (3:7, v/v). To investigate possible effects from the organic solvent, two aliquots of forage concentrated E1-2 had the solvent removed under a gentle stream of nitrogen. One aliquot was reconstituted in water, containing a small amount of 5% ammonium hydroxide solution (17:1, v/v sample:base ratio), and one aliquot was reconstituted in 5% ammonium hydroxide solution. After 1 hour, the ammonium hydroxide aliquot was acidified to pH 1 and the water aliquot was neutralized to pH 7 immediately prior to analysis.
3. To investigate the presence of an ammonium adduct, an aliquot of forage concentrated E1-2 was added to two vials. An equal amount of ¹⁴C clopyralid (dpm) was spiked into one of the vials, and both aliquots had the solvent removed under a gentle stream of nitrogen prior to reconstitution in an equivalent volume of 5% ammonium hydroxide solution. After 1 hour, both samples were acidified to pH 1 immediately prior to injection.
4. The results from the organic solvent experiments detailed above indicated that there may also be an impact from the pH during chromatography. To investigate this, two aliquots of forage concentrated E1-2 had the solvent removed under a gentle stream of nitrogen prior to reconstitution in an equivalent volume of 5% ammonium hydroxide solution. After 1 hour, one aliquot was

neutralized to pH 7 and one aliquot was acidified to pH 1 immediately prior to analysis.

5. Based on the structure of clopyralid, it was postulated that it may be an effective chelator in biological systems, similar to picolinic acid. Structural analogues of clopyralid have been shown to weakly chelate to heavy metal ions in matrix. To investigate this, it was suggested that Na⁺ ions may disrupt the chelation similar to the caustic used in the base treatment methods using methanol:10 N NaOH (100:1 v/v). Two aliquots of forage concentrated E1-2 had the solvent removed under a gentle stream of nitrogen. One aliquot was reconstituted in an equivalent volume of 5% ammonium hydroxide solution. Both aliquots had an equivalent volume of 1 M NaCl added to generate an excess of Na⁺ ions in the sample. The aliquot without 5% ammonium hydroxide acted as a control. After 1 hour, both aliquots were acidified to pH 1 immediately prior to analysis.

Control Tissue Fortification

Control oilseed rape forage tissue (*ca.* 5 or 10 g) was fortified with ¹⁴C clopyralid (0.38 or 2.27 µCi) and subjected to aqueous acetonitrile extraction (E1-E2). The extract was concentrated in preparation for HPLC. The same experiment was attempted twice on control oilseed rape forage tissue under this study.

Extraction of Oilseed Rape Forage for Apolar MS

To assist with metabolite identification analysis of the apolar region, an aliquot of oilseed rape forage was extracted as follows. Approximately 15 g of homogenised forage tissue was extracted with 1:1 acetonitrile:Milli-Q[®] water (v/v) at a solvent:sample ratio of 3.6:1 (mL:g). The mixture was blended using a Silverson L5T TopDrive homogeniser for approximately 5 minutes at room temperature. The solid and liquid phases were separated by centrifugation (*ca.* 3500 rpm, *ca.* 10 minutes, Thermo Heraeus Megafuge 40) and Extract 1 decanted. Aliquots of the extract were analyzed by liquid scintillation counting. Immediately following extraction, the extract was analysed by LC-MS/MS. Although initial LC-MS analysis was conducted on the day of extraction, further investigations were conducted on subsequent dates, as appropriate.

Concentration, Molecular Weight Filtration, and Methylation of the Neutral Organic Extract (Including the Apolar Region)

Concentration of the oilseed rape forage neutral organic extract for MS was conducted using a nitrogen stream to avoid any heating of the sample which was suspected to cause degradation of the apolar region back to clopyralid parent which had been observed on previous studies. The bulk extract (38 mL) was concentrated to approximately 3 mL and analysed by LC-MS.

The concentrated OSR Forage extract sample (1.8 mL) was split between 6 x Amicon Ultracel 3K Centrifugal Molecular weight filtration tubes and centrifuged at 13,000 rpm for 2 x 15 minute periods. The supernatant was removed as was the remaining liquid portion on the filter. LSC counting indicated that 47% of the radioactivity was present in the supernatant and 53% present in the unfiltered liquid. LC-MS analysis was conducted on both portions.

An aliquot of molecular weight filtered (3KDa Filter) OSR extract sample was taken forward for methylation using a TMS-diazomethane / methanol methylation procedure. An aliquot, 0.3 mL, of the concentrated OSR extract sample that had been subjected to centrifugal molecular weight filtration was diluted with 1.0 mL of methanol and 1.5 mL of trimethylsilyl diazomethane added. The reaction mixture was stirred at ambient temperature for 1h and the reaction quenched by the addition of 0.2 mL of acetic acid. The reaction mixture was concentrated to dryness and dissolved in 0.5 mL of Milli-Q water. LC-MS analysis was conducted on the reaction mixture.

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Metabolite Isolation and Identification

Non-radiolabeled clopyralid was used as a reference standard for chromatographical comparison. HPLC retention time comparisons were made between this reference standard and the radioactive peaks in the chromatograms in order to provide initial tentative identifications.

Based on the initial HPLC analyses, clopyralid fractions were targeted for structure confirmation. This was accomplished using neutral organic extracts (E1-2) both before and after base treatment in oilseed rape forage and in neutral organic extracts (E1-2) before base treatment oilseed rape seeds. These samples were submitted for radio LC-MS and LC-MS/MS analyses.

Analytical Methodology

Total ^{14}C measurement

Oxidative Combustion:

Approximately 0.05-0.3 g sub-samples (3-5 replicates of forage, trash and seeds samples; and one aliquot of pollen PES) of each sample were weighed into Combustocones[®] and combusted using a PerkinElmer Tri-Carb 307 Automatic Sample Oxidiser. The resultant $^{14}\text{CO}_2$ was absorbed in Carbo-Sorb[®], mixed automatically with Permafluor[®] scintillation fluid and the radioactivity determined by LSC.

The efficiency of the oxidiser was determined daily, and at regular intervals throughout each batch of analyses. Carbon-14 quality control standards were combusted at the beginning and at regular intervals throughout each batch of analyses. Combustion efficiencies were in excess of 98.3%. Combustion values were not corrected for the oxidiser efficiencies.

Liquid Scintillation Counting:

The liquid scintillation counters automatically converted the radioactivity counting rate in counts per minute (cpm) to disintegrations per minute (dpm) using an external standard to correct for sample quenching. The instrument was calibrated approximately every three months with a set of ten quenched standards. Each day of use, the instrument was normalized and its performance was checked with respect to background cpm value, unquenched standard cpm value, and quenched standard dpm value for a range of quenched standards. The scintillation counters used were Packard 2100TR Tri-Carb (Packard Instrument Co.). The radioactive content (dpm) of liquid samples was determined by LSC. Triplicate aliquots (0.005 – 5 mL) were taken from each sample and mixed with scintillation cocktail (Aquasafe 500 Plus scintillation cocktail, Zinsser Analytic, Maidenhead, UK).

Sample Concentration - E1-3 (Neutral and Base Treated) and FE1 (Caustic Extracts)

The general sample processing procedure for the aqueous acetonitrile pooled extract 1-2 was to concentrate aliquots by rotary evaporation or under a gentle stream of nitrogen, to a reduced volume or dryness before reconstitution to a known volume in a solvent suitable for HPLC (water:acetonitrile 7:3, v/v). Samples were centrifuged (*ca.* 13,000 rpm for *ca.* 10 minutes) and the supernatant analysed by LSC to monitor recovery and then by HPLC.

Aliquots of forage and trash extract 3 in forage and trash (E3, methanol:10 N NaOH, 100:1, v/v) and pollen extract 1 (E1, methanol:10 N NaOH, 100:1, v/v) were neutralised to *ca.* pH 7 using hydrochloric acid solution before concentration using the same techniques as the neutral organic extracts (E1-2).

Where required, aliquots of base treatment neutral organic extracts E1-2 (methanol:10 N NaOH, 100:1, v/v) and associated control samples (methanol:water, 100:1, v/v) were combined with the respective wash prior to concentration. Base treated samples of E1-2 were also neutralized prior to concentration. Control sample extracts were processed in a similar manner to the neutral organic extracts.

Aliquots of mild base further extracts (FE1) were neutralised to *ca.* pH 7 using hydrochloric acid solution before concentration to dryness under a gentle stream of nitrogen or by rotary evaporation to a reduced

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volume before reconstitution to a suitable volume with water. Samples were then analysed following a similar process to the neutral organic extracts.

Processing and Concentration of Seeds Methanolic Base Extracts

Oilseed rape seeds extracts E3-5 (methanol:10 N NaOH, 100:1, v/v) were combined in equal proportion (5% of each extract; total volume 5.3 mL) and added to a 15 mL centrifuge tube. One mL of 1 N NaOH was added and the sample placed under a gentle stream of nitrogen to remove the methanol. Once the methanol had been removed and *ca.* 1 mL NaOH remained, the sample was made to 5 mL with 1 N NaOH. The sample was then placed in a shaking water bath set to maintain *ca.* 90 °C for 4 hours. The sample was then allowed to cool prior to partitioning with 5 mL DCM. The sample was vortex mixed and sonicated thoroughly prior to centrifuging (*ca.* 3,000 rpm for *ca.* 2 minutes). The aqueous layer was removed. A further 5 mL 1 N NaOH was added to the DCM layer and a second partition performed (centrifuging at *ca.* 13,000 rpm for *ca.* 10 minutes). The two aqueous layers were acidified using 5 mL of 1 N HCl per aqueous phase and the pH confirmed to be strongly acidic using pH paper.

Two Waters Oasis HLB SPE cartridges (200 mg, 6 cc) were conditioned with 5 mL methanol followed by 5 mL 1 N HCl. The cartridges were dried under vacuum in the SPE manifold for *ca.* 10 seconds. The acidified samples were loaded onto the cartridges and the loading eluates collected separately. The cartridges were eluted with 1 mL 1 N HCl each and this collected into the loading eluates. The cartridges were then eluted with 4.5 mL acetonitrile:1 N formic acid (15:85, v/v) each, which was collected as a separate fraction. The cartridges were dried under vacuum (*ca.* 15 inches Hg) for 30 minutes to ensure that all the solvent was collected from the cartridge. The cartridges were then eluted with 14 mL DCM each which was collected as a separate fraction.

The DCM eluate was concentrated under a gentle stream of nitrogen to dryness and reconstituted in 1 mL 0.1% formic acid (aq): methanol (90:10, v/v). The concentrated sample was analysed by LSC to monitor recovery and then by HPLC.

A similar procedure was attempted for seed E6 without the hydrolysis for 4 hours at *ca.* 90 °C as E6 had already underwent elevated temperature during extraction.

High performance liquid chromatography (HPLC) for quantitation

HPLC analyses of all sample extracts were accomplished using a Waters SPHERISORB ODS 2 column (150 x 4.6 mm, 5 µm particle size; 1.0 mL/min; UV detection at 280 nm) and a 1 step, non-linear gradient.

Mass spectral analysis (LC/MS) for identification of transformation products

Neutral organic extracts (E1-2) both before and after base treatment in oilseed rape forage and in neutral organic extracts (E1-2) before base treatment oilseed rape seeds were used for confirmation of clopyralid by mass spectral analysis. Mass spectral analysis was also conducted on neutral organic extracts (E1-2) of forage which was extracted for apolar MS analysis.

RESULTS AND DISCUSSION

Results of In-Life Phase

An equal volume of the [¹⁴C]-clopyralid application solution was foliarly applied to each of five treated containers when the plants were at growth stage BBCH 30. Each container received 8.34 mg of the test item equivalent to 199.09 g a.e./ha (99.5% of target). Radiochemical purity and stability of the formulated application solution pre- and post-application were ≥98.7%, indicating the stability of the radio-labelled test item throughout the formulation and application process.

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Total Radioactive Residue (TRR) Levels

TRR levels in forage, trash and seed samples, expressed as mg/kg of parent equivalents are shown below.

Table 26: Total radioactive residues (TRRs) in Plant Samples Collected for Clopyralid Nature of Residue in Oilseed Rape Study

Matrix	Days after Application	TRR (mg eq./kg ¹)
Forage	23	1.839
Trash	94	0.224
Seed	94	0.069

¹ = mg eq/kg = mg parent equivalents per kg of tissue

Anthers containing pollen were not combusted prior to sample processing. The pollen was separated from the anthers using water and centrifugation. The pollen was characterized by extraction and final debris combustion. The residue in the remaining anthers post-washing fraction was not determined in this study and therefore an overall TRR is not available.

Distribution of Residues Following Extraction

Forage

Extractability was high in forage where 99.1% TRR (1.822 mg eq/kg) was extracted in neutral organic extracts, 5.3% TRR (0.097 mg eq/kg) in methanolic base extract (plus 1.7% TRR in further extract 1, 0.1 N NaOH and water rinses). The final non extractable residue (NER) accounted for 1.2% TRR (0.022 mg eq/kg). Good correlation between the extractable TRR and initial combustion analysis was observed (107.3%).

Trash

Extractability was high in trash, where 76.9% TRR (0.172 mg eq/kg) was extracted in neutral organic extracts and another 15.9% TRR (0.036 mg eq/kg) in methanolic base extract (plus 5.7% TRR in further extract 1, 0.1 N NaOH and water rinses). The final non-extractable residue (NER) accounted for 7.9% TRR (0.018 mg eq/kg). Good correlation between the extractable TRR and initial combustion analysis was observed (106.4%).

Seed

Neutral extractability was less than observed for forage and trash, although overall extractability was nearly 100%. The neutral acetonitrile/water extraction removed 40.8% TRR (0.028 mg eq/kg), while a total 35.9% TRR (0.025 mg eq/kg) was found in methanolic base extracts (E3-5) (plus 15.5% TRR in E6, 0.5 N NaOH and methanol rinses, and 4.5% TRR in Further Extract 1, 0.5 M NaOH). The final non-extractable residue (NER) accounted for 8.0% TRR (0.006 mg eq/kg). Good correlation was observed between the extractable TRR and initial combustion analysis (104.7%).

The distribution of the residues in the oilseed rape forage, trash and seed samples among the fractions generated following the extractions, expressed both as a percentage of the total sample residue and as mg/kg of clopyralid equivalents is shown below.

Table 27: Distribution and Characterisation of Residues in Oilseed Rape Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Spring Oilseed Rape					
	Forage		Trash		Seeds	
	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg
TRR ¹	100	1.839	100	0.224	100	0.069

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Pooled Extract 1-2 Acetonitrile:water (1/1, v/v)	99.1	1.822	76.9	0.172	40.8	0.028
Extract 3 Methanol:10 N NaOH (100/1, v/v)	5.3	0.097	15.9	0.036	9.7	0.007
Extract 4 Methanol:10 N NaOH (100/1, v/v)	NC	NC	NC	NC	11.0	0.008
Extract 5 (overnight) Methanol:10 N NaOH (100/1, v/ v)	NC	NC	NC	NC	15.2	0.010
Extract 6 0.5 N NaOH with Methanol washes	NC	NC	NC	NC	15.5	0.011
Sum of initial extracts (1-6)	104.4	1.919	92.8	0.208	92.2	0.064
Initial combustions of PES	4.1	0.075	15.1	0.034	16.2	0.011
Further Extract 1 0.1 M NaOH (forage and trash) 0.5 M NaOH (seeds)	1.7	0.031	5.7	0.013	4.5	0.003
Sum of initial and further extracts	106.1	1.950	98.5	0.221	96.7	0.067
Final Unextracted	1.2	0.022	7.9	0.018	8.0	0.006
Accountability (%) ²	107.3		106.4		104.7	

1 = TRR determined by initial combustion

2 = Accountability = % TRR total extractable + % TRR unextractable

NC = Not Conducted

Anthers/Pollen

The residues in the pollen/anther water washes, based on the harvest weight of anthers sample (containing pollen), were found to be 1.095 and 1.316 mg eq/kg for water wash 1 and 2, respectively. This is equivalent to 45.4 and 54.6 % of the total residue in the anthers sample (containing pollen) water washes.

Anther/pollen water washes contained radioactive residues associated with solubilized nectar and sugars. However, due to the high aqueous solubility of clopyralid these water washes, could also contain clopyralid residues associated with the anthers and pollen. Therefore, it was not possible to determine the total residue in the individual components of the anthers (e.g., pollen).

The isolated pollen residue following initial processing was extracted. The residues in the pollen extract and final solid residue were 0.592 and 0.100 mg eq/kg, based on the wet weight of isolated pollen. This is equivalent to 85.5 and 14.5% of the total residue in the isolated pollen sample. This is a minimum residue associated with the pollen as an unknown proportion of the residue in the water washes of the anthers (containing pollen) may also have been extracted from the pollen. The unextracted residue in isolated pollen accounted for 14.5% of total (0.100 mg eq/kg).

Table 28: Distribution and Characterisation of Residues in Oilseed Rape Anthers/Pollen Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Spring Oilseed Rape			
	Anthers (containing pollen) Water Washes		Isolated Pollen	
	% of Total ²	mg eq/kg	% of Total ³	mg eq/kg
% of Total ¹	100	2.411	100	0.692
Water Wash 1	45.4	1.095	-	-
Water Wash 2	54.6	1.316	-	-
Extract 1 Methanol:10 N NaOH (100:1 v/v)	-	-	85.5	0.592
Unextracted	NA	NA	14.5 ⁴	0.100 ⁴

1 = Sum of % extractable and unextractable, where applicable.

2 = % of total extractable residue in anthers (containing pollen) sample.

3 = % of total extractable and unextractable residue in isolated pollen.

4 = Due to limited sample it was only possible to combust a single aliquot of the post-extraction solid (PES). This aliquot was based on a wet weight of pollen PES as drying was not possible.

NA = Not Applicable

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Characterization and Identification of Residues

Forage:

Parent compound clopyralid (free, *i.e.*, neither bound nor conjugated) was a major component in the aqueous acetonitrile extract accounting for 28.8% TRR (0.530 mg eq/kg). The majority of the neutral extract eluted in a poorly resolved region that was less polar than clopyralid and accounted for a total of 64.0% TRR (1.178 mg eq/kg). Upon base treatment and preparation for chromatography, there was a slight loss of radioactivity prior to profiling, however the entire apolar region was converted to clopyralid, therefore, the entire apolar residue was characterized as base-labile clopyralid.

Parent compound clopyralid (free, *i.e.*, neither bound nor conjugated) was a major component in the aqueous acetonitrile extract flask wash accounting for 0.8% TRR (0.014 mg eq/kg). (E1-2 flask wash). As for the neutral extract, the majority of radioactivity in the flask wash was a poorly resolved, apolar region accounting for a total of 1.8% TRR (0.035 mg eq/kg).

Clopyralid was the only component detected in the organic mild base extract (E3), accounting for 5.1% TRR, 0.094 mg eq/kg. Because the extraction solvent and procedure hydrolysed clopyralid complexes to clopyralid, this region is characterised as base-labile clopyralid.

A further aqueous mild base extraction released 1.7% TRR (0.031 mg eq/kg). Clopyralid was the only component detected in the mild base further extract (FE1), accounting for 1.1% TRR, 0.020 mg eq/kg.

Overall, 106.1% of the radioactivity was extractable, of which 101.6% TRR (1.871 mg eq/kg) was shown to be clopyralid (free plus base-labile). Of this, 29.6% TRR (0.544 mg eq/kg) was “free” clopyralid and 72.0% TRR (1.327 mg eq/kg) was base-labile clopyralid.

Trash:

Parent component clopyralid (free, *i.e.*, neither bound nor conjugated) was a major component in the aqueous acetonitrile extract accounting for 40.2% TRR, 0.090 mg eq/kg. The remainder of the neutral extract eluted in a poorly resolved region that was less polar than clopyralid accounting for a total of 37.2% TRR (0.083 mg eq/kg). Upon base treatment and preparation for chromatography there was a slight loss of radioactivity prior to profiling, however the entire apolar region converted to clopyralid, therefore, the entire apolar residue was characterized as base-labile clopyralid.

Clopyralid was the only component detected in the organic mild base extract (E3), accounting for 13.4% TRR, 0.030 mg eq/kg. Because the extraction solvent and procedure hydrolysed clopyralid complexes to clopyralid, this region is characterised as base-labile clopyralid.

A further aqueous mild base extraction released 5.7% TRR (0.013 mg eq/kg). Clopyralid was the only component detected in this mild base further extract (FE1), accounting for 4.3% TRR, 0.010 mg eq/kg.

Overall, 98.5% of the radioactivity was extractable, of which 95.2% TRR (0.213 mg eq/kg) was shown to be clopyralid (free plus base-labile). Of this, 40.2% TRR (0.090 mg eq/kg) was “free” clopyralid and 55.0% TRR (0.123 mg eq/kg) was base-labile clopyralid.

Seed:

Parent compound clopyralid (free, *i.e.*, neither bound nor conjugated) was the major component in the aqueous acetonitrile extract accounting for 29.0% TRR (0.020 mg eq/kg). The remainder of the neutral extract eluted earlier than clopyralid and accounted for a total of 5.4% TRR (0.003 mg eq/kg). Upon base treatment all of the radioactivity in the neutral organic extract eluted with clopyralid.

Clopyralid was the only component detected in the methanolic base extracts (E3-5, DCM eluate from SPE), accounting for 35.9% TRR, 0.025 mg eq/kg. Because the extraction solvent and procedure hydrolyzed clopyralid complexes to clopyralid, this region is characterized as base-labile clopyralid.

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Although 15.5% TRR of the seed was extracted with 0.5 N NaOH (and associated methanol washes), this fraction (E6) was unable to be concentrated and prepared for HPLC. Attempts to concentrate E6 – either combined with E3-5 or individually – proved unsuccessful despite multiple attempts. Under the extraction conditions used for E6, the remaining oil would have been hydrolysed into smaller subunits (*e.g.*, fatty acids and glycerols). It is theorized that the formation of these hydrolysis products formed an emulsion layer, causing SPE cartridges to readily clog. Significant dilution of the sample with 1 N NaOH prior to the analytical method SPE procedure did not prove successful and low recoveries were observed.

A further mild base extraction (FE1) released 4.5% TRR (0.003 mg eq/kg). Due to the low levels of radioactivity in this extract, further characterisation was not necessary.

Overall, 96.7% of the radioactivity was extractable, of which 70.3% TRR (0.049 mg eq/kg) was shown to be clopyralid (free plus base-labile). Of this, 29.0% TRR (0.020 mg eq/kg) was “free” clopyralid and 41.3% TRR (0.030 mg eq/kg) was base-labile clopyralid.

Table 29: Clopyralid Levels in Oilseed Rape Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Spring Oilseed Rape					
	Forage		Trash		Seeds	
	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg
TRR ¹	100	1.839	100	0.224	100	0.069
Total Extractable	106.1	1.950	98.5	0.221	96.7	0.067
Total Analysed by HPLC ²	101.7	1.870	95.1	0.213	70.3	0.049
Clopyralid ³	29.6	0.544	40.2	0.090	29.0	0.020
Base-Labile Clopyralid ⁴	72.0	1.327	55.0	0.123	41.3	0.028
Total Identified as Clopyralid (HPLC/MS)	101.6	1.871	95.2	0.213	70.3	0.049
Total Characterised by HPLC	101.6	1.871	95.2	0.213	70.3	0.049
Total Characterised Not Analysed by HPLC	-	-	-	-	20.0	0.014
Unextracted	1.2	0.022	7.9	0.018	8.0	0.006
Accountability ⁵	107.3		106.4		104.7	

1 = TRR determined by combustion

2 = Total extracts that were prepared and analysed by HPLC including any losses/gains during processing

3 = Total free clopyralid detected in aqueous acetonitrile extracts.

4 = Sum of ‘unresolved region’ in aqueous acetonitrile extracts and clopyralid in base extracts (E3, E4, E5 and FE1, where applicable). This region readily converts to clopyralid, particularly upon treatment with base. Extensive investigation work was conducted on the ‘unresolved region’. Mild base treatment resulted in only clopyralid. Further experiments were conducted. No further conclusion can be drawn beyond the fact that this region is entirely base-labile clopyralid.

5 = Accountability = %TRR extractable + %TRR unextractable

Anthers/Pollen:

Following processing, the anthers (containing pollen) water washes were analysed by HPLC. The main component of the residue was free clopyralid: 29.2% of total extracted (0.705 mg eq/kg) in water wash 1 and 34.2% of total extracted (0.824 mg eq/kg) in water wash 2. A number of apolar components (maximum individual component 10.8% of total extracted; 0.259 mg eq/kg) were also detected, with the entire apolar region accounting for 16.2% of total extracted (0.391 mg eq/kg) in water wash 1 and 20.5% of total extracted (0.491 mg eq/kg) in water wash 2. Upon mild base treatment on forage and trash aqueous acetonitrile extracts, only clopyralid was detected. This was also demonstrated in the wheat NOR study. Therefore, the apolar components in anther washes is likewise characterised as base-labile clopyralid.

Pollen extract 1 was analysed by HPLC. The only component of the residue was base-labile clopyralid at 85.5% of total (0.592 mg eq/kg). The unextracted residue in isolated pollen accounted for 14.5% of total (0.100 mg eq/kg).

Table 30: Clopyralid Levels in Oilseed Rape Anthers/Pollen Following a Foliar Treatment with [¹⁴C]-Clopyralid

	Spring Oilseed Rape
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	Anthers (containing pollen)		Isolated Pollen	
	% Total ²	mg eq/kg	% Total ³	mg eq/kg
TRR ¹	100	2.411	100	0.692
Total Extractable	100	2.411	85.5	0.592
Total Analysed by HPLC ⁴	100	2.411	85.5	0.592
Clopyralid ⁵	63.4	1.529	-	-
Base-Labile Clopyralid ⁶	36.7	0.882	85.5	0.592
Total Identified as Clopyralid (HPLC/MS)	100.1	2.411	85.5	0.592
Total Characterised by HPLC	100.1	2.411	85.5	0.592
Unextracted	NA	NA	14.5	0.100

1 = Sum of % extractable and unextractable, where applicable.
2 = % of total extractable residue in anthers (containing pollen) sample.
3 = % of total extractable and unextractable residue in isolated pollen
4 = Total water washes and extracts that were prepared and analysed by HPLC not including any losses/gains during processing
5 = Total free clopyralid detected in water washes.
6 = Sum of ‘unresolved region’ in water washes and clopyralid in base extracts (E1). The apolar region is characterised as base-labile clopyralid is based on results of the oilseed rape forage and trash, as well as characterisation of wheat matrices.

Residue Analytical Method Confirmation:

Oilseed rape forage, trash, and seeds were also extracted following the analytical method (Dow AgroSciences 120610). Following concentration and further processing of the radiovalidation extracts the samples were analysed by HPLC. Chromatographic analysis of the extracts showed that only clopyralid was detected in forage, trash and seeds. These results are summarized in the table below. As shown, the analytical method was >90% efficient for determining the total clopyralid, free plus base-labile.

Table 31: Summary of Extraction Efficiency and Radiovalidation Using Dow Analytical Method 120610

Matrix	TRR (mg eq/kg)	Clopyralid Determined by Dow Method 120610		Total Clopyralid Determined Above		Dow Method 120610 Efficiency ¹
		% TRR	mg eq/kg	% TRR	mg eq/kg	
Forage	1.839	92.2	1.696	101.6	1.871	90.6%
Trash	0.224	91.4	0.205	95.2	0.213	96.2%
Seed	0.069	65.9	0.045	70.3	0.049	91.8%

1 = Method efficiency determined by dividing Clopyralid Determined by Dow Method 120610 into Total Clopyralid Determined Above, multiplied by 100%.

Metabolite Identification

Confirmation of Clopyralid

The identity of clopyralid was confirmed in neutral organic extracts (E1-2) both before and after base treatment in oilseed rape forage and in neutral organic extracts (E1-2) before base treatment oilseed rape seeds by qualitative mass spectrometry using radio LC-MS and LC-MS/MS. Identification was confirmed by comparison of retention time, isotope pattern, accurate mass measurement, and fragmentation with an authentic reference standard for clopyralid.

Characterisation of Apolar Unresolved Region

An unresolved region, less polar than clopyralid, was detected in concentrated aqueous acetonitrile extracts from forage and trash, eluting from 13.75 – 19 minutes and accounting for 37.3 – 65.8 %TRR (0.083 – 1.213 mg eq/kg). Significant attempts and experiments were made to characterize and identify the residue in this region.

Base Treatment of Treated Samples:

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Initially the aqueous acetonitrile extracts from forage, trash and seeds were treated with mild base (methanol:10 N NaOH, 100:1, v/v, ambient, overnight, and subsequent HPLC analysis resulted in only clopyralid was observed. The complete conversion of the unresolved region after a mild base treatment may be due to hydrolysis and/or a result of the change in sample pH. Therefore, additional investigations into the effect of base on the sample extracts were conducted.

pH Adjustment of Treated Samples:

To investigate the effects of pH on oilseed rape, the concentrated aqueous acetonitrile extracts (E1-2) of forage were subjected to a number of experiments as described below:

1. An aliquot of concentrated E1-2 was pH adjusted with the addition of 5% ammonium hydroxide solution (4:1, v/v sample:base ratio). HPLC analysis of the resulting sample was conducted after 0.5 and 24 hours.
Analysis at both 0.5 hours and 24 hours showed that the unresolved region was not present and only clopyralid and a second peak eluting just after clopyralid were observed.
2. To investigate possible effects from the organic solvent, two aliquots of forage concentrated E1-2 had the solvent removed under a gentle stream of nitrogen. One aliquot was reconstituted in water, containing a small amount of 5% ammonium hydroxide solution (17:1, v/v sample:base ratio), and one aliquot was reconstituted in 5% ammonium hydroxide solution. After 1 hour, the ammonium hydroxide aliquot was acidified to pH 1 and the water aliquot was neutralized to pH 7 immediately prior to analysis.

Analysis of both aliquots showed that the formation of the second peak was not dependent on organic solvent being present. However, the amount of the second peak did increase significantly in the ammonium hydroxide aliquot, which suggested that the concentration of ammonium hydroxide had an effect on the ratio of clopyralid to the second peak. Based on these results it was postulated that the second peak may be an ammonium adduct of clopyralid.

3. To investigate the presence of an ammonium adduct, two aliquots of forage concentrated E1-2 were added to separate vials and one fortified with an equivalent amount of ^{14}C clopyralid (dpm). Both aliquots were dried and reconstituted in an equivalent volume of 5% ammonium hydroxide solution. After 1 hour, both samples were acidified to pH 1 immediately prior to injection. The analysis showed that the addition of more clopyralid did not increase the amount of the second peak, despite the ammonium hydroxide being present in excess. This indicates that the second peak is not an ammonium adduct of clopyralid.
4. The results from the organic solvent experiments detailed above indicated that there may also be an impact from the pH during chromatography. To investigate this, two aliquots of forage concentrated E1-2 were concentrated and reconstituted in an equivalent volume of 5% ammonium hydroxide solution. After 1 hour, one aliquot was neutralized to pH 7 and one aliquot was acidified to pH 1 immediately prior to analysis.
Analysis at both pH 1 and pH 7 showed that the presence or ratio of clopyralid to the second peak (*ca.* 1:1) was not dependent on pH.
5. Based on the structure of clopyralid, it was postulated that it may be an effective chelator in biological systems, similar to picolinic acid. Structural analogues of clopyralid have been shown to weakly chelate to heavy metal ions in matrix. To investigate this, it was suggested that Na^+ ions may disrupt the chelation similar to the caustic used in the base treatment methods methanol:10 N NaOH (100:1 v/v). Two aliquots of forage concentrated E1-2 had the solvent removed under a gentle stream of nitrogen. One aliquot was reconstituted in an equivalent volume of 5% ammonium hydroxide solution. Both aliquots had an equivalent volume of 1 M NaCl added to generate an excess of Na^+ ions in the sample. The aliquot without 5% ammonium hydroxide acted as a control. After 1 hour, both aliquots were acidified to pH 1 immediately prior to analysis.

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The analysis showed that the addition of NaCl had no effect on the ratio of clopyralid to the second peak and the Na⁺ ions present did not disrupt the potential chelation, however, this does not rule out chelation as a potential property of clopyralid.

Overall, under certain conditions a second peak eluting just after clopyralid was observed during pH adjustment with 5% ammonium hydroxide solution. This was confirmed not to be an ammonium adduct of clopyralid and was shown to be related to clopyralid following treatment with NaOH.

Fortification of Control Tissue:

Fortification experiments were conducted under Charles River Laboratories' study 229882 – 'The Metabolism of [¹⁴C] Clopyralid in Spring Wheat' - to support the hypothesis that the unresolved region is clopyralid weakly interacting with endogenous plant matrix. Control grain tissue was fortified with ¹⁴C clopyralid and subjected to aqueous acetonitrile extraction. Following HPLC analysis, the unresolved region was observed to have been generated during the experiment. The same experiment was attempted twice on control oilseed rape forage tissue under this study. The same result was not observed however, with only clopyralid observed and no apolar region generated.

LC-MS of the Apolar Region:

LC-MS analysis of the apolar region was conducted on oilseed rape forage aqueous acetonitrile extract. Several attempts were made to directly analyse the apolar region, but no identifications of the components could be made. In order to characterize the region, molecular weight filtration and derivatization experiments were attempted. Following methylation of the sample, only one peak was detected and identified as the methyl ester of clopyralid. The apolar region was not isolated prior to methylation, and recovery during the procedure was not calculated, it is not clear whether the apolar peak released clopyralid prior to methylation, or if the apolar peak was otherwise degraded and only the original "free" clopyralid was methylated.

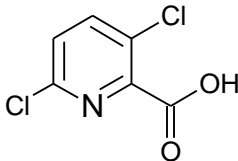
The results from the methylation experiment in conjunction with the other MS experiments indicated that the apolar region was most likely to be a loosely bonded coordinative complex of clopyralid with a low molecular weight matrix component.

Summary of Experiments into Unresolved Apolar Region:

It is hypothesised that this region is the result of chromatographic effects of clopyralid weakly binding and interacting with endogenous material, possibly through weak electrostatic bonds or chelation effects. Conversion to clopyralid is rapid under mild base conditions.

The structures, chemical names and the common names used in the study report for all the residue components that were identified or tentatively identified during this study are shown below.

Table 7: Identification of compounds from metabolism study

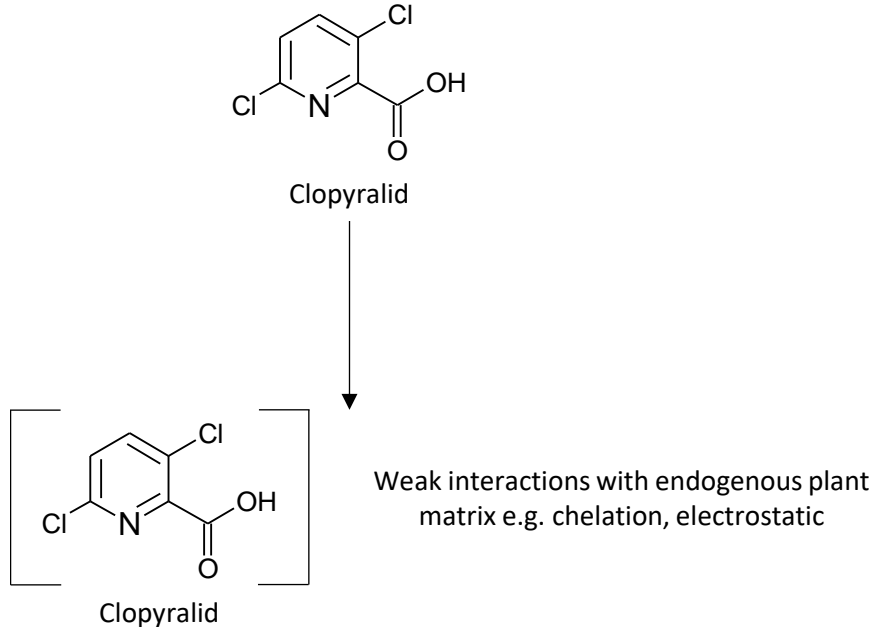
Common name/code number	Chemical name	Chemical structure
Clopyralid	3,6-Dichloropicolinic Acid	

Metabolic Pathway

A proposed metabolic pathway is presented below. Based on the results obtained from this study clopyralid undergoes interaction with endogenous oilseed rape matrix, in the form of weak chelation effects or

electrostatic interactions. No metabolites of clopyralid were detected in this study. This is consistent with previously reported metabolism in wheat.

Figure 4: Proposed metabolic pathway of Clopyralid in Oilseed Rape



Storage Stability

Determination of total radioactive residues (TRR), initial extraction of radioactivity and initial chromatography (including E1-2 for forage, trash and seeds, E3 for forage and trash, water washes of the anthers and methanolic base extraction of pollen) was completed within 41 days of collection.

Following the initial extractions of oilseed rape seed, additional extractions were performed. Characterisation of the principal radioactive residues in oilseed rape seeds was complete within 293 days of sampling. The profiles from the repeat seed extracts are virtually identical to the initial analysis, and therefore the residues of clopyralid are stable in oilseed rape seed samples under the storage conditions employed on this study.

In addition to the repeat extractions, samples of oilseed rape forage were analysed by LC-MS after 6 months. The radio chromatograms generated during LC-MS analysis are virtually identical to the initial analysis, and therefore the residues of clopyralid are also stable in oilseed rape forage under the storage conditions employed on this study.

Table 32: Summary of storage stability

Matrix	Storage temp. (°C)	Harvest date	Combustion analysis date	Initial extraction date	Initial chromatography date
Forage	-20 °C	11-Jun-2020	19-Jun-2020	01-Jul-2020	08-Jul-2020 (E1-2) 09-Jul-2021 (E3)
Trash	-20 °C	21-Aug-2020	03-Sep-2020	09-Sep-2020	01-Oct-2020 (E1-2) 01-Oct-2020 (E3)
Seed1	-20 °C	21-Aug-2020	03-Sep-2020	29-Jan-2021	04-Feb-2021 (E1-2) 10-Jun-2021 (E3-5)
Pollen/Anther	-20 °C ²	28-May-2020 - 19-Jun-2020 ²	NA	19-Jun-2020/ 02-Jul-2020 ³	21-Jul-2021/ 30-Jul-2020 ⁴

1 = Initial extraction and profiling of seeds was conducted within 41 days of harvest. The extraction and chromatography was repeated to provide full characterisation of the seeds. This repeat extraction data has been used for quantification of seeds.

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2 = Anthers/pollen were samples every 1-5 days over for *ca.* 3 weeks. During this time the harvest tissue was stored at *ca.* 4°C. Following the final harvest of anthers/pollen, the sample was processed to separate pollen from another capsules and water washes conducted on the same day prior to storage of all samples at -20 °C.

3 = Dates separated by: water washes conducted on anthers (containing pollen)/isolated pollen extraction.

4 = Dates separated by: HPLC analysis of water washes/HPLC analysis of isolated pollen.

CONCLUSION

The metabolism of clopyralid was investigated in spring oilseed rape following a single foliar spray application of [2,6-¹⁴C]-clopyralid at an achieved application rate of 199.09 g a.e./ha (99.5% of target) at BBCH 30.

TRR levels in forage, trash and seeds were 1.839, 0.224 and 0.069 mg eq/kg, respectively.

Under aqueous acetonitrile conditions, 99.1%, 76.9%, and 40.8% TRR was extracted from forage, trash and seeds, respectively. A further 5.3%, 15.9%, and 35.9% was released upon extraction with methanolic base. Additionally, 15.5% of the TRR (0.011 mg eq/kg) in seeds was released with 0.5 N NaOH with methanol washes. Accountability was 104.7 – 107.3%. Further caustic extractions were conducted on all samples, which released 1.7 – 5.7% TRR. The final non-extractable residues ranged from 1.2 - 8.0% TRR (0.022 mg eq/kg in forage and 0.006 mg eq/kg in seeds). Tissue samples were also extracted following the analytical method (Dow 120610), with extracts accounting for 1.696, 0.205 and 0.045 mg eq/kg.

HPLC analysis of the aqueous acetonitrile extracts from forage contained a resolved clopyralid peak (28.8% TRR, 0.530 mg eq/kg) and a broad less polar (apolar), unresolved region (64.0% TRR, 1.178 mg eq/kg). Trash was similar. The equivalent extracts from seeds contained a resolved clopyralid peak (29.0% TRR, 0.020 mg eq/kg) and two minor, more polar regions (2.1 – 3.3% TRR, 0.001 – 0.002 mg eq/kg). Upon mild base treatment (similar to Dow analytical method 120610, using methanol:10 N NaOH (100:1, v/v), overnight) of the neutral organic extracts, only clopyralid was detected (83.8% and 69.4% TRR in forage and trash, respectively). The methanol base extract and further basic extracts from each sample contained only clopyralid and were therefore characterized as base-labile clopyralid. In total, clopyralid (free and base-labile) accounted for 101.6% TRR (1.871 mg eq/kg) in forage, 95.2% TRR (0.213 mg eq/kg) in trash and 70.3% TRR (0.049 mg eq/kg) in seeds. Only clopyralid was detected in the extracts from the analytical method for all three commodities.

The anthers containing pollen were washed with water and centrifuged to separate the pollen. The isolated pollen was then extracted methanolic base. Both the water washes and the pollen extract were characterized by HPLC. The majority (63.4%) of the water wash eluted with clopyralid, while the remainder of the water wash eluted in the same apolar region as the forage and trash samples and is therefore characterized as base-labile clopyralid. The majority of the pollen residue was extractable (>85%) and eluted with clopyralid, and is therefore characterized as base-labile clopyralid.

Extensive experiments on the apolar unresolved region demonstrated that this region was readily converted to clopyralid in the presence of dilute base. Any light manipulation readily converted the apolar region to clopyralid, which strongly supports the hypothesis that the apolar region is a result of weak electrostatic interactions with endogenous plant matrix and/or chelation of clopyralid to metal ions in the plant. Although extensive attempts were made, no LC/MS mass or fragment ion related to clopyralid could be found in the apolar region, despite optimization of the mass spectrometer for clopyralid.

In total, clopyralid (free and base-labile) accounted for >70% of the TRR in all samples, including seed, forage, trash, and pollen/anthers. Furthermore, the amount of total clopyralid detected by Dow analytical method 120610 was in excellent agreement with the exhaustive methods used in a metabolism study, at greater than 90%.

A 2.1.2.1.2 Nature of residue in rotational crops

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No new data are submitted in the framework of this application.

A 2.1.2.1.3 Nature of residues in processed commodities

No new data are submitted in the framework of this application.

A 2.1.2.2 Nature of residues in livestock

No new data are submitted in the framework of this application.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Oilseed rape

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of ap- plications	Application rate per treatment	Interval be- tween applica- tion	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2005; Finland, 2005)	1	100 - 150 g ae/ha	nr	BBCH 12-32	nr
Intended cGAP, Oilseed rape (7*)	1	120 g ae/ha	nr	BBCH 30-51	nr

nr: Not relevant
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1 - 150534

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. The ap- plicant submitted 12 trials consistent with the proposed GAP for oilseed rape. The residues in seeds did not exceed the current MRL for rape of 0.5 mg/kg. Study is acceptable.
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Reference:	KCA 6.3.1/01
Report	Delmotte, R., (2017); Magnitude of the Residues of Halauxifen-methyl and Clopyralid in Oilseed rape (RAC Whole Plant, Seed and Straw), following One Application of GF-3488, Northern Europe - 2015; Study No. RDE-15- 20400; DAS Report No. 150534.
Guideline(s):	Guidelines for the generation of data concerning residues as provided in An- nex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the mar- ket : foreword 1607/VI/97 rev. 2 and Appendix B - General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments. OECD Guidelines for the Testing of Chemicals, TG 509: Crop Field Trial. Organisation for Economic Co-operation and Development, 7 September 2009. The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17. The Application of GLP Principles to Field Studies, OECD Series on Princi- ples of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22. The Application of the OECD Principles of GLP to the Organisation and Management of MultiSite Studies, OECD Series on Principles of GLP and

Compliance Monitoring Number 14, ENV/JM/MONO(2002)9.

Deviations: None that impact the integrity of the study
GLP: Yes
Acceptability: Yes

Materials and methods

Twelve field trials were conducted on oilseed rape in the United Kingdom (2), Poland (4), Germany (2) and Northern France (4) in 2015. Clopyralid was applied as GF-3488, an EC formulation containing 120 g ae/L. One foliar application was made at a nominal rate of 120 g ae/ha at growth stage BBCH 50.

Samples of seed and straw were taken at normal commercial harvest (NCH) in the eight harvest trials. In the four decline trials samples of seed and straw were taken at a PHI of 7 days, at NCH, and at 3 and 7 days after NCH. Samples of whole plant were taken at 0, 7 and 14 days after application. Samples were stored ≤ -18 °C for a maximum of 337 days. This is accommodated by the available storage stability data on high oil commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method 120610, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-10 mg/kg fortification, mean recovery 101%, RSD=7%, n=15; seed at 0.01-10 mg/kg fortification, mean recovery 96%, RSD=11%, n=15; straw at 0.01-5.0 mg/kg fortification, mean recovery 89%, RSD=11%, n=15.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

All trials applied clopyralid in accordance with the intended cGAP rate (within 25%). The trials were conducted at growth stage BBCH 50, compared to the cGAP at BBCH 51. These growth stages can be considered comparable, as both growth stages represent the beginning of inflorescence emergence with flower buds present, but enclosed, and this will not impact the final residue in rape seed. Therefore, the trials can be relied upon to support the intended cGAP. A residue in seed in a single trial (PL07) was identified as an outlier according to the Dixon's Q-test and therefore is not relied upon.

Trials were conducted with an EC formulation but the results can be extrapolated to support the EF-243 SL formulation, as in accordance with OECD 509, formulations diluted in water and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Eleven residue trials on oilseed rape were conducted in northern Europe and are considered supportive of the intended cGAP. Residues of clopyralid in oilseed rape are in the range <0.01-0.30 mg/kg.

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Table A 2: Summary of the study 1 trials

Reference:	Magnitude of the Residues of Halauxifen-methyl and Clopyralid in Oilseed rape (RAC Whole Plant, Seed and Straw), following One Application of GF-3488, Northern Europe - 2015, RDE-15-20400; DAS Report No. 150534			
GLP:	Yes	Sample storage conditions:	Max 337 days	
Crop/crop group:	Oilseed rape	Analytical method:	120610	
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):	0.01	
Formulation:	GF-3488	Limit of Detection (mg/kg):	0.003	
Content of active substance (g/kg or g/l):	120 g ae/L clopyralid + 4.797 g ae/L halauxifen-methyl	Residues calculated as:	clopyralid	

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid		
FR01 / 21200 Montigny lès Beaune, Bourgogne, France (EU Northern Zone)/ 2015	Winter oilseed rape / ES Athletic	1. 21-Aug-2014 2. N/A 3. 10-Jul-2015	116	199	59	26-Mar-2015	BBCH.50	Whole plant	3.26	0	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl); NCH = 99 DAT Maximum Storage: 315 days
									2.33	7	
									2.09	14	
								Seed	0.03	92	
									<u>0.02</u>	99	
									<0.01	102	
									0.01	106	
								Straw	0.31	92	
									0.28	99	
									0.30	102	
									0.25	106	

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treat- ment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid		
FR02 / 62860 Inchy en Artois, Nord Pas de Calais, France (EU Northern Zone)/ 2015	Winter oilseed rape / Grizzly	1. 08-Sep-2014 2. N/A 3. 23-Jul-2015	120	205	59	02-Apr-2015	BBCH.50	Seed Straw	<u>0.02</u> 0.18	112 112	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 208 days
FR03 / 49700 Doué la Fontaine, Pays de la Loire, France (EU Northern Zone)/ 2015	Winter oilseed rape / DK Expertise	1. 05-Sep-2014 2. N/A 3. 01-Jul-2015	117	200	59	25-Mar-2015	BBCH.50	Seed Straw	<u>0.06</u> 0.27	98 98	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 230 days
DE04 / 63863 Eschau, Bayern, Germany (EU Northern Zone)/ 2015	Winter oilseed rape / Avatar	1. 27-Aug-2014 2. N/A 3. 31-Jul-2015	121	207	59	07-Apr-2015	BBCH.50	Whole plant Seed Straw	4.32 2.92 2.30 <u>0.02</u> <u>0.06</u> 0.03 0.12 0.43 0.36	0 7 15 101 107 115 101 107 115	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl); NCH = 107 DAT Maximum Storage: 303 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treat- ment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid		
PL05 / 11-010 Bark, Warminsko Marzur- skie, Poland (EU Northern Zone)/ 2015	Spring oilseed rape / SW Svinto	1. 14-Apr-2015 2. N/A 3. 24-Aug-2015	120	307	39	04-Jun-2015	BBCH.50	Seed Straw	<u>0.10</u> 0.26	81 81	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 176 days
DE06 / 23919 Ron- deshagen, Schles- wig-Holstein, Ger- many (EU Northern Zone)/ 2015	Winter oilseed rape / Exquisite	1. 26-Sep-2014 2. N/A 3. 06-Aug-2015	123	210	59	10-Apr-2015	BBCH.50	Seed Straw	<u><0.01</u> 0.22	118 118	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 194 days
PL07 / 63-040 Chwalecin, Wielko- polska, Poland (EU Northern Zone)/ 2015	Spring oilseed rape / Markus	1. 08-Apr-2015 2. N/A 3. 25-Aug-2015	118	303	39	25-May- 2015	BBCH.50	Whole plant Seed Straw	3.87 4.17 2.97 0.77 0.91, 0.67 (0.79) 0.79 0.32 0.56 0.42 0.39 0.51	0 7 14 79 86 89 92 79 86 89 92	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl); NCH = 86 DAT Maximum Storage: 255 days Data point identified as an outlier according to Dixon's Q-test

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treat- ment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid		
PL08 / 64-840 Brze- zno, Wielkopolska, Poland (EU Nor- thern Zone)/ 2015	Winter oilseed rape / Granat	1. 30-Aug-2014 2. N/A 3. 29-Jul-2015	124	317	39	14-Apr-2015	BBCH.50	Seed Straw	<u>0.03</u> 0.17	106 106	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 204 days
PL09 / 11-034 To- maszkowo, War- minsko Marzurskie, Poland (EU Nor- thern Zone)/ 2015	Winter oilseed rape / DK Exquisite	1. 25-Aug-2014 2. N/A 3. 10-Aug-2015	120	307	39	16-Apr-2015	BBCH.50	Seed Straw	<u>0.03</u> 0.25	116 116	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 192 days
GB10 / Bucknell, Oxfordshire OX27 7LT, Great Britain (EU Northern Zone)/ 2015	Winter oilseed rape / Harper	1. 04-Sep-2014 2. N/A 3. 30-Jul-2015	121	207	58	25-Mar-2015	BBCH.50	Whole plant Seed Straw	3.67 2.75 2.25 0.12 <u>0.05</u> 0.01 0.02 0.15 0.23 0.09 0.15	0 7 14 105 112 115 118 105 112 115 118	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl); NCH = 112 DAT Maximum Storage: 316 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treat- ment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid		
FR11 / 02700 Me- nessis, Picardie, France (EU North- ern Zone)/ 2015	Spring oilseed rape / Mosaik	1. 14-May-2015 2. N/A 3. 08-Sep-2015	121	207	58	24-Jun-2015	BBCH.50	Seed Straw	<u>0.30</u> 0.76	76 76	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 163 days
GB12 / Kensworth, Bedfordshire LU6 3QZ, Great Britain (EU Northern Zone)/ 2015	Winter oilseed rape / Charger	1. 16-Aug-2014 2. N/A 3. 28-Jul-2015	121	207	58	25-Mar-2015	BBCH.50	Seed Straw	<u>0.02</u> 0.19	125 125	Appl. rate and conc. are based on actual content of product (117 g a.e./L clopyralid and 5 g a.e./L halauxifen-methyl) Maximum Storage: 205 days

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

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A 2.1.3.2 Barley, oat, wheat, rye, triticale**Table A 3: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Finland 2018a; EFSA, 2021)	1	122.4 g ae/ha	nr	BBCH 39	nr
Intended cGAP Spring barley, wheat, oat, rye, triticale (10*)	1	90 g ae/ha	nr	BBCH 30-39	nr
Intended cGAP Winter barley, wheat, oat, rye, triticale (11*)	1	90 g ae/ha	nr	BBCH 30-39	nr
Zonal GAP†	1	80-120 g ae/ha	nr	BBCH 30-39	nr

nr: Not relevant

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

† A more critical GAP exists in the central EU regulatory zone for product GF-1374 on winter cereals.

A 2.1.3.2.1 Study 1 - 140655 - Barley

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Study was evaluated by RMS Finland as part of the EU active substance renewal (Finland, 2018a; EFSA, 2018) and as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for barley in C-EU. Six residue trials on barley were conducted in northern Europe and are considered supportive of the zonal cGAP. Residues of clopyralid in barley grain are in the range 0.17-0.34 mg/kg (much below of current MRL of 2.0 mg/kg) and in barley straw are in the range 0.24-1.86 mg/kg.
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Reference: KCA 6.3.2/01

Report Boissinot, J.C., (2015); Magnitude of the Residues of Clopyralid in Spring Barley (RAC Whole Plant, Grain and Straw), Following One Application of GF-1966, Northern and Southern Europe - 2014; Study No. EGL-14-18930; DAS Report No. 140655.

Guideline(s): Commission Regulations (EU) No. 283/2013 and 284/2013, of 1 March 2013 setting out the data requirements for active substances or plant protection products, in accordance with Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997

Deviations: None that impact the integrity of the study

GLP: Yes

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Acceptability: Yes

Study No. 140655 was submitted and evaluated by RMS Finland as part of the EU active substance renewal (Finland, 2018a; EFSA, 2018) and as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for barley in C-EU.

Materials and methods

Six field trials were conducted on barley in Poland (2) and Northern France (4) in 2014. Four trials were conducted in southern Europe, but these are not relevant to this dossier and are therefore not summarized. Clopyralid was applied as GF-1966, an SG formulation containing 720 g ae/kg. One foliar application was made at a nominal rate of 120 g ae/ha at growth stage BBCH 39.

Samples of grain and straw were taken at normal commercial harvest (NCH) in all trials. In the one decline trial samples of whole plant were also taken at 0-26 days after application (DAA). Samples were stored \leq 18 °C for a maximum of 387 days. This is accommodated by the available storage stability data on high starch commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using an adaption of method 120610, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-5.0 mg/kg fortification, mean recovery 93%, RSD= 10%, n=7; grain at 0.01-1.0 mg/kg fortification, mean recovery 88%, RSD=13%, n=12; straw at 0.01-1.0 mg/kg fortification, mean recovery 93%, RSD=10%, n=11.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples, apart from trial FR02 where residues of 0.443 (grain) and 1.16 (straw) mg/kg were detected. The samples were therefore excluded from the evaluation.

Clopyralid was applied at an exaggerated rate compared to the intended cGAP and therefore the residues have been scaled in line with the proportionality principle. Although the trials were conducted at BBCH 39 compared to the zonal cGAP of BBCH 32, during the EU renewal, the RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since grain is not formed, only the stems are elongating between these growth stages. Therefore the trials conducted at BBCH 39 can be considered to support the zonal and intended cGAP.

Trials were conducted with an SG formulation but the results can be extrapolated to support the EF-243 SL formulation, as in accordance with OECD 509, formulations diluted in water and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Six residue trials on barley were conducted in northern Europe and are considered supportive of the zonal cGAP. Residues of clopyralid in barley grain are in the range 0.17-0.34 mg/kg and in barley straw are in the range 0.24-1.86 mg/kg. Scaled residues of clopyralid in barley grain are in the range 0.12-0.23 mg/kg and in barley straw are in the range 0.16-1.35 mg/kg.

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Table A 4: Summary of the study 1 trials

Reference:	Magnitude of the Residues of Clopyralid in Spring Barley (RAC Whole Plant, Grain and Straw), Following One Application of GF-1966, Northern and Southern Europe - 2014., Study No. EGL-14-18930, DAS Report No. 140655				
GLP:	Yes	Sample storage conditions:		Max 387 days	
Crop/crop group:	Spring Barley	Analytical method:		120610	
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):		0.01	
Formulation:	GF-1966	Limit of Detection (mg/kg):		0.003	
Content of active substance (g/kg or g/l):	720 g ae/kg clopyralid-olamine	Residues calculated as:		clopyralid	

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/Kg)			PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaling Factor	Scaled to 90 g ae/ha		
FR01 / 08360 Chateau-Por- cien, Cham- pagne -Ar- dennes France (EU Northern Zone)/ 2014	Spring Bar- ley / Ex- plorer	1. 12-Mar-2014 2. N/A 3. 23-Jul-2014	126	258	49	17-May- 2014	BBCH.39	Whole plant	2.17	0.71		0	Maximum Stor- age: 387 days
									0.90			7	
									0.90			13	
								Grain	0.90			26	
								Straw	<u>0.29</u>			67	
									<u>0.48</u>		<u>0.344</u>	67	
FR02 / 71350 Saunières, Burgundy France (EU Northern Zone)/ 2014	Spring Bar- ley / Beatrix	1. 17-Mar-2014 2. N/A 3. 25-Jul-2014	126	206	61	31-May- 2014	BBCH.39	Grain Straw	0.24* 0.36*	0.71	0.17 0.26	55 55	Maximum Stor- age: 385 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/Kg)			PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaling Factor	Scaled to 90 g ae/ha		
PL04 / 62- 290 Miesci- sko, Wielko- polska Poland (EU Northern Zone)/ 2014	Spring Bar- ley / Kormo- van	1. 31-Mar-2014 2. N/A 3. 22-Jul-2014	116	283	41	29-May- 2014	BBCH.39	Grain Straw	<u>0.33</u> <u>1.71</u>	0.78	<u>0.252</u> <u>1.327</u>	54 54	Maximum Stor- age: 149 days
FR09 / 37110 Auzouer en Touraine, Centre France (EU Northern Zone)/ 2014	Spring Bar- ley / Sebas- tian	1. 19-Mar-2014 2. N/A 3. 28-Jul-2014	131	320	41	28-May- 2014	BBCH.39	Grain Straw	<u>0.34</u> <u>0.80</u>	0.69	<u>0.230</u> <u>0.550</u>	61 61	Maximum Stor- age: 143 days
FR10 / 62156 Vis en Ar- tois, Nord Pas de Calais France (EU Northern Zone)/ 2014	Spring Bar- ley / Sebas- tian	1. 12-Mar-2014 2. N/A 3. 05-Aug-2014	132	323	41	19-May- 2014	BBCH.39	Grain Straw	<u>0.17</u> <u>0.24</u>	0.68	<u>0.116</u> <u>0.161</u>	78 78	Maximum Stor- age: 135 days
PL12 / 14- 100 Sambo- rowo, War- minsko ma- zurskie Poland (EU Northern Zone)/ 2014	Spring Bar- ley / Beatrix	1. 11-Apr-2014 2. N/A 3. 23-Jul-2014	124	303	41	30-May- 2014	BBCH.39	Grain Straw	<u>0.29</u> <u>1.86</u>	0.73	<u>0.207</u> <u>1.350</u>	54 54	Maximum Stor- age: 148 days

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* Mean of 3 analysed specimens (2 ship and 1 retain)

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2.2 Study 2 - 150644 - Barley

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Study evaluated by RMS Finland as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for barley in C-EU. Residues of clopyralid in barley grain are in the range 0.11-0.39 mg/kg (much below of current MRL of 2.0 mg/kg and in barley straw are in the range 0.36-1.70 mg/kg.
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Reference:	KCA 6.3.2/02
Report	Grall, E., (2016); Magnitude of the Residues of Clopyralid in Winter Barley (RAC Whole Plant, Grain and Straw), Following One Application of GF-1966, Northern and Southern Europe (France, Poland, UK and Spain) - 2015; Study No. EGL-15-22231; DAS Report No. 150644
Guideline(s):	ECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66). OECD Guidelines for the Testing of Chemicals, TG 509: Crop Field Trial. Organisation for Economic Co-operation and Development, 7 September 2009.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Study No. 150644 was submitted and evaluated by RMS Finland as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for barley in C-EU.

Materials and methods

Seven field trials were conducted on barley in the United Kingdom (2), Poland (2) and Northern France (3) in 2015. Five trials were conducted in southern Europe, but these are not relevant to this dossier and are therefore not summarized. Clopyralid was applied as GF-1966, an SG formulation containing 720 g ae/kg. One foliar application was made at a nominal rate of 120 g ae/ha at growth stage BBCH 39 or 45.

Samples of grain and straw were taken at normal commercial harvest (NCH) in all trials. Samples were stored ≤-18 °C for a maximum of 175 days. This is accommodated by the available storage stability data on high starch commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method 120610, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-5.0 mg/kg fortification, mean recovery 89%, RSD=9%, n=14; grain at 0.01-5.0 mg/kg fortification, mean recovery 91%, RSD=15%, n=15; straw at 0.01-5.0 mg/kg fortification, mean recovery 96%, RSD=10%, n=13.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples, apart from in trial GB12 where 0.0293 mg/kg were detected in straw. This was due to contamination from the combine harvester.

Clopyralid was applied at an exaggerated rate compared to the intended cGAP, and therefore the residues have been scaled in line with the proportionality principle. Although the trials were conducted at BBCH 39

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compared to the zonal cGAP of BBCH 32, during the EU renewal, the RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since grain is not formed, only the stems are elongating between these growth stages. Therefore the trials conducted at BBCH 39 can be considered to support the zonal cGAP. The single trial that applied clopyralid at BBCH 45 is relied upon as application is at a worst-case later growth stage, yet the residues are comparable to those observed when application was at BBCH 39.

Trials were conducted with an SG formulation but the results can be extrapolated to support the EF-243 SL formulation, as in accordance with OECD 509, formulations diluted in water and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Seven residue trials on barley were conducted in northern Europe and are considered supportive of the zonal cGAP. Residues of clopyralid in barley grain are in the range 0.11-0.39 mg/kg and in barley straw are in the range 0.36-1.70 mg/kg. Scaled residues of clopyralid in barley grain are in the range 0.077-0.27 mg/kg and in barley straw are in the range 0.26-1.20 mg/kg.

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Table A 5: Summary of the study 2 trials

Reference:	Magnitude of the Residues of Clopyralid in Winter Barley (RAC Whole Plant, Grain and Straw), Following One Application of GF-1966, Northern and Southern Europe (France, Poland, UK and Spain) - 2015, EGL-15-22231, DAS Report No. 150644.				
GLP:	No	Sample storage conditions:		Max 175 days	
Crop/crop group:	Winter barley	Analytical method:		120610	
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):		0.01	
Formulation:	GF-1966	Limit of Detection (mg/kg):		0.003	
Content of active substance (g/kg or g/l):	720 g ae/kg clopyralid-olamine	Residues calculated as:		clopyralid	

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/Kg)			PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaling Factor	Scaled to 90 g ae/ha		
FR01 / 62147 Moeuvres, Nord Pas de Calais France (EU Northern Zone)/ 2015	Winter bar- ley / Esterel	1. 03-Oct-2014 2. N/A 3. 01-Jul-2015	133	327	41	24-Apr- 2015	BBCH.39	Grain Straw	<u>0.22</u> <u>1.20</u>	0.68	<u>0.149</u> <u>0.812</u>	68 68	Maximum Stor- age: 118 days
FR02 / 49260 Le coudray Ma- couard, Pays de Loire France (EU Northern Zone)/ 2015	Winter bar- ley / Mangoo	1. 21-Oct-2014 2. N/A 3. 25-Jun-2015	125	357	35	20-Apr- 2015	BBCH.39	Grain Straw	<u>0.26</u> <u>0.36</u>	0.72	<u>0.187</u> <u>0.259</u>	66 66	Maximum Stor- age: 124 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/Kg)			PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaling Factor	Scaled to 90 g ae/ha		
FR03 / 21200 Montagny l'ès Beaune, Bur- gundy France (EU Northern Zone)/ 2015	Winter bar- ley / Mangoo	1. 25-Sep-2014 2. N/A 3. 19-Jun-2015	126	309	41	23-Apr- 2015	BBCH.39	Grain Straw	<u>0.19</u> <u>0.88</u>	0.71	<u>0.136</u> <u>0.629</u>	57 57	Maximum Stor- age: 130 days
PL04 / 11-034 Tomaszkowo, Warmian Masu- rian Poland (EU Northern Zone)/ 2015	Winter bar- ley / Sandra	1. 15-Sep-2014 2. N/A 3. 21-Jul-2015	128	313	40.9	08-May- 2015	BBCH.39	Grain Straw	<u>0.26</u> <u>1.70</u>	0.70	<u>0.183</u> <u>1.195</u>	74 74	Maximum Stor- age: 98 days
PL05 / 63-041 Kruczynek, Wielkopolska Poland (EU Northern Zone)/ 2015	Winter bar- ley / Wootan	1. 18-Sep-2014 2. N/A 3. 14-Jul-2015	126	310	40.8	05-May- 2015	BBCH.45	Grain Straw	<u>0.35</u> <u>0.94</u>	0.71	<u>0.250</u> <u>0.671</u>	70 70	Maximum Stor- age: 105 days
GB11 / Southmoor, Oxon OX13 5ED UK (EU Northern Zone)/ 2015	Winter bar- ley / Volume	1. 01-Nov-2014 2. N/A 3. 20-Jul-2015	131	213	61.4	08-May- 2015	BBCH.39	Grain Straw	<u>0.39</u> <u>1.29</u>	0.69	<u>0.268</u> <u>0.886</u>	73 73	Maximum Stor- age: 99 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/Kg)			PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaling Factor	Scaled to 90 g ae/ha		
GB12 / Finmere, Buckingham- shire MK18 4DP UK (EU Northern Zone)/ 2015	Winter bar- ley / Kassia	1. 29-Sep-2014	128	209	61.2	07-May- 2015	BBCH.39	Whole plant	1.92	0.70		0	Maximum Stor- age: 175 days
		2. N/A							0.47			7	
		3. 21-Jul-2015							0.66			13	
									0.41			26	
									<u>0.11</u>		<u>0.077</u>	75	
								Straw	<u>0.44</u>		<u>0.309</u>	75	

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2.3 Study 3 - 160618 - Wheat

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Study evaluated by RMS Finland as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for wheat in C-EU. Eight residue trials on wheat were conducted in northern Europe and are considered supportive of the zonal cGAP. Residues of clopyralid in wheat grain are in the range 0.34-1.08 mg/kg (below MRL of 3.0 mg/kg) and in wheat straw are in the range 0.29-1.595 mg/kg.
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Reference:	KCA 6.3.2/05
Report	Peterek, S., (2017); Magnitude of the Residues of Clopyralid in Winter and Spring Wheat (RAC Whole Plants, Straw and Grain), Following One Application of GF-1374, Northern Europe (France, Germany, United Kingdom and Hungary) - 2016; Study Report Code SPK-16-26573; DAS Report No. 160618.
Guideline(s):	General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Guidance Documents on Pesticide Residue Analytical Methods (SANCO/825/00 rev.8.1, 16 Nov. 2010). OECD (2007): Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17.
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes

Study No. 160618 was submitted and evaluated by RMS Finland as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for wheat in C-EU.

Materials and methods

Eight field trials were conducted on wheat in the United Kingdom (2), Hungary (1), Germany (2) and Northern France (3) in 2016. Clopyralid was applied as GF-1374, an EC formulation containing 80 g ae/L. One foliar application was made at a nominal rate of 80 g ae/ha at growth stage BBCH 37-39.

Samples of grain and straw were taken at normal commercial harvest (NCH) in all trials. In the four decline trials samples of whole plant were also taken at 0-30 days after application. Samples were stored ≤-18 °C for a maximum of 210 days. This is accommodated by the available storage stability data on high starch commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method 120610, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-5.0 mg/kg fortification, mean recovery 99%, RSD= 6%, n=24; grain at 0.01-2.0 mg/kg fortification, mean recovery 86%, RSD= 12%, n=6; straw at 0.01-5.0 mg/kg fortification, mean recovery 105%, RSD= 6%, n=6.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined.

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Residues of clopyralid were <LOQ in control samples.

Clopyralid was applied at an reduced rate compared to the zonal and to the intended cGAP and therefore the residues have been scaled in line with the proportionality principle. Although some trials were conducted at BBCH 37-39 compared to the cGAP of BBCH 32, during the EU renewal, the RMS agreed that BBCH 32 and BBCH 39 can be considered the same, since grain is not formed, only the stems are elongating between these growth stages. As BBCH 37 is between BBCH 32 and BBCH 39, the same argument applies and therefore the trials conducted at BBCH 37-39 can be considered to support the zonal cGAP.

Trials were conducted with an EC formulation but the results can be extrapolated to support the EF-243 SL formulation, as in accordance with OECD 509, formulations diluted in water and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Eight residue trials on wheat were conducted in northern Europe and are considered supportive of the zonal cGAP. Scaled residues of clopyralid in wheat grain are in the range 0.34-1.08 mg/kg and in wheat straw are in the range 0.29-1.595 mg/kg.

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Table A 6: Summary of the study 3 trials

Reference: Magnitude of the Residues of Clopyralid in Winter and Spring Wheat (RAC Whole Plants, Straw and Grain), Following One Application of GF-1374, Northern Europe (France, Germany, United Kingdom and Hungary) - 2016, SPK-16-26573, DAS Report No. 160618

GLP: Yes

Crop/crop group: Winter wheat

Indoor/Outdoor: Outdoor (field)

Formulation: GF-1374

Content of active substance (g/kg or g/l): 80 g ae/L clopyralid + 2.5 g ai/L florasulam

Sample storage conditions: Max 210 days

Analytical method: 120610

Limit of Quantification (mg/kg): 0.01

Limit of Detection (mg/kg): 0.003

Residues calculated as: clopyralid

+ 99.94 g ae/L fluroxypyr-meptyl

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/Kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 90 g ae/ha		
FR01 / 08310 - Menil LÉpinois, Champagne Ardenne, France (EU Northern Zone)/ 2016	Winter wheat / Lear	1. 05-Oct-2015	83	263	32	11-May-2016	BBCH.37	Whole plant	1.79		0	Maximum Storage: 210 days
		2. N/A							0.46		7	
		3. 31-Jul-2016							0.52		14	
									0.476		27	
								Grain	0.52	<u>0.564</u>	81	
								Straw	0.41	<u>0.445</u>	81	
FR02 / 62860 - Inchy en Artois, Haut de France, France (EU Northern Zone)/ 2016	Winter wheat / Rubisko	1. 12-Nov-2015	84	320	26	11-May-2016	BBCH.37	Grain	0.40	<u>0.429</u>	78	Maximum Storage: 97 days
		2. N/A							0.43	<u>0.461</u>	78	
		3. 28-Jul-2016						Straw				

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion an- alysed	Residues (mg/Kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 90 g ae/ha		
FR03 / 37110 - Dame-Ma- rie-les-bois, Centre, France (EU Northern Zone)/ 2016	Winter wheat / Pakito	1. 30-Oct-2015 2. N/A 3. 20-Jul-2016	79	250	32	03-May- 2016	BBCH.37	Whole plant Grain Straw	2.29 0.89 1.14 0.87 0.65 1.40	 <u>0.741</u> <u>1.595</u>	0 8 14 30 78 78	Maximum Stor- age: 168 days
DE04 / 63916 - Amorbach- Beuchen, Ba- varia, Ger- many (EU Northern Zone)/ 2016	Winter wheat / JB Asano	1. 25-Oct-2015 2. N/A 3. 16-Aug-2016	82	207	40	25-May- 2016	BBCH.39	Grain Straw	0.44 0.37	<u>0.483</u> <u>0.406</u>	83 83	Maximum Stor- age: 78 days
DE05 / 64823 - Kleestadt, Hesse, Ger- many (EU Northern Zone)/ 2016	Winter wheat / Elixer	1. 27-Oct-2015 2. N/A 3. 17-Aug-2016	82	208	39	18-May- 2016	BBCH.39	Whole plant Grain Straw	1.07 0.50 0.58 0.55 0.31 0.26	 <u>0.340</u> <u>0.285</u>	0 7 15 28 91 91	Maximum Stor- age: 155 days
HU08 / 5000 - Szolnok, Jász- Nagykun- Szolnok, Hungary (EU Northern Zone)/ 2016	Winter wheat / MV Mag- daleine	1. 30-Oct-2015 2. N/A 3. 04-Jul-2016	80	203	39	17-May- 2016	BBCH.39	Grain Straw	0.96 0.26	<u>1.080</u> <u>0.293</u>	48 48	Maximum Stor- age: 121 days

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Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion an- alysed	Residues (mg/Kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 90 g ae/ha		
UK06 / OX13 5JA - Southmoor, South East, Great Britain (EU Northern Zone)/ 2016	Winter wheat / JB Diego	1. 10-Nov-2015 2. N/A 3. 11-Aug-2016	83	209	40	17-May- 2016	BBCH.37	Grain Straw	0.45 0.33	<u>0.488</u> <u>0.358</u>	86 86	Maximum Stor- age: 83 days
UK07 / OX27 7LT - Bucknell, South East, Great Britain (EU Northern Zone)/ 2016	Spring wheat / Arantes	1. 05-May-2016 2. N/A 3. 29-Sep-2016	85	216	39	06-Jul-2016	BBCH.39	Whole plant Grain Straw	3.76 1.46 1.01 0.77 0.36 0.38	<u>0.381</u> <u>0.402</u>	0 7 14 27 85 85	Maximum Stor- age: 106 days

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2.4 Study 4 - GHE-P-9385 - Wheat

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Study evaluated by RMS Finland as part of the EU active substance renewal (Finland, 2018a; EFSA, 2018) and as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for wheat in C-EU. Residues of clopyralid in wheat grain are in the range 0.64-0.75 mg/kg (below MRL of 3.0 mg/kg) and in wheat straw are in the range 0.35 – 0.48 mg/kg.
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Reference:	KCA 6.3.6/04 (CA 6.3.3/10)
Report	Residues of clopyralid in wheat at intervals following a single application of LONTREL 100 (EF-1136), EU Northern Zone – 2001; Rawle, N.W. and A. Khosab; 2002; Study No. CEMS-1544; GHE-P-9385
Guideline(s):	The trials encompassed the objectives of the evaluation of active substances and formulated products, as detailed in Annex II and III of EC Directive 91/414/EEC, concerning the placement of plant protection products on the market, as amended by EC Directive 96/68/EC and also the EC working document 1607/VI/97 ("The Lundehrn Document").
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes

Study No. CEMS-1544/GHE-P-9385 was submitted and evaluated by RMS Finland as part of the EU active substance renewal (Finland, 2018a; EFSA, 2018) and as part of an MRL evaluation (Finland, 2018b; EFSA, 2021). The data supports the intended critical GAP for wheat in C-EU.

Materials and methods

Two trials were conducted, one in Northern France and one in Germany (ED Northern Zone). A single application of the Formulation EF-1136 (a SL formulation, containing 100 g as clopyralid/L) was made, at a nominal application rate of 150 g as/ha (corresponding to 1.5 L/ha), spray volume 200 - 400 L/ha at BBCH Stage 49.

For trial CEMS-1544A (Northern France) samples of whole plant were taken after application (0) and at intervals of 15, 29 and 46 days after application. Samples of grain and straw were taken at 60 days after application. For trial CEMS-1544B (Germany) samples of whole plant were taken after application (0) and at intervals of 20, 39 and 56 days after application. Samples of grain and straw were taken at 77 days after application.

Samples arrived at CEM Analytical Services in good condition on 8th August 2001 (CEMS-1544A) and 29th October 2001 (CEMS-1544B). All specimens were stored deep-frozen at below -18°C in deep-freezers within 5 h 35 of sampling. They were kept at below - 18°C from storage to shipment at the analytical laboratory. Samples were stored for a maximum of 236 days (France) and 222 days (Germany).

Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg and a LOD of 0.002 mg/kg. Recoveries were 85% to 97 % (mean 91%) for whole plant, 86% to 106% (mean 96%) for grain and 99% to 110% (mean 105%) for straw. The detector response was shown to be linear over the range 0.0001 – 0.05 pg/mL.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were Not Detected (<0.002 mg/kg) and <LOQ in control samples.

Clopyralid was applied at an exaggerated rate compared to the intended cGAP and therefore the residues have been scaled in line with the proportionality principle. In addition, the applications were made at a later growth stage, BBCH 49 versus BBCH 39 but are still considered representative.

Whole plants sampled before the harvest of grains are considered representative of wheat forage/silage. In one trial a more critical residue was observed at a later PHI, therefore this is relied upon for risk assessment. Grains and Straw sampled at NCH represent the growth stage at application was representative of the range in the zonal cGAP, all trials were relied upon, regardless of the PHI.

Conclusions

Two residue trials on wheat was conducted in Northern Europe (France and Germany) and are considered supportive of the intended cGAP on wheat whole plant, grain and straw. Scaled residues of clopyralid in wheat grain are in the range 0.64 – 0.75 mg/kg and in wheat straw are in the range 0.35 – 0.48 mg/kg.

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Table A 7: Summary of the study 4 trials

Reference: Residues of Clopyralid in Wheat at Intervals following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone - 2001., CEMS-1544

GLP: Yes Sample storage conditions: Max 236 days

Crop/crop group: Wheat Analytical method: \GRM 01.16

Indoor/Outdoor: Outdoor (field) Limit of Quantification (mg/Kg): 0.01

Formulation: EF-1136 Limit of Detection (mg/Kg): 0.002

Content of active substance (g/kg or g/l): 100 g ae/L clopyralid-olamine Residues calculated as: clopyralid

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/Kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)					clopyralid	Residues scaled to 90 g ae/ha		
CEMS-1544A / F-37110 Le Boulay, France (EU Northern Zone)/ 2001	Wheat / Apache	1. 25-Oct-2000 2. N/A 3. 16-Jul-2001	149.2	298	--	17-May-2001	BBCH.49	Whole plant	2.07		0	Maximum Storage: 236 days
									1.34		15	
									1.12		29	
									1.62		46	
									1.06	<u>0.640</u>	60	
CEMS-1544B / 21739, Döllern, Lower Saxonia, Germany. (EU Northern Zone)/ 2001	Wheat / Ritmo	1. 07-Oct-2000 2. N/A 3. 16-Aug-2001	151.71	303	--	31-May-2001	BBCH.49	Whole plant	0.58	<u>0.350</u>	60	Maximum Storage: 222 days
									2.08		0	
									1.16		20	
									0.94		39	
									1.15		56	
								Grain	<u>1.26</u>	<u>0.746</u>	77	
									<u>0.81</u>	<u>0.480</u>	77	
								Straw				

A 2.1.3.3 Maize (grain and forage)

Table A 8: Comparison of intended and critical EU GAPs

Type of GAP	Number of ap- plications	Application rate per treatment	Interval be- tween applica- tion	Growth stage at last application	PHI (days)
cGAP EU (Finland, 2008)	1	125 g ae/ha	nr	BBCH 14-32	42
Intended cGAP Maize grain and forage (16*)	1	102 g ae/ha	nr	BBCH 30-32	60 (forage) 90 (grain)

nr: Not relevant
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.3.1 Study 1 - 201513

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Eight residue trials on maize were conducted in Northern Europe. Seven trials are considered supportive of the intended cGAP on maize grain and rest of plant (stover). Four trials are considered supportive of the intended cGAP on maize forage. Residues of clopyralid in maize forage/silage are in the range 0.23-0.28 mg/kg, in maize grain are in the range 0.03-0.33 mg/kg (below current MRL of 2.0 mg/kg) and in maize stover are in the range 0.11-1.06 mg/kg.
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Reference:	KCA 6.3.3/01
Report	Devine, C., (2021); Residues of Clopyralid in Maize at Intervals at Harvest Following a Single Application of GF-1966 – Northern Europe – 2020; Study No. CEMS-9387; DAS Report No. 201513.
Guideline(s):	OECD Principles of Good Laboratory Practice [ENV IMC/CHEM(98) 17] and country-specific regulations embodying these principles where appropriate.
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes

Materials and methods

Eight field trials were conducted on maize in Northern European countries (Northern France, Poland, Germany, and Hungary). A single application of GF-1966 (a SG – Water Soluble Granules formulation, containing 720 g ae clopyralid) was made at BBCH 32 at 125 g ae/ha, spray volume 100 – 400 L/ha, without adjuvant.

Specimens were collected from each plot at each sampling timepoint and consisted of field grown sugar beet roots and tops. There was one sampling timepoint for the harvest (MOR) trials, and six sampling timepoints for the decline (DEC) trials. The MOR trials were sampled at normal commercial harvest (NCH). The DEC trials were sampled at NCH and at nominal 1, 3, 5, 7 and 14 days after NCH.

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Upon receipt at CEMAS, samples were transferred immediately to a temperature-monitored freezer set to $<-18^{\circ}\text{C}$, where they were always kept except when removed for preparation and analysis. Samples were stored for a maximum of 161 days considering all trials.

Residues of clopyralid were determined using method ID 120610, with a LOQ of 0.01 mg/kg and a LOD of 0.003 mg/kg. Acceptable procedural recoveries were obtained: mean procedural recoveries for clopyralid were within 70 – 110% with relative standard deviations (RSDs) less than 10%. This demonstrates that the analytical method is suitable for use throughout the course of the project.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were Not Detected (<0.003 mg/kg) and $<\text{LOQ}$ in control samples.

Whole plants sampled before the harvest of the cob are considered representative of maize forage/silage. In one trial a more critical residue was observed at a later PHI, therefore this is relied upon for risk assessment. Cobs sampled at NCH represent maize grain and as the growth stage at application was representative of the range in the zonal cGAP, all trials were relied upon, regardless of the PHI. The rest of plant samples are considered representative of maize stover.

Conclusions

Eight residue trials on maize were conducted in Northern Europe. Residues were scaled to the intended cGAP rate. Seven trials are considered supportive of the intended cGAP on maize grain and rest of plant (stover). Four trials are considered supportive of the intended cGAP on maize forage. Scaled residues of clopyralid in maize forage/silage are in the range 0.23-0.28 mg/kg, in maize grain are in the range 0.03-0.33 mg/kg and in maize stover are in the range 0.11-1.06 mg/kg.

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Table A 9: Summary of the study 1 trials

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Maize

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Maize / ZEAMX

Producer of commercial product

Dow AgroSciences

Responsible body for reporting (name & address): Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon

Study type

Residue

OX14 4RN, UK

Indoor/Glasshouse/Outdoor:

Outdoor

Country:

Northern France

Residues calculated as:

Clopyralid

Trial location (region):

La Chapelle de Guinchay, Bourgogne-Franche-Comté, Northern France

Residue method and LOQ

120610 / 0.01 mg/kg

Content of active substance (g/kg or g/l):

720 g ae/kg

Max frozen storage time prior to analysis

181 days

Formulation number:

GF-1966

Study no. / DAS Study ID

CEMS-9387 / 201513

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387A La Chapelle de Guinchay, Bour- gogne-Franche- Comté, Northern France	Maize / SF8386	1) 08 May 20 2) Not Recorded 3) 06 Oct 20	Broadcast fo- liar spray with air com- pressed back- pack boom sprayer with 6 x Flat Fan, Teejet XR 11002VS noz- zles	62.5	187.6	117.283	1	23 Jun 20	32	Whole Plant	0.181	<u>0.231</u>	49	Mean Recovery
										Forage	0.252		56	Whole Plant Forage: 91%
											0.166		62	
											<u>0.266</u>		<u>69</u>	
										Grain	0.121	<u>0.138</u>	98	Grain: 93%
											0.143		105	
											<u>0.159</u>		112	
											0.112		118	
										Stover	0.129	<u>0.107</u>	98	NCH: 105 days
											0.090		105	
											0.096		112	
											<u>0.123</u>		118	

(a) According to EEC and Codex classifications (both) should be used.

(e)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(b) Only if relevant.

(f)

Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of

(g)

Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites

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- equipment must be indicated.
(d) Year must be indicated.

Included, method of storage, storage stability, analysis date and analytical method.
Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

Active substance (common name): **Clopyralid**
 Crop group: **Maize**
 Commercial Product (name): **GF-1966**
 Other active substance in the formulation (common name and content): None
 Crop / EPPO code: Maize / ZEAMX
 Producer of commercial product: Dow AgroSciences
 Responsible body for reporting (name & address): Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK
 Study type: Residue
 Indoor/Glasshouse/Outdoor: Outdoor
 Residues calculated as: Clopyralid
 Residue method and LOQ: 120610 / 0.01 mg/kg
 Country: Poland
 Trial location (region): Murczynek, kujawsko-pomorskie, Poland
 Content of active substance (g/kg or g/l): 720 g ae/kg
 Max frozen storage time prior to analysis: 180 days
 Formulation number: GF-1966
 Study no. / DAS Study ID: CEMS-9387 / 201513
 Formulation type (e.g. WP): SG

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387B Murczynek, ku- jawsko-pomor- skie, Poland	Maize / P8400	1) 18 Apr 20 2) Not Recorded 3) 26 Oct 20	Broadcast fo- liar spray with air com- pressed back- pack boom sprayer with 6 x Flat Fan, AIXR 10015 nozzles	50.0	241.5	120.760	1	10 Jul 20	32-33	Whole Plant	0.519	0.678	33	Mean Recovery
										Forage	0.721		41	
											0.742		48	
											0.802		56	
										Grain	0.340	0.323	101	Whole Plant Forage: 91%
											0.352		108	
											0.382		115	
											0.285		122	
										Stover	0.808	1.055	101	Grain: 93%
											0.979		108	
											1.249		115	
											0.878		122	

- (a) According to EEC and Codex classifications (both) should be used.
 (b) Only if relevant.
 (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of
 (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429
 (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
 (g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites

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- equipment must be indicated.
(d) Year must be indicated.

Included, method of storage, storage stability, analysis date and analytical method.
Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

Active substance (common name): **Clopyralid**
Crop group: **Maize**
Commercial Product (name): **GF-1966**
Other active substance in the formulation (common name and content): **None**
Crop / EPPO code: **Maize / ZEAMX**
Producer of commercial product: **Dow AgroSciences**
Responsible body for reporting (name & address): **Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK**
Study type: **Residue**
Indoor/Glasshouse/Outdoor: **Outdoor**
Residues calculated as: **Clopyralid**
Residue method and LOQ: **120610 / 0.01 mg/kg**
Country: **Poland**
Max frozen storage time prior to analysis: **185 days**
Trial location (region): **Rąbłów, Poland**
Study no. / DAS Study ID: **CEMS-9387 / 201513**
Content of active substance (g/kg or g/l): **720 g ae/kg**
Formulation number: **GF-1966**
Formulation type (e.g. WP): **SG**

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commodity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387C Rąbłów, Poland	Maize / Pioneer	1) 13 May 20 2) Not Recorded 3) 27 Oct 20	Broadcast foliar spray with air compressed backpack boom sprayer with 6 x Flat Fan, Teejet 11/02 nozzles	41.7	297	123.729	1	06 Jul 20	32	Whole Plant Forage	0.307 0.444 0.225 0.530	<u>0.437</u>	32 39 46 52	Mean Recovery
										Grain	0.023 <u>0.035</u> 0.031 0.033	<u>0.029</u>	106 113 119 126	Whole Plant Forage: 91%
										Stover	0.907 <u>0.668</u> 0.272 0.337	<u>0.550</u>	106 113 119 126	Grain: 93%
														Stover: 95%
														NCH: 113 days

- (a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites
Included, method of storage, storage stability, analysis date and analytical method.

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(d) Year must be indicated.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

Active substance (common name):

Clopyralid

Crop group:

Maize

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Maize / ZEAMX

Producer of commercial product

Dow AgroSciences

Responsible body for reporting (name & address): Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Northern France

Trial location (region):

Framerville-Rainecourt, 80131, Northern France

Content of active substance (g/kg or g/l):

720 g ae/kg

Max frozen storage time prior to analysis

181 days

Formulation number:

GF-1966

Study no. / DAS Study ID

CEMS-9387 / 201513

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387D Framerville- Rainecourt, 80131, Northern France	Maize / Ha- ruka	1) 17 Apr 20 2) Not Recorded 3) 08 Oct 20	Broadcast fo- liar spray with knapsack sprayer and boom with 8 x Flat Fan, Teejet XR 110015 VS nozzles	41.7	296	123.4	1	18 Jun 20	32	Whole Plant Forage	0.326 0.259 <u>0.333</u> 0.275	<u>0.275</u>	55 62 <u>68</u> 76	Mean Recovery
										Grain	0.213 0.218 <u>0.244</u> 0.228	<u>0.201</u>	105 112 119 125	Whole Plant Forage: 91%
										Stover	0.242 0.140 <u>0.216</u> 0.151	<u>0.179</u>	105 112 119 125	Grain: 93%
														Stover: 95%
														NCH: 112 days

(a) According to EEC and Codex classifications (both) should be used.

(e)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(b) Only if relevant.

(f)

Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(g)

Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

(d) Year must be indicated.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

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Active substance (common name):	Clopyralid	Commercial Product (name):	GF-1966
Crop group:	Maize	Other active substance in the formulation (common name and content):	None
Crop / EPPO code:	Maize / ZEAMX	Producer of commercial product	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK	Study type	Residue
Country:	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Simandre, Bourgogne-Franche-Comté, Northern France	Residues calculated as:	Clopyralid
Content of active substance (g/kg or g/l):	720 g ae/kg	Residue method and LOQ	120610 / 0.01 mg/kg
Formulation number:	GF-1966	Max frozen storage time prior to analysis	188 days
Formulation type (e.g. WP):	SG	Study no. / DAS Study ID	CEMS-9387 / 201513

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commodity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387E Simandre, Bourgogne-Franche-Comté, Northern France	Maize / DKC 4590	1) 01 May 20 2) Not Recorded 3) 17 Sep 20	Broadcast foliar spray with air compressed backpack boom sprayer with 6 x Flat Fan, XR Teejet 11002VS nozzles	62.49	206.7	129.177	1	22 Jun 20	32	Whole Plant Forage	1.126		44	Mean Recovery
										Grain	0.678		87	Whole Plant Forage: 91%
										Stover	1.947		87	Grain: 93%
														Stover: 95%
														NCH: 87 days

(a) According to EEC and Codex classifications (both) should be used.

(e)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(b) Only if relevant.

(f)

Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(g)

Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites

(d) Year must be indicated.

Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

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Active substance (common name):	Clopyralid	Commercial Product (name):	GF-1966
Crop group:	Maize	Other active substance in the formulation (common name and content):	None
Crop / EPPO code:	Maize / ZEAMX	Producer of commercial product	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK	Study type	Residue
Country:	Poland	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Strzyżewo Smykowie, Poland	Residues calculated as:	Clopyralid
Content of active substance (g/kg or g/l):	720 g ae/kg	Residue method and LOQ	120610 / 0.01 mg/kg
Formulation number:	GF-1966	Max frozen storage time prior to analysis	173 days
Formulation type (e.g. WP):	SG	Study no. / DAS Study ID	CEMS-9387 / 201513

Formulation type (e.g. W1):															
SG															
1	2	3	4	5			6		7	8	9		10	11	
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)		PHI	Remarks:	
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)	
CEMS-9387F Strzyżewo Smy- kowie, Poland	Maize / P8400	1) 18 Apr 20 2) Not Recorded 3) 06 Nov 20	Broadcast fo- liar spray with air com- pressed back- pack boom sprayer with 6 x Flat Fan, AIXR 10015 nozzles	50.0	241.8	120.909	1	09 Jul 20	32	Whole Plant Forage	0.569	0.480	42	Mean Recovery	
										Grain	0.251	0.212	120	Whole Plant Forage: 91%	
										Stover	0.935	0.789	120	Grain: 93%	
															NCH: 120 days

- (a) According to EEC and Codex classifications (both) should be used.
 (b) Only if relevant.
 (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.
 (d) Year must be indicated.

- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429
 (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
 (g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.
 Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

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Active substance (common name):	Clopyralid	Commercial Product (name):	GF-1966
Crop group:	Maize	Other active substance in the formulation (common name and content):	None
Crop / EPPO code:	Maize / ZEAMX	Producer of commercial product	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK	Study type	Residue
Country:	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Neckarwestheim, Heilbronn, Baden-Württemberg, 74382, Germany	Residues calculated as:	Clopyralid
Content of active substance (g/kg or g/l):	720 g ae/kg	Residue method and LOQ	120610 / 0.01 mg/kg
Formulation number:	GF-1966	Max frozen storage time prior to analysis	173 days
Formulation type (e.g. WP):	SG	Study no. / DAS Study ID	CEMS-9387 / 201513

1	2	3	4	5			6		7	8	9		10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)		PHI	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)
CEMS-9387G Neckarwest- heim, Heilbronn, Baden-Württem- berg, 74382, Germany	Maize / Amaveritas	1) 28 Apr 20 2) Not Recorded 3) 06 Oct 20	Broadcast fo- liar spray with air com- pressed back- pack boom sprayer with 6 x Flat Fan, Teejet DG110015 VS nozzles	31.3	426.667	133.334	1	04 Jul 20	32	Whole Plant Forage	0.625	0.478	47	Mean Recovery
										Grain	0.345	0.264	94	Whole Plant Forage: 91%
										Stover	0.694	0.531	94	Grain: 93%
														Stover: 95%
														NCH: 94 days

- (a) According to EEC and Codex classifications (both) should be used. (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429
- (b) Only if relevant. (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated. (g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.
- (d) Year must be indicated. Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses

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Active substance (common name):	Clopyralid	Commercial Product (name):	GF-1966
Crop group:	Maize	Other active substance in the formulation (common name and content):	None
Crop / EPPO code:	Maize / ZEAMX	Producer of commercial product	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences, Member of the Corteva Agriscience Group of Companies, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, UK	Study type	Residue
Country:	Hungary	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Göd, 2132, Hungary	Residues calculated as:	Clopyralid
Content of active substance (g/kg or g/l):	720 g ae/kg	Residue method and LOQ	120610 / 0.01 mg/kg
Formulation number:	GF-1966	Max frozen storage time prior to analysis	187 days
Formulation type (e.g. WP):	SG	Study no. / DAS Study ID	CEMS-9387 / 201513

Formulation type (e.g. WP):															SU														
1		2		3		4		5			6		7		8		9			10		11							
Trial No. Location (region)		Commod- ity/Variety		Date of 1) Sowing or Planting 2) Flowering 3) Harvest		Method of Treatment		Application rate per treat- ment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion ana- lysed (commodity)	Residues (mg/kg)			PHI	Remarks:										
		(a)		(b) – if relevant		(c)		g ae/hL	Water (L/ha)	g ae/ha		(d)		(e)		(a)	Clopyralid	Scaled to 102 g ae/ha	(days) (f)	(g)									
CEMS-9387H Göd, 2132, Hun- gary		Maize / Dek- alb 390		1) 14 Apr 20 2) Not Recorded 3) 07 Oct 20		Broadcast fo- liar spray with knapsack sprayer and boom with 6 x Flat Fan, Agro Top Air Mix 110 02 nozzles		41.5	309.99	128.8		1	24 Jun 20	32	Whole Plant Forage	1.409	1.116	43	Mean Recovery										
															Grain	0.414	0.328	105	Whole Plant Forage: 91%										
															Stover	1.031	0.817	105	Grain: 93%										
																			Stover: 95%										
																				NCH: 105 days									

- | | | | |
|-----|---|-----|---|
| (a) | According to EEC and Codex classifications (both) should be used. | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429 |
| (b) | Only if relevant. | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) |
| (c) | High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated. | (g) | Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method. |
| (d) | Year must be indicated. | | Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses |

A 2.1.3.3.2 Study 2 - GHE-P-10534

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Two residue trials on maize were conducted in northern Europe and are considered supportive of the intended cGAP on maize forage/silage and maize grain. Residues were scaled to the intended cGAP rate. Scaled residues of clopyralid in maize forage/silage are in the range 0.38-0.78 mg/kg, in maize grain are in the range 0.13-0.27 mg/kg and in maize stover are in the range 0.45-0.55 mg/kg.
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Reference:	KCA 6.3.3/02
Report	Devine, H. C., (2003); Residues of Clopyralid in Maize at Intervals and At Harvest Following One or Two Applications of LONTREL 100 (EF-1136), Northern and Southern Europe - 2002; Study No. CEMS-1786; DAS Report No. GHE-P-10534.
Guideline(s):	Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990.
Deviations:	None that impact the integrity of study
GLP:	Yes
Acceptability:	Yes

Materials and methods

Four field trials were conducted on maize in the Germany (2) and Northern France (2) in 2002. Four trials were conducted in southern Europe, and these have been summarised in the SEU section as study 2. Clopyralid was applied as EF-1136, an SL formulation containing 100 g ae/L. Two application regimes were used: 1) Two foliar applications were made at a nominal rate of 100 + 200 g ae/ha at BBCH 16 or 2) One foliar application was made at a nominal rate of 125 g ae/ha at growth stage BBCH 32.

In the trials that applied a single application, samples of whole plant were sampled at intervals at PHIs of 0-74 days. Samples of rest of plant and cobs were taken at normal commercial harvest (NCH). In the trials that applied two applications, sample of whole plant were taken at a PHI of 81-90 days. Samples were stored ≤-18 °C for a maximum of 275 days. This is accommodated by the available storage stability data on high starch and high water commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-10 mg/kg fortification, mean recovery 101%, RSD=11%, n=4; cobs at 0.01-0.1 mg/kg fortification, mean recovery 100%, n=2; rest of plant at 0.01-0.1 mg/kg fortification, mean recovery 100%, n=2.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

Only the trials that applied a single application of clopyralid are relied upon to support the intended cGAP. Whole plants sampled before the harvest of the cob are considered representative of maize forage/silage and were sampled at PHIs in accordance with the intended cGAP. In one trial a more critical residue at a

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later PHI was observed and therefore this was used for risk assessment purposes. Cobs sampled at NCH (BBCH 89) represent maize grain and as the growth stage of application was cGAP compliant, all trials were relied upon, regardless of the PHI. Clopyralid was applied at an exaggerated rate compared to the intended cGAP and therefore residues have been scaled to the intended cGAP rate.

Conclusions

Two residue trials on maize were conducted in northern Europe and are considered supportive of the intended cGAP on maize forage/silage and maize grain. Residues were scaled to the intended cGAP rate. Scaled residues of clopyralid in maize forage/silage are in the range 0.38-0.78 mg/kg, in maize grain are in the range 0.13-0.27 mg/kg and in maize stover are in the range 0.45-0.55 mg/kg.

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Table A 10: Summary of the study 2 trials

Reference: Residues of Clopyralid in Maize at Intervals and At Harvest Following One or Two Applications of LONTREL 100 (EF-1136), Northern and Southern Europe - 2002, CEMS-1786; DAS Report No. GHE-P-10534

GLP: Yes Sample storage conditions: Max 342 days

Crop/crop group: Grain Type Maize Analytical method: GRM 01.16

Indoor/Outdoor: Outdoor (field) Limit of Quantification (mg/kg): 0.01

Formulation: EF-1136 Limit of Detection (mg/kg): 0.002

Content of active substance (g/kg or g/l): 100 g ae/L clopyralid-olamine Residues calculated as: clopyralid

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 102 g ae/ha		
CEMS-1786E / F-37110 MORAND France (EU Northern Zone)/ 2002	Forage Type Maize / Dolfice (Fodder variety)	1. 22-Apr-2002 2. N/A 3. 02-Sep-2002	97 210	290 315	-- --	29-May-2002 13-Jun-2002	BBCH.16	Whole plant	0.68		81	Maximum Storage: 205 days Growth stage at harvest: BBCH 85
CEMS-1786F / F51220 Brimont France (EU Northern Zone)/ 2002	Grain Type Maize / Nexxos (Grain variety)	1. 04-Apr-2002 2. N/A 3. 16-Oct-2002	119	283	--	24-Jun-2002	BBCH.32	Whole plant	2.99 0.91 0.63	<u>0.780</u>	0 60 74	Maximum Storage: 275 days
								Rest of plant Cob	0.53 0.32	<u>0.454</u> <u>0.274</u>	114 114	Growth stage at harvest of cob: BBCH 89

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Trial No. / Location / Year	Commod- ity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 102 g ae/ha		
CEMS- 1786G / Olbronn- Durn 75248 Germany (EU North- ern Zone)/ 2002	Forage Type Maize / Lukas (Fodder va- riety)	1. 15-May- 2002 2. N/A 3. 12-Sep-2002	107 208	320 312	-- --	24-May-2002 14-Jun-2002	BBCH.16	Whole plant	0.17		90	Maximum Stor- age: 195 days Growth stage at harvest: BBCH 83
CEMS- 1786H / Enzberg 75417 Germany (EU North- ern Zone)/ 2002	Grain Type Maize / Palermo (Grain vari- ety)	1. 17-May- 2002 2. N/A 3. 07-Oct-2002	133	320	--	05-Jul-2002	BBCH.32	Whole plant Rest of plant Cob	3.69 0.49 0.49 0.72 0.17	 <u>0.376</u> <u>0.552</u> <u>0.130</u>	0 60 74 94 94	Maximum Stor- age: 264 days Growth stage at harvest of cob: BBCH 89

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

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A 2.1.3.4 Sugar beet, fodder beet, red beet, mangels**Table A 11: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
cGAP EU Sugar beet (EFSA, 2005; Finland, 2005)	2	100 + 200 g ae/ha	21 days	BBCH 10-39	nr
Intended cGAP Sugar beet, Fodder beet, Red beet (1*)	1	120 g ae/ha	nr	BBCH 12-39	42
Zonal cGAP‡	1	150-200 g ae/ha	nr	BBCH 31-39	42

nr: Not relevant

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

‡ A more critical GAP for sugar beet exists in the central EU regulatory zone for product GF-2000.

In accordance with SANTE/2019/12752, data on sugar beet may be extrapolated to fodder beet, mangels and red beet, which is the case here.

A 2.1.3.4.1 Study 1 - 200809 – Sugar beet

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Twelve residue trials on sugar beet were conducted in Northern and eight trials are considered supportive of the intended cGAP on sugar beet and four trials are considered supportive of the zonal cGAP. Residues of clopyralid found in the treated sugar beet tops samples ranged from 0.080 to 0.56 mg/kg. Residues of clopyralid found in the treated sugar beet roots samples ranged from 0.072 to 0.56 mg/kg (MRL=1.0 mg/kg).
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Reference: KCA 6.3.4/01

Report Pirie, D., 2021. Magnitude and Decline of Residues of Clopyralid in Sugar Beet Following Applications of GF-1966 in Northern Europe and the UK, Initiated in 2020. Charles River Laboratories Edinburgh Ltd. Study No. 684083/200809.

Guideline(s): OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice. The application of the OECD principles of GLP to the Organisation and Management of Multi-Site Studies (June 2002). OECD Guideline 509, for the Testing of Chemicals, Crop Field Trial (September 2009). SANCO/3029/99 Revision 4 11/07/00 Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.

Deviations: None that impact the integrity of the study

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GLP: Yes

Acceptability: Yes

Materials and methods

Twelve trials were conducted, Poland (2 – Trials 1 and 9), Germany (2 – Trials 2 and 8), The Netherlands (1 – Trial 3), United Kingdom (4 – Trials 4, 10, 11 e 12), Belgium (1 – Trial 5) and North France (2 – Trials 6 and 7), being of this total 6 “Harvest” Trials (Trials 1, 2, 3, 4, 5 and 11) and 6 “Decline” Trials (6, 7, 8, 9, 10 and 12). A single application of the Formulation GF-1966 (a SG – Water Soluble Granules formulation, containing 720 g as clopyralid/kg) was made, at a nominal application rate of 125 g ae/ha (corresponding to 0.174 kg/ha), spray volume 100 - 400 L/ha at BBCH Stage 35 at Trials 1-3 and 5-9; and a single application of the Formulation GF-1966 (a SG – Water Soluble Granules formulation, containing 720 g as clopyralid/kg) was made, at a nominal application rate of 200 g ae/ha (corresponding to 0.278 kg/ha), spray volume 100 - 400 L/ha at BBCH Stage 35 at Trials 4 and 10-12. There were no surfactants/additives included in the spray mixture.

In magnitude of residue tests, control and treated plots were sampled at normal commercial harvest (NCH) and consisted of sugar beet roots and tops. Two control specimens and two treated specimens were submitted for analysis. In decline of residue tests, the control plot was sampled at normal commercial harvest (NCH) and the treated plot was sampled at normal commercial harvest (NCH), 1, 3, 5, 7 and 14 days after NCH and consisted of sugar beet roots and tops. Two control specimens and twelve treated specimens were submitted for analysis.

Specimens were analysed for residues of clopyralid in sugar beet using a method based on analytical method, Dow AgroSciences Study ID 120610, this method was supplied by the Sponsor (Reference 1). The analysis of clopyralid in sugar beet roots and tops samples is reported in the analytical phase report CEMR-9487 “Determination of Residues of Clopyralid in Sugar Beets – Analytical Phase”. Concurrent recoveries from untreated samples of all matrices fortified at the LOQ to as high as 5.0 mg/kg ranged from 75-108%. The determined Limit of Quantification (LOQ) was 0.010 mg/kg for all analytes. The Limit of Detection (LOD) was <0.003 mg/kg for all analytes.

For each test, after collection/preparation the specimens were stored in a freezer set to maintain *ca* -20°C at the Field Test Sites until the date of shipping. During the shipment the samples were kept deep frozen at *ca* -18°C. Treated samples were stored at *ca* -20°C for less than approximately 6 months (maximum storage interval of 161 days) between sampling and analysis.

Samples were analysed in analytical batches, each consisting of two untreated control samples, one reagent blank, one control sample fortified at the limit of detection (LOD) level, at least two control samples fortified at the limit of quantitation (LOQ) and at least two control samples fortified at 10×LOQ or at a higher level. Over all of the analytical batches, there were at least five control samples fortified at the limit of quantitation (LOQ) and at least five control samples fortified at 10×LOQ or at a higher level.

Results and Discussion

All tests show an overall consistent residue profile when the GF-1966 is applied in accordance with the defined good agricultural practice. Residues of clopyralid found in treated samples collected at normal commercial harvest (NCH) or longer sampling intervals, following one foliar application of GF-1966 formulated product are adequate to derive relevant study endpoints. The residue data demonstrate the following in the residue tests conducted in 2020 in which GF-1966 was applied at 95-105 % of the targeted rate of application:

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- Clopyralid residues in treated field-sugar beet roots following foliar application ranged from 0.072 mg/kg to 0.56 mg/kg;
- Clopyralid residues in treated field-sugar beet tops following foliar application ranged from 0.080 mg/kg to 0.56 mg/kg.

Conclusions

Twelve residue trials on sugar beet were conducted in Northern Europe (Poland, Germany, The Netherlands, United Kingdom, Belgium and North France) and eight trials are considered supportive of the intended cGAP on sugar beet and four trials are considered supportive of the zonal cGAP. Residues of clopyralid found in the treated sugar beet tops samples ranged from 0.080 to 0.56 mg/kg. Residues of clopyralid found in the treated sugar beet roots samples ranged from 0.072 to 0.56 mg/kg.

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Table A 12: Summary of the study 1 trials

Active ingredient (a.i.)(common name) :	GF-1966 (Clpyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using an air compressed boom sprayer (Agrotop PL2)
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Poland	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clpyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clpyralid	(d)
Sponsor Reference No.: 200809 Urbanowice, 47-270, Kędzierzynsko-Kozielski, Opole, Poland	Sugar Beet / Graciana	1. 03 Apr 2020 2. NA 3. 19 Oct 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			127.44*	306	41.7	15 Jun 2020	35	49	Top	0.17	126 (NCH)
									Roots	0.10	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

* g a.e/ha rounded to 2 decimal places

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using an air compressed boom sprayer (Agrotop PL1)
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Germany	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Blankenhagen, Rostock, 18182 Mecklenburg-Western Pomerania, Germany	Sugar Beet / Advena	1. 02 Apr 2020 2. NA 3. 09 Oct 2020	--	--	--	Untreated	--	49	Top	<LOQ (0.008)	--
									Roots	ND	
			126.77*	304	41.7	10 Jun 2020	35	49	Top	0.12	121 (NCH)
									Roots	0.20	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

* g a.e/ha rounded to 2 decimal places

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a portable knapsack boom sprayer
Country :	The Netherlands	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Ottersum, 6595 ME, Gennep, Limburg The Netherlands	Sugar Beet / NEENA	1. 06 Apr 2020 2. NA 3. 14 Sep 2020	--	--	--	Untreated	--	49	Top	0.015	--
									Roots	ND	
			123.4	393	31.4	06 Jun 2020	35	49	Top	0.12	100 (NCH)
									Roots	0.14	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) ^(f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Holme-on-Spalding-Moor, YO43 4DQ, East Yorkshire, United Kingdom	Sugar Beet / Haydn	1. 17 Apr 2020 2. NA 3. 08 Oct 2020	--	--	--	Untreated	--	49	Top	<LOQ (0.007)*	--
									Roots	ND*	
			207.79	312	66.60	15 Jun 2020	35	49	Top	0.56	115 (NCH)
									Roots	0.28	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

* Quantified using Confirmatory ion

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	Belgium	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) ^(f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Templeuve, 7520, Hainaut, Belgium	Sugar Beet / Tes-silia	1. 09 Apr 2020 2. NA 3. 20 Oct 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			128.70	258	49.88	08 Jun 2020	35	49	Top	0.14	134 (NCH)
									Roots	0.16	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Active ingredient (a.i.)(common name)	:	GF-1966 (Clopyralid)	Commercial product (name)	:	GF-1966
Crop/crop group	:	Sugar Beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting (name, address)	:	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
Country	:	North France	Indoor/Outdoor	:	Outdoor
Content of active substance: (g/kg)	:	719 g/kg acid equivalence	Other active substance in the formulation	:	None
Formulation (e.g., WP)	:	SG	Other active substance content (g/kg or g/L)	:	None
			Residues calculated as	:	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) ^(f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Senlis-le-Sec, 80300, Hauts-de-France North France	Sugar Beet / Tisserin	1. 30 Mar 2020 2. NA 3. 07 Oct 2020	--	--	--	Untreated	--	49	Top	ND*	--
									Roots	ND*	
			124.39	248	50.16	03 Jun 2020	35	49	Top	0.10	126 (NCH)
									Roots	0.18	
								49	Top	0.085	127
									Roots	0.11	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

* Quantified using Confirmatory ion

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	North France	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALAP
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Senlis-le-Sec, 80300, Hauts-de-France North France	Sugar Beet / Tisserin	1. 30 Mar 2020 2. NA 3. 07 Oct 2020	124.39	248	50.16	03 Jun 2020	35	49	Top	0.20	129
									Roots	0.18	
								49	Top	0.12	131
									Roots	0.19	
								49	Top	0.080	133
									Roots	0.16	
								49	Top	0.14	140
									Roots	0.17	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	North France	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(^a)	(^b)	g a.e/ha	Water (L/ha)	g a.e/hL	(^c)	A	S		Clopyralid	(^d)
Sponsor Reference No.: 200809 Beuvraignes, 80700, Hauts-de-France North France	Sugar Beet / Frisbee	1. 25 Mar 2020 2. NA 3. 16 Sep 2020	--	--	--	Untreated	--	49	Top	ND*	--
									Roots	ND*	
			131.58	262	50.22	03 Jun 2020	35	49	Top	0.12	105 (NCH)
									Roots	0.20	
								49	Top	0.11	106
									Roots	0.12	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

* Quantified using Confirmatory ion

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Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	North France	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DAL
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Beuvraignes, 80700, Hauts-de-France North France	Sugar Beet / Frisbee	1. 25 Mar 2020 2. NA 3. 16 Sep 2020	131.58	262	50.22	03 Jun 2020	35	49	Top	0.19	108
									Roots	0.17	
								49	Top	0.16	110
									Roots	0.15	
								49	Top	0.14	112
									Roots	0.13*	
								49	Top	0.14	119
									Roots	0.13	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

* Mean result of two analysis

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Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using a portable knapsack boom sprayer
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Germany	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Velen-Ramsdorf, 46342, Borken, North Rhine-Westphalia Germany	Sugar Beet / MARLEY	1. 14 Apr 2020 2. NA 3. 15 Sep 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			126.7	406	31.2	03 Jun 2020	35	49	Top	0.22	104 (NCH)
									Roots	0.12	
								49	Top	0.17	105
									Roots	0.14	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using a portable knapsack boom sprayer
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Germany	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Velen-Ramsdorf, 46342, Borken, North Rhine-Westphalia Germany	Sugar Beet / MARLEY	1. 14 Apr 2020 2. NA 3. 15 Sep 2020	126.7	406	31.2	03 Jun 2020	35	49	Top	0.19	107
									Roots	0.12	
								49	Top	0.15	109
									Roots	0.15	
								49	Top	0.17	111
									Roots	0.17	
								49	Top	0.15	118
									Roots	0.13	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using an Air compressed boom sprayer (Agrotop PL2)
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Poland	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Peckowo, 64-520, Greater Poland Poland	Sugar Beet / Kujavia	1. 06 Apr 2020 2. NA 3. 30 Sep 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			119.27*	286	41.7	19 Jun 2020	35	49	Top	0.084	103 (NCH)
									Roots	0.079	
								49	Top	0.093	104
									Roots	0.093	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

*g a.e/ha rounded to 2 decimal places

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	E. I. du Pont de Nemours and Company	Method of treatment (e) :	Foliar application using an Air compressed boom sprayer (Agrotop PL2)
(name, address) :	Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Indoor/Outdoor :	Outdoor
Country :	Poland	Other active substance in the formulation :	None
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance content (g/kg or g/L) :	None
Formulation (e.g., WP) :	SG	Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Pęckowo, 64-520, Greater Poland Poland	Sugar Beet / Kujavia	1. 06 Apr 2020 2. NA 3. 30 Sep 2020	119.27*	286	41.7	19 Jun 2020	35	49	Top	0.095	106
									Roots	0.081	
								49	Top	0.091	108
									Roots	0.093	
								49	Top	<u>0.17</u>	110
									Roots	0.072	
								49	Top	0.13	117
									Roots	<u>0.13</u>	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

*g a.e/ha rounded to 2 decimal places

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Slingsby, York, YO62 4AY, North Yorkshire United Kingdom	Sugar Beet / Haydn	1. 26 Apr 2020 2. NA 3. 09 Oct 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			199.16	299	66.61	26 Jun 2020	35	49	Top	0.41	105 (NCH)
									Roots	0.40	
								49	Top	0.44	106
									Roots	0.37	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALAP
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Slingsby, York, YO62 4AY, North Yorkshire United Kingdom	Sugar Beet / Haydn	1. 26 Apr 2020 2. NA 3. 09 Oct 2020	199.16	299	66.61	26 Jun 2020	35	49	Top	0.42	108
									Roots	0.56	
								49	Top	0.55	110
									Roots	0.50	
								49	Top	0.45	112
									Roots	0.47	
								49	Top	0.39	119
									Roots	0.40	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Moulton Eaugate, PE12 0SZ Spalding, Lincolnshire, United Kingdom	Sugar Beet / Daphna	1. 03 Apr 2020 2. NA 3. 29 Sep 2020	--	--	--	--	--	49	Top	ND	--
									Roots	ND	
			200.60	301	66.64	12 Jun 2020	35	49	Top	<u>0.12</u>	109 (NCH)
									Roots	<u>0.14</u>	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (.). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Moreby, York, YO19 6HJ, North Yorkshire United Kingdom	Sugar Beet / Hornet	1. 24 Apr 2020 2. NA 3. 05 Oct 2020	--	--	--	Untreated	--	49	Top	ND	--
									Roots	ND	
			204.20	306	66.73	17 Jun 2020	35	49	Top	0.29	110 (NCH)
									Roots	0.35	
								49	Top	0.28	111
									Roots	0.25	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

NCH = Normal commercial harvest

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Active ingredient (a.i.)(common name) :	GF-1966 (Clopyralid)	Commercial product (name) :	GF-1966
Crop/crop group :	Sugar Beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting (name, address) :	E. I. du Pont de Nemours and Company Member of the Corteva Agriscience Group of Companies, Wilmington, Delaware, 19805, USA	Method of treatment (e) :	Foliar application using a Knapsack sprayer
Country :	United Kingdom	Indoor/Outdoor :	Outdoor
Content of active substance: (g/kg) :	719 g/kg acid equivalence	Other active substance in the formulation :	None
Formulation (e.g., WP) :	SG	Other active substance content (g/kg or g/L) :	None
		Residues calculated as :	Clopyralid

1	2	3	4			5	6		7	8	9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate (A1)			Dates of treatment(s)	BBCH Growth stage at Application (A) and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)	DALA
	(a)	(b)	g a.e/ha	Water (L/ha)	g a.e/hL	(c)	A	S		Clopyralid	(d)
Sponsor Reference No.: 200809 Moreby, York, YO19 6HJ, North Yorkshire United Kingdom	Sugar Beet / Hor-net	1. 24 Apr 2020 2. NA 3. 05 Oct 2020	204.20	306	66.73	17 Jun 2020	35	49	Top	0.20	113
									Roots	0.29	
								49	Top	0.28	115
									Roots	0.27	
								49	Top	0.56	117
									Roots	0.30	
								49	Top	0.24	124
									Roots	0.26	

^a According to EEC and Codex Class Classification (both) should be used^b Only if relevant^c Year must be indicated^d Days after last application

NA = Not applicable

^e High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated^f Analytical method: Based on Dow AgroSciences Study ID 120610

LOQ 0.010 mg/kg; Samples below the LOQ is reported as <LOQ

Residue values below the LOD (0.003 mg/kg) are reported as 'ND' (not detected).

Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as LOQ with the uncorrected concentration in parentheses (). Values are rounded to 1 significant figure. Residues equal to or greater than 0.01 mg/kg (i.e. ≥LOQ) are reported as their values rounded to 2 significant figures.

A 2.1.3.5 Onion from seed

Table A 13: Comparison of intended and critical EU GAPs

Type of GAP	Number of ap- plications	Application rate per treatment	Interval be- tween applica- tion	Growth stage at last application	PHI (days)
cGAP EU (Finland 2008)	2	100 + 200 g ae/ha	21 days	BBCH 13-16	nr
Intended cGAP, Onion (17*)	1	120.24 g ae/ha	nr	BBCH 11-16	42

nr: Not relevant
 * Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.5.1 Study 1 - GHE-P-10805

Comments of zRMS:	The study has already been positively evaluated by RMS Finland. Under the conditions of the test, at PHI of 42 d, residues of clopyralid in onions did not exceed EU MRL of 0.5 mg/kg.
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Reference:	KCA 6.3.5/01
Report	Devine, H.C., (2004); Residues of Clopyralid in Onions at Harvest and at Intervals Following Two Application of Lontrel 100 (EF-1136), UK - 2003; DAS Study No. CEMS-2030; DAS Report No. GHE-P-10805
Guideline(s):	Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990.
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes.

Study No. CEMS-2030/GHE-P-10805 was submitted, evaluated and deemed acceptable by RMS Finland as part of an MRL evaluation (Finland, 2008) but was not reviewed at EU level because two additional N-EU trials were required. The data also supports the intended critical GAP for onion in C-EU. This study can be deemed as previously evaluated by a competent authority. Therefore, does not require re-evaluation.

Materials and methods

Four field trials were conducted on onions in the United Kingdom in 2003. Clopyralid was applied as LONTREL 100 (EF-1136), an SL formulation containing 100 g ae/L. Two foliar applications were made, the first at a nominal rate of 100 g ae/ha and the second at 200 g ae/ha. The first application was made at growth stage BBCH 10-11 and the second at BBCH 14-16, 42 days before harvest.

Samples of mature onion bulbs were taken 42 days after the last application (DALA). Samples were stored ≤-18 °C for a maximum of 155 days. This is accommodated by the available storage stability data on high water commodities reviewed during the EU evaluation (EFSA, 2018a).

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Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-1.0 mg/kg fortification, mean recovery 87%, RSD=5%, n=3; bulbs at 0.01-0.1 mg/kg fortification, mean recovery 87%, n=2.

Results and Discussion

The residue trials are summarized in the following table, and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

A single trial was cancelled, as the farmer harvested the crop before the end of the trial, so three independent trials are available. Although the residue trials applied two applications, the interval between applications was *ca.* 1 month, and it is recognised that the final application generally determines residues in samples at harvest so the trials with two applications may be used to support the proposed GAP with a single application. All residues have been scaled to the cGAP rate with respect to the final application rate.

Trials were conducted with an SL formulation but the results can be extrapolated to support the GF-1966 SG formulation, as in accordance with OECD 509, formulations diluted in water, with no organic solvents and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Three residue trials on onions were conducted in the UK and are considered supportive of the intended cGAP. Residues have been scaled with respect to the final application rate. Scaled residues of clopyralid in onions are in the range 0.012-0.033 mg/kg.

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Table A 14: Summary of the study 1 trials

Reference:	Residues of Clopyralid in Onions at Harvest and at Intervals Following Two Application of Lontrel 100 (EF-1136), UK - 2003, CEMS-2030; DAS Report No. GHE-P-10805				
GLP:	Yes	Sample storage conditions:	Max 155 days		
Crop/crop group:	Onions	Analytical method:	GRM 01.16		
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):	0.01		
Formulation:	EF-1136	Limit of Detection (mg/kg):	0.002		
Content of active substance (g/kg or g/l):	100 g ae/L clopyralid-olamine	Residues calculated as:	clopyralid		

Trial No. / Location / Year	Commod- ity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
CEMS- 2030A / Thetford, Norfolk, IP24 1LS UK (EU North- ern Zone)/ 2003	Onions / Red Baron	1. 09-Mar- 2003 2. N/A 3. 22-Jul-2003	98 184	207 185	-- --	01-May- 2003 10-Jun- 2003	BBCH.16	Bulb Whole plant	0.05 0.10 2.82 0.34 0.35	0.033	42 <0 0 14 28	Maximum Stor- age: 155 days
CEMS- 2030B / Nayland, Colchester, Essex, CO6 4JB UK (EU North- ern Zone)/ 2003	Onions / Renate	1. 13-Mar- 2003 2. N/A 3. 22-Jul-2003	85 206	178 207	-- --	01-May- 2003 10-Jun- 2003	BBCH.14	Bulb Whole plant	0.02 0.09 0.59 0.16 0.10	0.012	42 <0 0 14 28	Maximum Stor- age: 66 days

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Trial No. / Location / Year	Commod- ity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
CEMS- 2030C / Great Hor- kesley, Col- chester, Es- sex, CO6 4AP UK (EU North- ern Zone)/ 2003	Onions / Hyfort	1. 10-Mar- 2003 2. N/A 3. 22-Jul-2003	108 222	227 223	-- --	01-May- 2003 10-Jun- 2003	BBCH.14	Bulb	0.04	0.022	42	Maximum Stor- age: 9 days

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.5.2 Study 2 - GHE-P-11080

Comments of zRMS:	The study has already been positively evaluated by RMS Finland. Under the conditions of the test, residues of clopyralid in onions did not exceed EU MRL of 0.5 mg/kg.
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Reference:	KCA 6.3.5/02
Report	Devine, H. C., (2005); Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe - 2004; Study No. CEMS-2346; DAS Report No. GHE-P-11080
Guideline(s):	Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990.
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes.

Study No. CEMS-2346/GHE-P-11080 was submitted, evaluated and deemed acceptable by RMS Finland as part of an MRL evaluation (Finland, 2008) but was not reviewed at EU level because two additional N-EU trials were required. The data also supports the intended critical GAP for onion in C-EU. This study can be deemed as previously evaluated by a competent authority. Therefore, does not require re-evaluation.

Materials and methods

Two field trials were conducted on onions in the United Kingdom (1) and Northern France (1) in 2004. Clopyralid was applied as LONTREL 100 (EF-1136), an SL formulation containing 100 g ae/L. Two foliar applications were made, the first at a nominal rate of 100 g ae/ha and the second at 200 g ae/ha. The first application was made a growth stage BBCH 10-11 and the second at BBCH 14-16, 42-66 days before harvest.

Samples of mature onion bulbs were taken 42-66 days after the last application (DALA). Samples were stored ≤ -18 °C for a maximum of 238 days. This is accommodated by the available storage stability data on high water commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-0.1 mg/kg fortification, mean recovery 105%, RSD=4%, n=4; bulbs at 0.01-0.1 mg/kg fortification, mean recovery 92%, n=2.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

Although the residue trials applied two applications, the interval between applications was *ca.* 1 month and it is recognised that the final application generally determines residues in samples at harvest so the trials with two applications may be used to support the proposed GAP with a single application. All residues have been scaled to the cGAP rate with respect to the final application rate. The PHI in one trial was 66

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days, but the trial was conducted at a matching growth stage to the intended GAP; therefore, it is considered suitable to support the intended GAP.

Trials were conducted with an SL formulation but the results can be extrapolated to support the GF-1966 SG formulation, as in accordance with OECD 509, formulations diluted in water, with no organic solvents and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Two residue trials on onions were conducted in northern Europe and are considered supportive of the intended cGAP. Residues have been scaled with respect to the final application rate. Scaled residues of clopyralid in onions are in the range <0.01-0.10 mg/kg.

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Table A 15: Summary of the study 2 trials

Reference:	Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe - 2004, CEMS-2346; DAS Report No. GHE-P-11080		
GLP:	Yes	Sample storage conditions:	Max 238 days
Crop/crop group:	Onions	Analytical method:	GRM 01.16
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):	0.01
Formulation:	EF-1136	Limit of Detection (mg/kg):	0.002
Content of active substance (g/kg or g/l):	100 g ae/L clopyralid-olamine	Residues calculated as:	Clopyralid

Trial No. / Location / Year	Commodity / Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
CEMS-2346A / Higham, Suffolk UK (EU Northern Zone)/ 2004	Onions / Samira	1. 03-Mar-2004	107	213	--	20-May-2004	BBCH.14 to 15	Bulb	<0.01	<0.01	42	Maximum Storage: 223 days
		2. N/A	183	187	--	30-Jun-2004		Whole plant	0.06		<0	
		3. 11-Aug-2004							1.02		0	
									0.16		14	
									0.04		28	
CEMS-2346B / Vinzelles (71) France (EU Northern Zone)/ 2004	Onions / Bonus	1. 20-Feb-2004	106	319	--	05-May-2004	BBCH.15 to 16	Bulb	0.17	0.10	66	Maximum Storage: 238 days
		2. N/A	204	307	--	15-Jun-2004		Whole plant	0.08		<0	
		3. 20-Aug-2004							0.71		0	
									0.25		14	
									0.12		28	
									0.17		44	

(a) According to CODEX Classification / Guide

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(b) Only if relevant

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(c) Year must be indicated

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A 2.1.3.5.3 Study 3 - GHE-P-11272

Comments of zRMS:	The study has already been positively evaluated by RMS Finland. Under the conditions of the test, residues of clopyralid in onions did not exceed EU MRL of 0.5 mg/kg.
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Reference: KCA 6.3.5/03

Report Devine, H. C., (2006); Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe-2005; Study No. CEMS-2696; DAS Report No. GHE-P-11272

Guideline(s): Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990.

Deviations: None that impact the integrity of the study

GLP: Yes

Acceptability: Yes.

Study No. CEMS-2696/GHE-P-11272 was submitted, evaluated and deemed acceptable by RMS Finland as part of an MRL evaluation (Finland, 2008) but was not reviewed at EU level because two additional N-EU trials were required. The data also supports the intended critical GAP for onion in C-EU. This study can be deemed as previously evaluated by a competent authority. Therefore, does not require re-evaluation.

Materials and methods

A single field trial was conducted on onions in the United Kingdom in 2005. Clopyralid was applied as LONTREL 100 (EF-1136), an SL formulation containing 100 g ae/L. Two foliar applications were made, the first at a nominal rate of 100 g ae/ha and the second at 200 g ae/ha. The first application was made a growth stage BBCH 10-11 and the second at BBCH 13-15, 42 days before harvest.

Samples of mature onion bulbs were taken 42 days after the last application (DALA). Samples were stored ≤-18 °C for a maximum of 182 days. This is accommodated by the available storage stability data on high water commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: whole plant at 0.01-1.0 mg/kg fortification, mean recovery 105%, n=2; bulbs at 0.01-0.1 mg/kg fortification, mean recovery 98%, n=2.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

Although the residue trial applied two applications, the interval between applications was *ca.* 1 month and it is recognised that the final application generally determines residues in samples at harvest so the trials with two applications may be used to support the proposed GAP with a single application. All residues have been scaled to the cGAP rate with respect to the final application rate

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Trials were conducted with an SL formulation but the results can be extrapolated to support the GF-1966 SG formulation, as in accordance with OECD 509, formulations diluted in water, with no organic solvents and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

One residue trial on onions was conducted in the UK and is considered supportive of the intended cGAP. Residues have been scaled with respect to the final application rate. Scaled residues of clopyralid in onions are 0.012 mg/kg.

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Table A 16: Summary of the study 3 trials

Reference:	Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF-1136), Northern Europe-2005, CEMS-2696; DAS Report No. GHE-P-11272		
GLP:	Yes	Sample storage conditions:	Max 182 days
Crop/crop group:	Onions	Analytical method:	GRM 01.16
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):	0.01
Formulation:	EF-1136	Limit of Detection (mg/kg):	0.002
Content of active substance (g/kg or g/l):	100 g ae/L clopyralid-olamine	Residues calculated as:	clopyralid

Trial No. / Location / Year	Commod- ity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120.24 g ae/ha		
CEMS-2696 / Scrooby, Doncaster, Nottingham- shire UK (EU North- ern Zone)/ 2005	Onions / Hyskin	1. 21-Mar- 2005	101	202	--	11-May- 2005	BBCH.13 to 15	Bulb	0.02	0.012	42	Maximum Stor- age: 182 days
		2. N/A	197	306	--	22-Jun- 2005		Whole plant	0.10		<0	
		3. 03-Aug- 2005							5.16		0	
									0.24		14	
									0.11		28	

- (a) According to CODEX Classification / Guide (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (b) Only if relevant (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
- (c) Year must be indicated

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A 2.1.3.5.4 Study 4 - GHE-P-12680

Comments of zRMS:	The study has already been positively evaluated by RMS Finland. Under the conditions of the test, residues of clopyralid in onions did not exceed EU MRL of 0.5 mg/kg.
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Reference: KCA 6.3.5/04

Report Rawle, N. W., (2012); Residues of Clopyralid in Bulb Onions following Two Applications of EF-1136 - Northern Europe - 2011; DAS Study No. CEMS-4969; DAS Report No. GHE-P-12680.

Guideline(s): Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, Oct.21, 1996 and "Commission Working Document 7029NII95 Rev. 5, General Recommendations for the Design, Preparation and Realisation of Residue Trials, July 22, 1997".

Deviations: None that impact the integrity of the study

GLP: Yes

Acceptability: Yes.

Study No. CEMS-4969/GHE-P-12680 was submitted, evaluated and deemed acceptable by RMS Finland as part of an MRL evaluation (Finland, 2008) but was not reviewed at EU level because two additional N-EU trials were required. The data also supports the intended critical GAP for onion in C-EU. This study can be deemed as previously evaluated by a competent authority. Therefore, does not require re-evaluation.

Materials and methods

Two field trials were conducted on onions in Northern France in 2011. Clopyralid was applied as LONTREL 100 (EF-1136), an SL formulation containing 100 g ae/L. Two foliar applications were made, the first at a nominal rate of 100 g ae/ha and the second at 200 g ae/ha. The first application was made a growth stage BBCH 10-11 and the second at BBCH 13-16, 44 days before harvest.

Samples of mature onion bulbs were taken 44 days after the last application (DALA). Samples were stored ≤18 °C for a maximum of 108 days. This is accommodated by the available storage stability data on high water commodities reviewed during the EU evaluation (EFSA, 2018a).

Residues of clopyralid were determined using method GRM 01.16, with an LOQ of 0.01 mg/kg. Acceptable procedural recoveries were obtained: bulbs at 0.01 mg/kg fortification, mean recovery 96%, n=2.

Results and Discussion

The residue trials are summarized in the following table and residues used for risk assessment are underlined. Residues of clopyralid were <LOQ in control samples.

Although the residue trials applied two applications, the interval between applications was 8-14 days and it is recognised that the final application generally determines residues in samples at harvest so the trials with two applications may be used to support the proposed GAP with a single application. All residues have been scaled to the cGAP rate with respect to the final application rate. The two trials were conducted in the same location, but used different varieties and different application dates and are therefore considered independent.

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Trials were conducted with an SL formulation but the results can be extrapolated to support the GF-1966 SG formulation, as in accordance with OECD 509, formulations diluted in water, with no organic solvents and with a PHI of >7 days are considered equivalent for residue purposes.

Conclusions

Two residue trials on onions were conducted in Northern France; however these trials are not considered independent. Therefore, one trial is considered supportive of the intended cGAP and are considered supportive of the intended cGAP. Residues have been scaled with respect to the final application rate. Scaled residues of clopyralid in onion are in the range 0.014-0.018 mg/kg.

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Table A 17: Summary of the study 4 trials

Reference:	Residues of Clopyralid in Bulb Onions following Two Applications of EF-1136 - Northern Europe - 2011, CEMS-4969; DAS Report No. GHE-P-12680		
GLP:	Yes	Sample storage conditions:	Max 108 days
Crop/crop group:	Bulb onion	Analytical method:	GRM 01.16
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/kg):	0.01
Formulation:	EF-1136	Limit of Detection (mg/kg):	0.003
Content of active substance (g/kg or g/l):	100 g ae/L clopyralid-olamine	Residues calculated as:	clopyralid

Trial No. / Location / Year	Commodity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
CEMS-4969A / La Chapelle de Guinchay, Burgundy (1) France (EU Northern Zone)/ 2011	Bulb onion / Stuttgarter	1. 25-Mar-2011 2. N/A 3. 09-Jun-2011	105 203	263 254	40 80	12-Apr-2011 26-Apr-2011	BBCH.14 to 15	Bulb	0.03	0.018	44	Maximum Storage: 104 days

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Trial No. / Location / Year	Commodity / Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
CEMS-4969B / La Chapelle de Guinchay, Burgundy (2) France (EU Northern Zone) / 2011	Bulb onion / Red Baron	1. 25-Mar-2011 2. N/A 3. 05-Jun-2011	108 218	271 272	40 80	14-Apr-2011 22-Apr-2011	BBCH.13 to 14	Bulb	0.025	0.014	44	Maximum Storage: 108 days Trial not independent; value not used in risk assessment

(a) According to CODEX Classification / Guide (c) Year must be indicated (e) Remarks may include: Climatic conditions; Reference to analytical
 (b) Only if relevant (d) Days after last application (Label pre-harvest interval, PHI, underline) method and information which metabolites are include

A 2.1.3.5.5 Study 5 - GHE-P-7289

Comments of zRMS:	The study is considered supportive. Under the conditions of the study, residues of clopyralid in onions did not exceed EU MRL of 0.5 mg/kg.
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Reference:

KCA 6.3.5/01

Report

Butler, R. E.; Reynens, P. (1998); Determination of Residues of Clopyralid in Onions following a single application of Lontrel 100 (EF-1136), Belgium, 1997; Study Plan No. R97-030; DAS Report No. GHE-P-7289

Guideline(s):

OECD Principles of Good Laboratory Practice.

Deviations:

None that impact the integrity of the study

GLP:

Yes

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Acceptability:**Yes.****Materials and methods**

Two trials were undertaken in Belgium during 1997 and each consisted of one untreated and one treated plot. The treated plots were sprayed with EF-I136 at a nominal rate of 1.5 L/ha (150 g as/ha) at growth stage BBCH 14-15. Samples of whole plant were taken at intervals up to harvest when onion bulb was taken, 62 days after application.

Residues in onions were determined using Dow AgroSciences Analytical Method ERC 97.20 which has a lowest validated level of 0.02 mg /kg clopyralid. All residue values equivalent to less than 20% of lowest validated level are classified as "not detected" (ND). All analyses were performed in duplicate.

Clopyralid was extracted from onions by macerating and shaking with caustic methanol. An aliquot was acidified and clopyralid was partitioned into methyl-tertiary-butyl ether (MTBE) then into aqueous sodium bicarbonate, which was acidified and clopyralid was extracted back into MTBE. The organic phase was evaporated to dryness and the residuum treated with 4% v/v concentrated sulphuric acid / n-butanol to form clopyralid butyl ester. Following the addition of water, clopyralid butyl ester was partitioned into hexane. The hexane extract was then analysed by capillary gas chromatography using mass selective detection.

Results and Discussion

The detector response was checked and found to be linear over the range 0.0025 – 0.12 µg/mL for clopyralid butyl ester.

The mean procedural recovery for onions was 99%. No residues were detected in any of the untreated samples in either trial. Samples were stored up to 361 days, which is covered by storage stability data.

In trial R97-030A, residues of clopyralid in whole plant immediately after application were 0.60 mg/kg declining to 0.14 mg/kg in onion bulb after 62 days. In trial R97-030B, residues of clopyralid in whole plant immediately after application were 0.44 mg/kg declining to 0.08 mg/kg in onion bulb after 62 days.

Conclusions

Two residue trials on onions were conducted in Belgium and are considered supportive of the intended cGAP. Residues have been scaled with respect to the final application rate. Scaled residues of clopyralid in onion are in the range 0.06-0.114 mg/kg.

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Table A 18: Summary of the study 5 trials

Reference:	Determination of Residues of Clopyralid in Onions at Intervals Following a Single Application of Lontrel 100 (EF-1136), Belgium, 1997, R97-030		
GLP:	Yes	Sample storage conditions:	Max 361 days
Crop/crop group:	Bulb onion	Analytical method:	ERC 97.20
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/Kg):	0.02
Formulation:	EF-1136	Limit of Detection (mg/Kg):	0.004
Content of active substance (g/kg or g/l):	100 g ae/L clopyralid-olamine	Residues calculated as:	Clopyralid

Residue trial summary for Bulb onion												
Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treat- ment or num- ber and last date	Growth Stage at last treatment	Portion an- alysed	Residues (mg/Kg)		PHI (days)	Remarks:
			g ae/ha	Water (L/ha)	g ae/hL				clopyralid	Scaled to 120 g ae/ha		
R97-030A / Chemin de la Siberie, 4, B- 5030 Gembloux (EU Northern Zone)/ 1997	Bulb onion / Hystar	1. 06-Mar-1997	147	204.5	71.9	10-Jul-1997	BBCH.14 to 15	Bulb	0.14	0.114	62	Ave Recovery: 99%
		2. N/A										
		3. 10-Sep-1997						Whole plant	0.595 0.14 0.235 0.22		0 14 28 49	Maximum Storage: 361 days
R97-030B / Rue Xavier Dumont de Chassart, 16, B-6210 Villers- Perwin (EU Northern Zone) 1997	Bulb onion / Rocky	1. 27-May-1997	149.6 3	207	72.3	23-Jul-1997	BBCH.14 to 15	Bulb	0.075	0.060	62	Ave Recovery: 99%
		2. N/A										
		3. 23-Sep-1997						Whole plant	0.445 0.165 0.295 0.095		0 14 28 49	Maximum Storage: 348 days

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new data are submitted in the framework of this application.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new data are submitted in the framework of this application.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Sugar beet

Study 1 - GH-C 3305

Comments of zRMS:	The study was performed according to guidelines and GLP requirements, however before revision of GLP principles in 1997. Root (RAC) pulp, sugar and molasses were analysed. The processing factor for pulp was 0.77, for white sugar was 0.14 and for molasses was 9.2. Residues of clopyralid are reduced when processed into pulp and white sugar, but concentrated in molasses.
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Reference:	KCA 6.5.3/01
Report	Phillips, A.M., (1994); Determination of residues of clopyralid in sugar beet processed fractions; DAS Report No. GH-C 3305.
Guideline(s):	Environmental Protection Agency under Section 171-4(c)(2)(iv), Subdivision 0 of the EPA Pesticide Assessment Guideline.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Materials and methods

Sugar beet was treated with clopyralid formulation Stinger (formulation XRM-3972) at 841 g ae/ha in

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1974/5 in the USA.

Samples of mature sugar beets were taken at normal commercial harvest (131 days after treatment). Processing was conducted at Spreckels Sugar Company, Woodlawn, California to obtain samples of pulp, molasses and sugar in procedures representative of commercial production. All samples were stored frozen (-20°C) for a maximum of 96 days prior to analysis. This is accommodated by the available storage stability data on high water and high starch commodities reviewed during the EU evaluation (EFSA, 2018a).

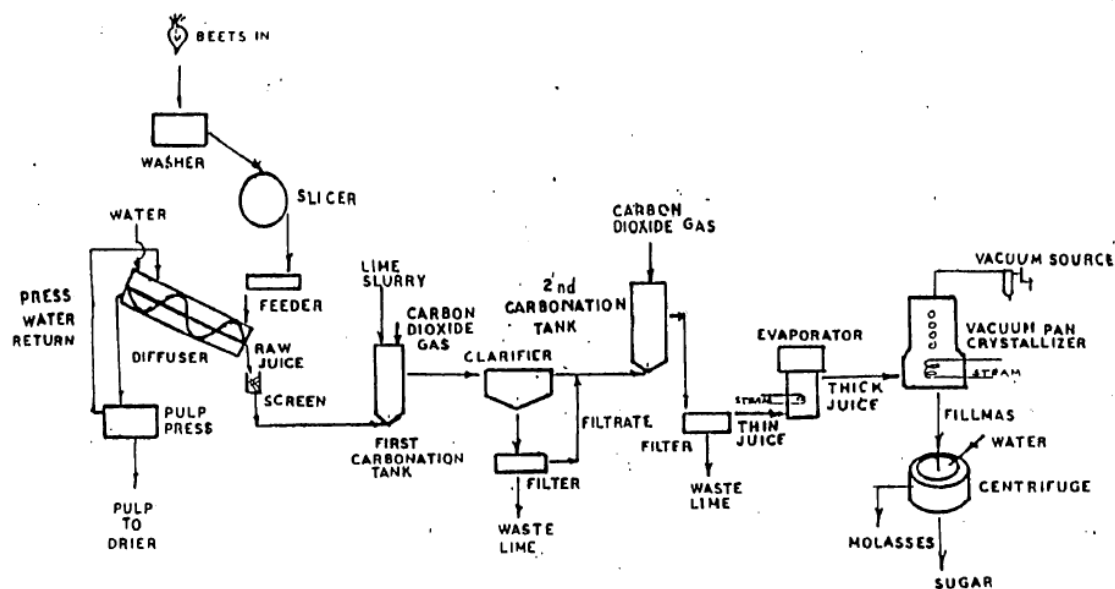
Residues of clopyralid were determined by method GRM 94.04, with an LOQ of 0.05 mg/kg. The method is based on extraction of samples with a solution of 0.5% sodium hydroxide in water. An aliquot of the sample was extracted into methyl t-butyl ether (MTBE) and then into 0.25M sodium bicarbonate. The sample was acidified and again extracted into MTBE. After evaporating the MTBE, the sample was derivatised with 14% boron trifluoride in methanol to form the methyl derivative. The sample was treated with potassium permanganate. Excess potassium permanganate was reduced with sodium sulfite and then the sample was extracted into 20:80 diethyl ether:hexane. An aliquot of the sample in diethyl ether:hexane was solvent exchanged into toluene and internal standard was added. The final sample in toluene was then transferred to an auto sampler vial for analysis by gas chromatography (GC). Average procedural recoveries of fortified control samples were 80% for sugar beet roots (n=18, 0.05-1.0 mg/kg, %RSD=5); 85% for pulp (n=18, 0.05-1.0 mg/kg, %RSD=10); 92% for molasses (n=18, 0.05-1.0 mg/kg, %RSD=11) and 90% for sugar (n=18, 0.05-1.0 mg/kg, %RSD=7).

Processing phase: The sugar beets were washed with water and hand cleaned with a brush. Clean beets were sliced and the sugar extracted with a mixture of hot water and pulp press water. The spent pulp was mechanically pressed and solar dried to about 20-30% and then further dried using a combination of oven drying at 130 °C and a microwave oven. Diffusion juice was treated with approximately 1.8% lime (CaO) and carbonated, filtered and concentrated to a thick juice. Thick Juice was heated to 75-80 °C and filtered. Sugar (sucrose) was crystallized from filtered thick juice in a vacuum pan by concentrating the juice to a state of supersaturation and then seeding with very fine sugar crystals. Crystallized sugar was separated from its mother liquor (molasses) by centrifugation and washed with hot deionized water. The resulting wet, white sugar was agitated in a stainless steel bowl and dried with warm air.

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Figure A1: Processing phase for sugar beet**Results and discussions**

Details of the trials and the results of the processing trials are displayed in the tables below.

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Table A 19: Summary of processing study 1

Reference: Determination of residues of clopyralid in sugar beet processed fractions; DAS Report No. GH-C 3305
 GLP: Yes Sample storage conditions: 96 days
 Crop/crop group: Sugar beet Analytical method: GRM 94.04
 Indoor/Outdoor: Outdoor (field) Limit of Quantification (mg/Kg): 0.05 mg/kg
 Formulation: XRM-3972 Limit of Detection (mg/Kg): -
 Content of active substance (g/kg or g/l): 42.6% monoethanolamine salt Residues calculated as: clopyralid

Trial No. / Location / Year	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment		Dates of treatment or number and last date	Growth Stage at last treat- ment	Portion ana- lysed	Residues (mg/Kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)				clopyralid		
Fresno, California, USA/ 1975	Sugar beet / SS-502	1. 05.05.93 2. - 3. 26.10.93	841	-	17.06.93	6-8 leaf	Root (RAC) Pulp Sugar Molasses	0.64, 0.57 (0.61) 0.47, 0.46 (0.47) 0.084, 0.082 (0.083) 5.3, 5.72 (5.6)	131	

- (a) According to CODEX Classification / Guide
 (b) Only if relevant
 (c) Year must be indicated
 (d) Days after last application (Label pre-harvest interval, PHI, underline)
 (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

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Table A 20: Residue data from sugar beet processing study with clopyralid

RAC	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/ Reference
Sugar beet	0.61	131	Pulp	0.47	0.77	
			Sugar (white)	0.083	0.14	
			Molasses	5.6	9.2	

* processing factor

Conclusion

The processing factor for pulp was 0.77, for white sugar was 0.14 and for molasses was 9.2. Residues of clopyralid are reduced when processed into pulp and white sugar, but concentrated in molasses.

Study 2 - 181493

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Root (RAC), top with leaves, roots prior to processing, sugar juice molasses, non-refined sugar, pulp brown sugar and white sugar were analysed. Residues of clopyralid do not concentrate on processing to pulp (PF 0.733), brown sugar (PF 0.912), sugar juice (PF 0.514) or white sugar (PF 0.439). Residues of clopyralid do concentrate on processing to molasses (PF 4.236) and non-refined sugar (PF 4.061).
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Reference: KCA 6.5.3/02

Report Devine, H.C., (2020); Residues of Clopyralid in Sugar Beet and Process Fractions Following Multiple Applications of GF-1966 – Northern Europe – 2019; Study No. CEMS-8908; DAS Report No. 181493..

Guideline(s): Commission Regulations (EU) No.283/2013 and 284/2013, implementing Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC and are designed to comply with the “Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997” and 7035/VI/95 rev.5 July 22 1997 (Processing Studies).

Deviations: None

GLP: Yes

Acceptability: Yes.

Materials and methods

Sugar beet was treated with clopyralid formulation GF-1966 (an SG formulation containing 720 g ae/kg)

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in 2019 in the Northern France. Two applications were made at 100 g ae/ha + 200 g ae/ha, at growth stages BBCH 18 + BBCH 35.

Samples of mature sugar beets and tops with leaves were taken at normal commercial harvest. Processing was conducted at SAGEA Centro di Saggio, Italy to obtain samples of pulp, molasses, brown sugar, sugar juice, non-refined sugar and white sugar in procedures representative of commercial production. All samples were stored frozen (-20°C) for a maximum of 163 days prior to analysis. This is accommodated by the available storage stability data on high water and high starch commodities reviewed during the EU evaluation (EFSA, 2018a).

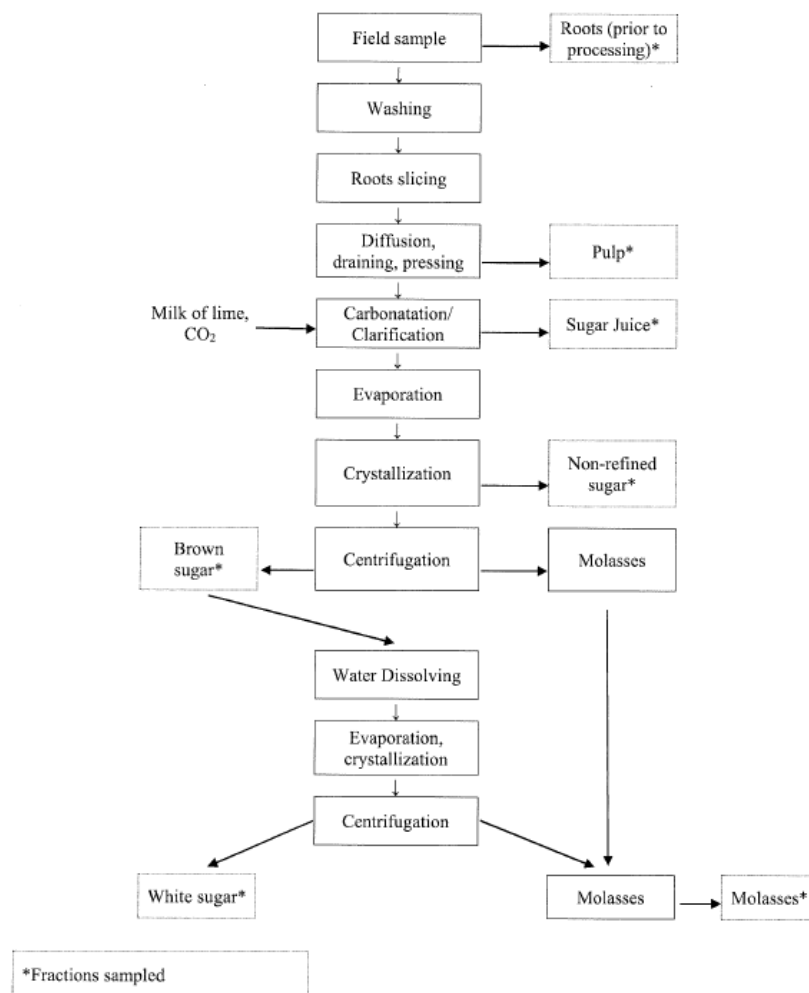
Residues of clopyralid were determined by method 120610, with an LOQ of 0.01 mg/kg. Average procedural recoveries of fortified control samples were 90% for tops (n=10, 0.01-1.0 mg/kg, %RSD=8); 78% for roots (n=17, 0.01-5.0 mg/kg, %RSD=7); 81% for juice (n=10, 0.01-1.0 mg/kg, %RSD=11); 86% for molasses (n=17, 0.01-5.0 mg/kg, %RSD=5); 74% for non-refined sugar (n=10, 0.01-5.0 mg/kg, %RSD=3); 76% for pulp (n=10, 0.01-5.0 mg/kg, %RSD=6); 81% for brown sugar (n=10, 0.01-5.0 mg/kg, %RSD=6) and 83% for white sugar (n=10, 0.01-5.0 mg/kg, %RSD=8).

Processing phase: Sugar beet roots were rapidly washed, sliced and immersed in water at 80°C for 2 hours. The juice and pulp were separated and the pulp was pressed and a sample taken. The juice was carbonated/clarified with lime and the clear juice separated and sampled. The sugar juice was concentrated by heating and seeded with sugar crystals to enhance crystallisation of the sugar, non refined sugar was obtained and a sample taken. The sugar was centrifuged to separate brown sugar and molasses. Brown sugar was washed with steam to obtain white sugar. The white sugar was oven dried to obtain the final white sugar sample.

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Figure A2: Processing phase for sugar beet

Results and discussions

Details of the trials and the results of the processing trials are displayed in the tables below.

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Table A 21: Summary of processing study 2

Reference:	Residues of Clopyralid in Sugar Beet and Process Fractions Following Multiple Applications of GF-1966 – Northern Europe – 2019; Study No. CEMS-8908; DAS Report No. 181493			
GLP:	Yes	Sample storage conditions:	max. 161 days	
Crop/crop group:	Sugar beet	Analytical method:	120610	
Indoor/Outdoor:	Outdoor (field)	Limit of Quantification (mg/Kg):	0.01	
Formulation:	GF-1966	Limit of Detection (mg/Kg):	0.003	
Content of active substance (g/kg or g/l):	720 g ae/kg	Residues calculated as:	clopyralid	

Trial No. / Location / Year	Commodity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Application rate per treatment		Dates of treatment or number and last date	Growth Stage at last treatment	Portion analysed	Residues (mg/Kg)	PHI (days)	Remarks:
			g ae/ha	Water (L/ha)				clopyralid		
CEMS-8908A La Chapelle de Guinchay, Bourgogne-Franche-Comté, France / 2019	Sugar beet / Millenia KWS	1) 25 Apr 19 2) N/A 3) 02 Sep 19	105.2 198.0	262.8 247.4	13 Jun 19 05 Jul 19	BBCH 18 BBCH 35	Root (RAC) Top with leaves Roots prior to processing Sugar juice Molasses Non-refined sugar Pulp Brown sugar White sugar	1.001* 0.586 0.799* 0.399 3.220 3.059 0.590 0.700 0.231	59	Maximum storage (days): 163 tops 161 roots 86 roots pre-process 98 pulp 88 molasses 95 brown sugar 86 sugar juice 90 non refined sugar 96 white sugar

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CEMS-8908B Effiat, Auvergne Rhone Alpes, France / 2019	Sugar beet / Nautille	1) 22 Mar 19	105.4	315.8	04 Jun 19	BBCH	Root (RAC)	0.530*	83	Maximum stor- age (days): 156 tops 154 roots 99 roots pre-pro- cess 111 pulp 101 molasses 108 brown sugar 99 sugar juice 103 non refined sugar 109 white sugar
		2) N/A	202.3	303.3	18 Jun 19	18	Top with leaves	0.703		
		3) 09 Sep 19				BBCH	Roots prior to processing	0.614*		
						35	Sugar juice	0.325		
							Molasses	2.728		
							Non-refined sugar	2.637		
							Pulp	0.447		
							Brown sugar	0.582		
							White sugar	0.361		

N/A Not applicable

* Mean of 3 analyses

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

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Table A 22: Residue data from sugar beet processing study with clopyralid

Trial	RAC	Residues in RAC (un-washed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/Reference
CEMS-8908A	Sugar beet root (prior to processing)	0.799		Pulp	0.590	0.738	
				Molasses	3.220	4.029	
				Brown sugar	0.700	0.875	
				Sugar juice (after clarification)	0.399	0.499	
				Non-refined sugar	3.059	3.828	
				White sugar	0.231	0.289	
CEMS-8908B	Sugar beet root (prior to processing)	0.614	83	Pulp	0.447	0.727	
				Molasses	2.728	4.442	
				Brown sugar	0.582	0.948	
				Sugar juice (after clarification)	0.325	0.529	
				Non-refined sugar	2.637	4.293	
				White sugar	0.361	0.588	
Mean PF							
					Pulp	0.733	
					Molasses	4.236	
					Brown sugar	0.912	
					Sugar juice	0.514	
					Non-refined sugar	4.061	
					White sugar	0.439	

* processing factor, Pf = Residue level in processed commodity / Residue level in sugar beet root prior to processing. Calculated using unrounded data.

Overview of sugar beet processing factors

Table A 23: Summary of sugar beet processing study with clopyralid

Processed commodity	Individual PFs	Mean/median PF
Pulp	0.727, 0.738, 0.77	0.738
Molasses	4.029, 4.442, 9.2	4.442
Brown sugar	0.875, 0.948	0.912
Sugar juice (after clarification)	0.499, 0.529	0.514
Non-refined sugar	3.828, 4.293	4.061
White sugar	0.14, 0.289, 0.588	0.289

Conclusion

Residues of clopyralid do not concentrate on processing to pulp (PF 0.733), brown sugar (PF 0.912), sugar juice (PF 0.514) or white sugar (PF 0.439). Residues of clopyralid do concentrate on processing to molasses (PF 4.236) and non-refined sugar (PF 4.061).

A 2.1.6 Magnitude of residues in representative succeeding crops

One new field crop rotation study (Study No.190557) is available for clopyralid.

A 2.1.6.1 Study 1: 190557

Comments of zRMS:	The study was performed according to guidelines and GLP requirements. Study is acceptable. Six crop rotational trials were conducted in northern Europe (three trials) and Southern Europe (three trials) to determine residues of clopyralid in rotational crops. The study included the following crop groups: leafy and brassica vegetables, root and tuber vegetables, tops of root and tuber vegetables, oilseeds and cereals. The study demonstrated that no residues are expected in succeeding leafy crops or oilseed seeds even at the shortest PBI of 30 days. In root and tuber crops, no significant residues in roots are expected at the PBI of 90 days or longer, while in tops, no significant residues are expected at PBI of 125 days and longer. In cereal grain and straw, significant residues are not expected at all PBIs. The residue levels in did not exceed the current MRLs for any of the crops in respective crop groups.
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Reference:	KCA 6.6.2/01
Report	Devine, C., 2021; Determination of Residues of Clopyralid after One Application of GF-1966 (EC Formulation) on Bare Soil in Rotational Crops at 3 Sites in Northern Europe and 3 Sites in Southern Europe 2019-2020; CEM Analytical Services Ltd (CEMAS); Study No. CEMS-9009/190557.
Guideline(s):	Commission Regulations (EU) No.283/2013 and 284/2013, implementing Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC and are designed to comply with the "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997".
Deviations:	None that impact the integrity of the study
GLP:	Yes
Acceptability:	Yes

Materials and methods

Six crop rotational trials were conducted in northern Europe (three trials) and Southern Europe (three trials) to determine residues of clopyralid in crops grown as rotational crops at harvest following one application of GF-1966 to bare soil in 2019 and 2020. One additional trial in Southern Europe was added after a few plots were lost and could not be restarted at the original trial site.

GF-1966 is an SG (Water Soluble Granule) formulation, containing a nominal concentration of 949 g/kg clopyralid monoethanolamine, corresponding to 720 g ae/kg of clopyralid. The formulation was applied

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using appropriate application equipment at the proposed normal use rates and timings. The trials took place in regions typical of Northern and Southern European growing areas for the crops.

GF-1966 was applied once to bare soil at a nominal rate of 60, 80, or 125 g ae/ha with a nominal application volume of 200-400 L/ha. Following plant back intervals (PBI) of a nominal 270-365, 125, 90 or 30 days before replanting the plot were planted with root crop, leafy crop, cereal, or oilseed.

Specimens of radish roots and tops with leaves were collected at normal commercial harvest for root crop. Specimens of whole cabbage were collected at normal commercial harvest for leafy crop at normal commercial harvest. Specimens of barley or wheat whole plant at BBCH 30-39 and barley or wheat straw and grain were collected at normal commercial harvest for cereals. Specimens of oilseed rape whole plant at BBCH 61-69 or sunflower whole plant at BBCH 51-55 and oilseed rape or sunflower seed and rest of plant were collected at normal commercial harvest for oilseed. Samples of soil were taken from each plot before each planting/sowing but after tillage. Analysis of these was not required. A sample of soil was taken from each trial for GLP characterization.

All samples for residue analysis were placed in freezers within 8 hours of sampling and transported frozen to CEMAS except for 2 soil specimens (CSR-9009-002 & 006) which were put in the freezer within 8.5 hours of sampling. Samples were stored at CEMAS in a freezer set to maintain a sample temperature of < -18 °C. Radish root and radish tops with leaves samples from three sites in Northern France, Poland and Southern France were stored for longer than 443 days and were excluded from further evaluations.

Residues of clopyralid were determined using the Dow Agrosiences Method described in Study No. 120610 using LC-MS/MS with a limit of quantification of 0.01 mg/kg.

Results and discussion

Clopyralid procedural recoveries were in the range 72% to 99% (87% mean) for radish root, 87% to 109% (87% mean) for radish roots, 73% to 110% (90% mean) for radish tops with leaves, 69% to 95% (82% mean) for whole cabbage, 76% to 107% (92% mean) for barley whole plant, 70% to 99% (83% mean) for barley grain, 71% to 102% (88% mean) for barley straw, 85% to 102% (92% mean) for wheat whole plant, 78% to 105% (91% mean) for wheat grain, 80% to 122% (95% mean) for wheat straw, 74% to 105% (85% mean) for oilseed rape whole plant, 68% to 101% (84% mean) for oilseed rape seed, 70% to 109% (85% mean) for oilseed rape rest of plant, 72% to 92% (82% mean) for sunflower whole plant, 73% to 95% (85% mean) for sunflower seed and 78% to 93% (84% mean) for sunflower rest of plant.

The detector response was shown to be linear over the range of 0.5–50 ng/mL (equivalent to 0.0025 – 0.25 mg/kg for clopyralid).

No residues of Clopyralid were detected in any untreated samples with the exception of trial CEMs-9009C where residues were detected in one sample of wheat straw at (0.003 mg/kg) and two samples of wheat grain at (0.009) and 0.011 mg/kg. The retention samples for all untreated wheat straw and grain from this trial were analyzed. For wheat straw these were all not detected. For wheat grain these were all not detected except for the samples from the two plots that had a residue in the shipped sample. These both had residues of (0.004) mg/kg.

Residue data presented in this report are not corrected for procedural recovery except for the wheat straw batch BIS 1564/21 where recovery values are corrected for the residue as the residue in the control is >0.003 mg/kg.

The following table is a summary of the clopyralid residues for all representative commodities at treatment rates 60, 80, and 125 g ae/ha at each PBI.

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Crop Group/Representative Crop matrix	Rate (g ae/ha)	Clopyralid residues (mg/kg) per Plant-back interval (days)			
		30	90	125	270-365
Leafy and Brassica Vegetables / Head Cabbage	60	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	80	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	125	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
Root and Tuber vegetables / Radish root	60	5 x <0.01*, 0.041	6 x <0.01 †	6 x <0.01	6 x <0.01
	80	6 x <0.01*	6 x <0.01 †	6 x <0.01	6 x <0.01
	125	4 x <0.01*, 0.027, 0.042	6 x <0.01 †	6 x <0.01	6 x <0.01
Tops of Root and Tuber vegetables / Radish tops with leaves	60	4 x <0.01*, 0.17, 0.38	6 x <0.01 †	6 x <0.01	6 x <0.01
	80	4 x <0.01*, 0.17, 0.52	5 x <0.01 †, 0.025	6 x <0.01	6 x <0.01
	125	3 x <0.01, 0.017**, 0.54, 0.63	6 x <0.01 †	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower whole plant	60	4 x <0.01, 0.086, 0.15	6 x <0.01	6 x <0.01	6 x <0.01
	80	4 x <0.01, 0.11, 0.21	6 x <0.01	6 x <0.01	6 x <0.01
	125	4 x <0.01, 0.097, 0.11	6 x <0.01	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower seed	60	6 x <0.01	6 x <0.01	5 x <0.01	6 x <0.01
	80	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	125	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower rest of plant	60	4 x <0.01, 0.022, 0.023	6 x <0.01	5 x <0.01	6 x <0.01
	80	4 x <0.01, 0.024, 0.075	6 x <0.01	6 x <0.01	6 x <0.01
	125	3 x <0.01, 0.015, 0.027, 0.089	6 x <0.01	6 x <0.01	6 x <0.01
Cereals / Barley and Wheat whole plant	60	3 x <0.01, 0.018, 0.083, 0.21	4 x <0.01, 0.012, 0.028	6 x <0.01	6 x <0.01
	80	3 x <0.01, 0.029, 0.14, 0.56	6 x <0.01	6 x <0.01	5 x <0.01, 0.017
	125	2 x <0.01, 0.034, 0.20, 0.52, 0.58	5 x <0.01, 0.084	6 x <0.01	6 x <0.01
Cereals / Barley and Wheat grain	60	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	80	4 x <0.01, 0.14, 0.15	6 x <0.01	5 x <0.01, 0.015	5 x <0.01, 0.037
	125	2 x <0.01, 0.035, 0.053, 0.13, 0.17	5 x <0.01, 0.011	5 x <0.01, 0.012	5 x <0.01, 0.025
Cereals / Barley and Wheat straw	60	2 x <0.01, 0.018, 0.024, 0.040, 0.12	6 x <0.01	6 x <0.01	4 x <0.01, <0.01, 0.012
	80	2 x <0.01, 0.015, 0.027, 0.12, 0.27	6 x <0.01	6 x <0.01	4 x <0.01, 0.012, 0.015
	125	2 x <0.01, 0.10, 0.16, 0.18, 0.28	6 x <0.01	6 x <0.01	4 x <0.01, 0.016, 0.036

* Residue value of <0.01 mg/kg is excluded from the evaluation due to exceedance of frozen storage stability.

† Two residue values of <0.01 mg/kg are excluded from the evaluation due to exceedance of frozen storage stability.

** Residue value of 0.017 mg/kg is excluded from the evaluation due to exceedance of frozen storage stability.

Residues of clopyralid in head cabbage were <0.01 mg/kg at all application rates and at all plantback intervals (PBI). Residues of clopyralid in radish roots ranged from <0.01 to 0.042 mg/kg at all application rates at the shortest PBI of 30 days and were < 0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in oilseed rape and sunflower seeds were <0.01 mg/kg at all application rates and at all PBI. Residues of clopyralid in barley and wheat grain ranged from <0.01 to 0.17 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.037 mg/kg at all application rates at a 90-day or longer PBI.

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For livestock feed commodities, residues of clopyralid in radish tops with leaves ranged from <0.01 to 0.54 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.025 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in oilseed rape and sunflower whole plant (forage commodity) ranged from <0.01 to 0.21 mg/kg at all application rates at the shortest PBI of 30 days and were <0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in the rest of the oilseed rape and sunflower plants after seed harvest ranged from <0.01 to 0.089 mg/kg at all application rates at the shortest PBI of 30 days and were <0.01 mg/kg at all application rates at a 90-day or longer PBI. Residues of clopyralid in barley and wheat whole plant (forage commodity) ranged from <0.01 to 0.58 mg/kg at all application rates at the shortest PBI of 30 days, ranged from <0.01 to 0.084 mg/kg at all application rates at the 90-day PBI, and ranged from <0.01 to 0.017 at all application rates at a 125-day or longer PBI. Residues of clopyralid in the rest of the barley and wheat plants after seed harvest ranged from <0.01 to 0.28 mg/kg at all application rates at the shortest PBI of 30 days and ranged from <0.01 to 0.036 mg/kg at all application rates at a 90-day or longer PBI.

Conclusions

Six crop rotational trials were conducted in northern Europe (three trials) and Southern Europe (three trials) to determine residues of clopyralid in rotational crops and are considered supportive to propose plant-back intervals for crops groups potentially grown in rotation with clopyralid-treated crops, with the exception of individual samples of radish root and radish tops with leaves that were stored in excess of available frozen storage stability data.

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

Table A 24: Rotational trial summary for study 1**RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Crop / EPPO code:

Responsible body for reporting (name & address):

Country:

Trial location (region):

Content of active substance (g/kg or g/l):

Formulation number:

Formulation type (e.g. WP):

Clopyralid**Root and tuber vegetables**

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

France

49350 Gennes Val De Loire (EU Northern Zone)

720 g ae/L

GF-1966

SG

Commercial Product (name):

Other active substance in the formulation (common name and content):

Producer of commercial product

Study type

Indoor/Glasshouse/Outdoor:

Residues calculated as:

Residue method and LOQ

GF-1966

None

Dow AgroSciences

Residue

Outdoor

Clopyralid

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

Study no. / DAS Study ID

320 days

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Radish / EXPO F1	1) 24 Jun 20 2) N/A 3) 29 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	265	63.32	1	05 Jul 19	N/A	Radish roots Radish tops with leaves	ND ND	390 390	Mean Recovery
				32.0	256	81.82	1	05 Jul 19	N/A	Radish roots Radish tops with leaves	ND ND	390 390	Radish roots 87%
				50.1	250	125.28	1	05 Jul 19	N/A	Radish roots Radish tops with leaves	ND ND	390 390	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Root and tuber vegetables

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

320 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Radish / EXPO F1	1) 24 Jun 20 2) N/A 3) 29 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	265	63.32	1	07 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	173 173	Mean Recovery
				32.0	259	82.77	1	07 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	173 173	Radish roots 87%
				50.1	262	131.25	1	07 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	173 173	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

319 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Radish / EXPO F1	1) 24 Jun 20 2) N/A 3) 30 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	250	59.76	1	13 Mar 20	N/A	Radish roots Radish tops with leaves	ND ND	139 139	Mean Recovery
				32.0	259	82.77	1	13 Mar 20	N/A	Radish roots Radish tops with leaves	ND ND	139 139	Radish roots 87%
				50.1	244	122.30	1	13 Mar 20	N/A	Radish roots Radish tops with leaves	ND ND	139 139	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites

Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

451 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Radish / EXPO F1	1) 12 Sep 19 2) N/A 3) 22 Oct 19	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	241	57.63	1	12 Aug 19	N/A	Radish roots Radish tops with leaves	ND (0.009)	71 71	Mean Recovery
				32.0	262	83.73	1	12 Aug 19	N/A	Radish roots Radish tops with leaves	ND ND	71 71	Radish roots 87%
				50.1	241	120.81	1	12 Aug 19	N/A	Radish roots Radish tops with leaves	ND 0.017	71 71	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Brassicas**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

216 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Cabbage / Impala	1) 24 Jun 20 2) N/A 3) 18 Nov 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	262	62.61	1	05 Jul 19	N/A	Cabbage	ND	502	Mean Recovery Whole Cabbage 82%
				32.0	253	80.87	1	05 Jul 19	N/A	Cabbage	ND	502	
				50.1	253	126.77	1	05 Jul 19	N/A	Cabbage	(0.005)	502	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

216 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Cabbage / Impala	1) 23 Jun 20 2) N/A 3) 18 Nov 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	262	62.61	1	07 Feb 20	N/A	Cabbage	ND	285	Mean Recovery Whole Cabbage 82%
				32.0	253	80.87	1	07 Feb 20	N/A	Cabbage	(0.006)	285	
				50.1	253	126.77	1	07 Feb 20	N/A	Cabbage	(0.004)	285	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

216 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Cabbage / Impala	1) 22 Jun 20 2) N/A 3) 18 Nov 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	253	60.47	1	13 Mar 20	N/A	Cabbage	ND	250	Mean Recovery Whole Cabbage 82%
				32.0	256	81.82	1	13 Mar 20	N/A	Cabbage	(0.008)	250	
				50.1	253	126.77	1	13 Mar 20	N/A	Cabbage	(0.004)	250	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

315 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Cabbage / Caraflex	1) 12 Sep 19 2) N/A 3) 03 Mar 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	259	61.89	1	12 Aug 19	N/A	Cabbage	ND	204	Mean Recovery Whole Cabbage 82%
				32.0	256	81.82	1	12 Aug 19	N/A	Cabbage	ND	204	
				50.1	262	131.25	1	12 Aug 19	N/A	Cabbage	ND	204	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

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Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

370 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Barley / RGT Planet	1) 06 Apr 20 2) N/A 3) 22 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	253	60.47	1	05 Jul 19	N/A	Whole Plant	ND	334	Mean Recovery
										Straw	ND	383	Whole Plant 92%
										Grain	ND	383	
				32.0	250	79.92	1	05 Jul 19	N/A	Whole Plant	ND	334	Straw 88%
										Straw	ND	383	
										Grain	ND	383	Grain 83%
				50.1	253	126.77	1	05 Jul 19	N/A	Whole Plant	ND	334	
										Straw	ND	383	
										Grain	ND	383	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Barley / HORVW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

327 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Barley / KWS Jaguar	1) 18 Nov 19 2) N/A 3) 08 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	241	57.63	1	05 Jul 19	N/A	Whole Plant Straw Grain	ND ND ND	285 369 369	Mean Recovery
				32.0	256	81.82	1	05 Jul 19	N/A	Whole Plant Straw Grain	ND ND ND	285 369 369	Whole Plant 92%
				50.1	253	126.77	1	05 Jul 19	N/A	Whole Plant Straw Grain	ND ND ND	285 369 369	Straw 88%
													Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Barley / HORVW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

327 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Barley / KWS Jaguar	1) 18 Nov 19 2) N/A 3) 07 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	247	59.05	1	07 Aug 19	N/A	Whole Plant Straw Grain	ND ND ND	252 335 335	Mean Recovery
				32.0	259	82.77	1	07 Aug 19	N/A	Whole Plant Straw Grain	ND ND ND	252 335 335	Whole Plant 92%
				50.1	262	131.25	1	07 Aug 19	N/A	Whole Plant Straw Grain	ND ND ND	252 335 335	Straw 88%
													Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

382 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Barley / RGT Planet	1) 13 Mar 20 2) N/A 3) 17 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	256	61.18	1	07 Feb 20	N/A	Whole Plant	ND	105	Mean Recovery Whole Plant 92%
										Straw	ND	161	
										Grain	ND	161	
				32.0	253	80.87	1	07 Feb 20	N/A	Whole Plant	ND	105	Straw 88% Grain 83%
										Straw	ND	161	
										Grain	ND	161	
				50.1	259	129.75	1	07 Feb 20	N/A	Whole Plant	(0.005)	105	
										Straw	ND	161	
										Grain	ND	161	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

**Clopyralid
Oilseeds**

Crop group:

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Sunflower / HELAN

Producer of commercial product

Dow AgroSciences

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Max frozen storage time prior to analysis

319 days

Content of active substance (g/kg or g/l):

720 g ae/L

Study no. / DAS Study ID

CEMS-9009 / 190557

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Sunflower / Serin	1) 02 Jun 20 2) N/A 3) 06 Nov 20	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	259	61.89	1	05 Jul 19	N/A	Whole Plant	ND	384	Mean Recovery
										Seed	ND	490	Whole Plant 82%
										Rest of Plant	ND	490	
				32.0	250	79.92	1	05 Jul 19	N/A	Whole Plant	ND	384	Seed 85%
										Seed	ND	490	
										Rest of Plant	ND	490	Rest of Plant 84%
				50.1	256	128.26	1	05 Jul 19	N/A	Whole Plant	ND	384	
										Seed	ND	490	
										Rest of Plant	ND	490	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

146 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Oilseed Rape / Cadran	1) 19 Oct 19 2) N/A 3) 30 Jul 21	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	259	61.89	1	26 Jun 20	N/A	Whole Plant	ND	298	Mean Recovery
				32.0	256	81.82	1	26 Jun 20	N/A	Whole Plant Seed	ND ND	298 399	Whole Plant 85% Seed 84%
				50.1	253	126.77	1	26 Jun 20	N/A	Rest of Plant	ND	399	Rest of Plant 85%
										Whole Plant Seed Rest of Plant	ND ND ND	298 399 399	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

146 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Oilseed Rape / Cadran	1) 28 Sep 19 2) N/A 3) 30 Jul 21	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	265	63.32	1	26 Jun 20	N/A	Whole Plant	ND	298	Mean Recovery
										Seed	ND	399	Whole Plant 85%
										Rest of Plant	ND	399	
				32.0	262	83.73	1	26 Jun 20	N/A	Whole Plant	ND	298	Seed 84%
										Seed	ND	399	
										Rest of Plant	ND	399	Rest of Plant 85%
				50.1	262	131.25	1	26 Jun 20	N/A	Whole Plant	ND	298	
										Seed	ND	399	
										Rest of Plant	ND	399	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

49350 Gennes Val De Loire (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

146 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009A 49350 Gennes Val De Loire, France	Oilseed Rape / Cadran	1) 28 Sep 20 2) N/A 3) 30 Jul 21	Broadcast spraying directed to the ground, knapsack sprayer with 7 x XR TeeJet AI 110015 VS noz- zles	23.9	259	61.89	1	26 Aug 20	N/A	Whole Plant	ND	237	Mean Recovery
										Seed	ND	338	Whole Plant 85%
										Rest of Plant	ND	338	
				32.0	256	81.82	1	26 Aug 20	N/A	Whole Plant	ND	237	Seed 84%
										Seed	ND	338	
										Rest of Plant	ND	338	Rest of Plant 85%
				50.1	253	126.77	1	26 Aug 20	N/A	Whole Plant	ND	237	
										Seed	ND	338	
										Rest of Plant	ND	338	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

243 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Radish / Krasa TOR	1) 02 Apr 20 2) N/A 3) 29 May 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	302	60.723	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.005)	351 351	Mean Recovery
				26.7	302	80.721	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	351 351	Radish roots 87%
				41.6	304	126.437	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.004)	351 351	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites
Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

190 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Radish / Krasa TOR	1) 15 Jun 20 2) N/A 3) 21 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	296	59.277	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	159 159	Mean Recovery
				26.7	300	80.000	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	159 159	Radish roots 87%
				41.7	300	125.000	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND (0.004)	159 159	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

218 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Radish / Krasa TOR	1) 11 May 20 2) N/A 3) 23 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	296	59.277	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND (0.006)	131 131	Mean Recovery
				26.7	308	82.162	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	131 131	Radish roots 87%
				41.8	308	128.592	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND (0.006)	131 131	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Root and tuber vegetables

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

243 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Radish / Krasa TOR	1) 02 Apr 20 2) N/A 3) 29 May 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	19.9	298	59.277	1	05 Mar 20	N/A	Radish roots Radish tops with leaves	0.041 0.381	85 85	Mean Recovery
				26.7	300	80.000	1	05 Mar 20	N/A	Radish roots Radish tops with leaves	0.041 0.516	85 85	Radish roots 87%
				41.6	304	126.437	1	05 Mar 20	N/A	Radish roots Radish tops with leaves	0.042 0.541	85 85	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

132 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Cabbage / Report F1	1) 11 May 20 2) N/A 3) 15 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	302	60.723	1	13 Jun 19	N/A	Cabbage	ND	460	Mean Recovery Whole Cabbage 82%
				26.7	302	80.721	1	13 Jun 19	N/A	Cabbage	ND	460	
				41.8	294	122.845	1	13 Jun 19	N/A	Cabbage	ND	460	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

94 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Cabbage / Report F1	1) 15 Jun 20 2) N/A 3) 23 Oct 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	292	58.554	1	13 Feb 20	N/A	Cabbage	ND	253	Mean Recovery Whole Cabbage 82%
				26.8	304	81.441	1	13 Feb 20	N/A	Cabbage	ND	253	
				41.8	308	128.592	1	13 Feb 20	N/A	Cabbage	ND	253	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

132 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Cabbage / Report F1	1) 11 May 20 2) N/A 3) 15 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	288	57.831	1	13 Feb 20	N/A	Cabbage	ND	215	Mean Recovery Whole Cabbage 82%
				26.7	308	82.162	1	13 Feb 20	N/A	Cabbage	ND	215	
				41.7	296	123.563	1	13 Feb 20	N/A	Cabbage	ND	215	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

132 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Cabbage / Report F1	1) 12 May 20 2) N/A 3) 15 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	19.9	294	58.554	1	15 Apr 20	N/A	Cabbage	ND	153	Mean Recovery Whole Cabbage 82%
				26.7	300	80.000	1	15 Apr 20	N/A	Cabbage	ND	153	
				41.6	302	125.718	1	15 Apr 20	N/A	Cabbage	ND	153	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

238 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Wheat / Telimena	1) 02 Apr 20 2) N/A 3) 12 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	304	60.723	1	13 Jun 19	N/A	Whole Plant	(0.004)	363	Mean Recovery
										Straw	ND	426	Whole Plant 92%
										Grain	ND	426	
				26.4	292	77.117	1	13 Jun 19	N/A	Whole Plant	0.017	363	Straw 95%
										Straw	0.015	426	
										Grain	(0.006)	426	Grain 91%
				41.6	302	125.718	1	13 Jun 19	N/A	Whole Plant	(0.007)	363	
										Straw	(0.004)	426	
										Grain	(0.003)	426	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

279 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Wheat / JB Asano	1) 10 Oct 19 2) N/A 3) 11 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	308	61.446	1	13 Jun 19	N/A	Whole Plant	ND	322	Mean Recovery
										Straw	ND	425	Whole Plant 92%
										Grain	ND	425	
				26.8	304	81.441	1	13 Jun 19	N/A	Whole Plant	ND	322	Straw 95%
										Straw	(0.009)	425	
										Grain	ND	425	Grain 91%
				41.7	300	125.000	1	13 Jun 19	N/A	Whole Plant	(0.006)	322	
										Straw	ND	425	
										Grain	(0.004)	425	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Wheat / TRZAW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

279 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Wheat / JB Asano	1) 10 Oct 19 2) N/A 3) 11 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	286	57.108	1	12 Jul 19	N/A	Whole Plant	0.012	293	Mean Recovery
										Straw	ND	396	Whole Plant 92%
										Grain	ND	396	
				26.7	292	77.838	1	12 Jul 19	N/A	Whole Plant	(0.005)	293	Straw 95%
										Straw	(0.004)	396	
										Grain	ND	396	Grain 91%
				41.8	294	122.845	1	12 Jul 19	N/A	Whole Plant	(0.007)	293	
										Straw	(0.004)	396	
										Grain	ND	396	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

238 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Wheat / Telimena	1) 02 Apr 20 2) N/A 3) 12 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	306	61.446	1	05 Mar 20	N/A	Whole Plant	0.210	97	Mean Recovery
										Straw	0.108	160	Whole Plant 92%
										Grain	0.082	160	
				26.6	304	80.721	1	05 Mar 20	N/A	Whole Plant	0.561	97	Straw 95%
										Straw	0.274	160	
										Grain	0.153	160	Grain 91%
				41.6	302	125.718	1	05 Mar 20	N/A	Whole Plant	0.515	97	
										Straw	0.159	160	
										Grain	0.134	160	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

230 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Oilseed Rape / Delight	1) 02 Apr 20 2) N/A 3) 12 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	310	62.169	1	13 Jun 19	N/A	Whole Plant	(0.004)	369	Mean Recovery
										Seed	ND	426	Whole Plant 85%
										Rest of Plant	ND	426	
				26.8	304	81.441	1	13 Jun 19	N/A	Whole Plant	ND	369	Seed 84%
										Seed	ND	426	
										Rest of Plant	ND	426	Rest of Plant 85%
				41.6	306	127.155	1	13 Jun 19	N/A	Whole Plant	(0.006)	369	
										Seed	ND	426	
										Rest of Plant	ND	426	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

267 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Oilseed Rape / LG Augusta	1) 29 Sep 19 2) N/A 3) 20 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	302	60.723	1	01 Jun 19	N/A	Whole Plant	ND	334	Mean Recovery
										Seed	ND	415	Whole Plant 85%
										Rest of Plant	ND	415	
				26.6	304	80.721	1	01 Jun 19	N/A	Whole Plant	ND	334	Seed 84%
										Seed	ND	415	
										Rest of Plant	(0.003)	415	Rest of Plant 85%
				41.7	300	125.000	1	01 Jun 19	N/A	Whole Plant	ND	334	
										Seed	ND	415	
										Rest of Plant	(0.005)	415	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Max frozen storage time prior to analysis

267 days

Formulation number:

GF-1966

Study no. / DAS Study ID

CEMS-9009 / 190557

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Oilseed Rape / LG Augusta/	1) 06 Sep 19 2) N/A 3) 20 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	300	60.000	1	13 Jun 19	N/A	Whole Plant	ND	322	Mean Recovery
										Seed	ND	403	Whole Plant 85%
										Rest of Plant	ND	403	
				26.7	294	78.559	1	13 Jun 19	N/A	Whole Plant	ND	322	Seed 84%
										Seed	ND	403	
										Rest of Plant	(0.010)	403	Rest of Plant 85%
				41.7	300	125.000	1	13 Jun 19	N/A	Whole Plant	ND	322	
										Seed	ND	403	
										Rest of Plant	(0.003)	403	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

Krościna Mała, 55-110 Prusice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

230 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009B Krościna Mała, 55- 110 Prusice, Po- land	Oilseed Rape / Delight	1) 02 Apr 20 2) N/A 3) 12 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	308	61.446	1	05 Mar 20	N/A	Whole Plant	0.147	103	Mean Recovery
										Seed	ND	160	Whole Plant 85%
										Rest of Plant	0.023	160	
				26.7	308	82.162	1	05 Mar 20	N/A	Whole Plant	0.212	103	Seed 84%
										Seed	ND	160	
										Rest of Plant	0.075	160	Rest of Plant 85%
				41.6	304	126.437	1	05 Mar 20	N/A	Whole Plant	0.097	103	
										Seed	(0.005)	160	
										Rest of Plant	0.027	160	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

383 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Radish / Krasa TOR	1) 06 Apr 20 2) N/A 3) 27 May 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	310	62.169	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	350 350	Mean Recovery
				26.8	304	81.441	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.005)	350 350	Radish roots 87%
				41.6	302	125.718	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.009)	350 350	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

329 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Radish / Krasa TOR	1) 12 Jun 20 2) N/A 3) 20 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	315	62.892	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	158 158	Mean Recovery
				26.8	304	81.441	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	158 158	Radish roots 87%
				41.7	296	123.563	1	13 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	158 158	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

605 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Radish / Krasa TOR	1) 05 Sep 19 2) N/A 3) 18 Oct 19	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.4	302	61.463	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	128 128	Mean Recovery
				26.7	292	77.838	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	128 128	Radish roots 87%
				41.6	304	126.437	1	12 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	128 128	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites
Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

383 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Radish / Krasa TOR	1) 06 Apr 20 2) N/A 3) 27 May 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	313	62.892	1	04 Mar 20	N/A	Radish roots Radish tops with leaves	(0.009) 0.174	84 84	Mean Recovery
				26.6	304	80.721	1	04 Mar 20	N/A	Radish roots Radish tops with leaves	(0.008) 0.167	84 84	Radish roots 87%
				41.7	300	125.000	1	04 Mar 20	N/A	Radish roots Radish tops with leaves	0.027 0.627	84 84	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Brassicas**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

281 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Cabbage / Report F1	1) 18 May 20 2) N/A 3) 14 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	304	60.723	1	12 Jun 19	N/A	Cabbage	ND	460	Mean Recovery Whole Cabbage 82%
				26.7	300	80.000	1	12 Jun 19	N/A	Cabbage	ND	460	
				41.7	298	124.282	1	12 Jun 19	N/A	Cabbage	ND	460	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

242 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Cabbage / Report F1	1) 12 Jun 20 2) N/A 3) 23 Oct 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	304	60.723	1	13 Feb 20	N/A	Cabbage	ND	253	Mean Recovery Whole Cabbage 82%
				26.7	308	82.162	1	13 Feb 20	N/A	Cabbage	ND	253	
				41.7	296	123.563	1	13 Feb 20	N/A	Cabbage	ND	253	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

281 days

Study no. / DAS Study ID

CEMS-9009 / 190557

30													
1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Cabbage / Report F1	1) 18 May 20 2) N/A 3) 14 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	300	60.000	1	13 Feb 20	N/A	Cabbage	ND	214	Mean Recovery Whole Cabbage 82%
				26.8	304	81.441	1	13 Feb 20	N/A	Cabbage	ND	214	
				41.7	288	119.971	1	13 Feb 20	N/A	Cabbage	ND	214	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

281 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Cabbage / Report F1	1) 18 May 20 2) N/A 3) 14 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	302	60.723	1	16 Apr 20	N/A	Cabbage	ND	151	Mean Recovery Whole Cabbage 82%
				26.7	300	80.000	1	16 Apr 20	N/A	Cabbage	ND	151	
				41.6	304	126.437	1	16 Apr 20	N/A	Cabbage	ND	151	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

414 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Wheat / Telimena	1) 06 Apr 20 2) N/A 3) 13 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	306	61.446	1	12 Jun 19	N/A	Whole Plant	ND	364	Mean Recovery
										Straw	(0.006)	428	Whole Plant 92%
										Grain	0.012	428	
				26.7	302	80.721	1	12 Jun 19	N/A	Whole Plant	ND	364	Straw 95%
										Straw	0.012	428	
										Grain	0.037	428	Grain 91%
				41.6	306	127.155	1	12 Jun 19	N/A	Whole Plant	ND	364	
										Straw	(0.010)	428	
										Grain	0.025	428	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Wheat / TRZAW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

406 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Wheat / JB Asano	1) 14 Oct 19 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.4	302	61.463	1	12 Jun 19	N/A	Whole Plant Straw Grain	ND ND (0.009)	328 412 412	Mean Recovery
				26.6	306	81.441	1	12 Jun 19	N/A	Whole Plant Straw Grain	ND (0.006) 0.015	328 412 412	Straw 95%
				41.6	290	120.690	1	12 Jun 19	N/A	Whole Plant Straw Grain	ND (0.005) 0.012	328 412 412	Grain 91%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Wheat / TRZAW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

414 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Wheat / JB Asano	1) 14 Oct 19 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	296	59.277	1	12 Jul 19	N/A	Whole Plant	ND	298	Mean Recovery
										Straw	(0.004)	382	Whole Plant 92%
										Grain	(0.008)	382	
				26.7	292	77.838	1	12 Jul 19	N/A	Whole Plant	ND	298	Straw 95%
										Straw	(0.009)	382	
										Grain	0.015	382	Grain 91%
				41.6	290	120.690	1	12 Jul 19	N/A	Whole Plant	(0.004)	298	
										Straw	ND	382	
										Grain	0.011	382	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

398 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Wheat / Telimena	1) 06 Apr 20 2) N/A 3) 13 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	300	60.000	1	04 Mar 20	N/A	Whole Plant	0.083	98	Mean Recovery
										Straw	0.040	162	Whole Plant 92%
										Grain	0.090	162	
				26.6	304	80.721	1	04 Mar 20	N/A	Whole Plant	0.138	98	Straw 95%
										Straw	0.115	162	
										Grain	0.143	162	Grain 91%
				41.8	308	128.592	1	04 Mar 20	N/A	Whole Plant	0.195	98	
										Straw	0.183	162	
										Grain	0.167	162	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

341 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Oilseed Rape / Delight	1) 06 Apr 20 2) N/A 3) 13 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	300	60.000	1	12 Jun 19	N/A	Whole Plant	ND	371	Mean Recovery
										Seed	ND	428	Whole Plant 85%
										Rest of Plant	(0.007)	428	
				26.7	308	82.162	1	12 Jun 19	N/A	Whole Plant	(0.004)	371	Seed 84%
										Seed	ND	428	
										Rest of Plant	(0.009)	428	Rest of Plant 85%
				41.7	300	125.000	1	12 Jun 19	N/A	Whole Plant	(0.003)	371	
										Seed	ND	428	
										Rest of Plant	(0.008)	428	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

384 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Oilseed Rape / LG Augusta	1) 28 Sep 19 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.1	313	62.892	1	31 May 19	N/A	Whole Plant	ND	340	Mean Recovery
										Seed	ND	424	Whole Plant 85%
										Rest of Plant	ND	424	
				26.7	310	82.883	1	31 May 19	N/A	Whole Plant	ND	340	Seed 84%
										Seed	ND	424	
										Rest of Plant	ND	424	Rest of Plant 85%
				41.6	285	118.534	1	31 May 19	N/A	Whole Plant	ND	340	
										Seed	ND	424	
										Rest of Plant	ND	424	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

384 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Oilseed Rape / LG Augusta/	1) 05 Sep 19 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	300	60.000	1	12 Jun 19	N/A	Whole Plant	ND	328	Mean Recovery
										Seed	ND	412	Whole Plant 85%
										Rest of Plant	ND	412	
				26.7	302	80.721	1	12 Jun 19	N/A	Whole Plant	ND	328	Seed 84%
										Seed	ND	412	
										Rest of Plant	ND	412	Rest of Plant 85%
				41.6	302	125.718	1	12 Jun 19	N/A	Whole Plant	ND	328	
										Seed	ND	412	
										Rest of Plant	(0.007)	412	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Poland

Trial location (region):

55-011 Siechnice (EU Northern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

341 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009C 55-011 Siechnice, Poland	Oilseed Rape / Delight	1) 06 Apr 20 2) N/A 3) 13 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet 11002 VS nozzles	20.0	304	60.723	1	04 Mar 20	N/A	Whole Plant	0.086	105	Mean Recovery
										Seed	ND	162	Whole Plant 85%
										Rest of Plant	0.022	162	
				26.7	313	83.604	1	04 Mar 20	N/A	Whole Plant	0.113	105	Seed 84%
										Seed	(0.004)	162	
										Rest of Plant	0.024	162	Rest of Plant 85%
				41.6	304	126.437	1	04 Mar 20	N/A	Whole Plant	0.106	105	
										Seed	(0.004)	162	
										Rest of Plant	0.089	162	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

France

Country:

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

308 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Radish / Nelson	1) 15 Jun 20 2) N/A 3) 06 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	195	58.36	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	384 384	Mean Recovery
				40.0	190	75.97	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	384 384	Radish roots 87%
				62.6	198	123.98	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	384 384	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

France

Country:

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

343 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Radish / Nelson	1) 15 Jun 20 2) N/A 3) 06 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	214	63.81	1	12 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	145 145	Mean Recovery
				40.0	195	78.05	1	12 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	145 145	Radish roots 87%
				62.5	214	133.76	1	12 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	145 145	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

444 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Radish / Diablus	1) 19 Sep 19 2) N/A 3) 29 Oct 19	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	188	56.03	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	133 133	Mean Recovery
				39.9	198	79.09	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	133 133	Radish roots 87%
				62.7	195	122.34	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	133 133	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

France

Country:

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

308 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Radish / Nelson	1) 15 Jun 20 2) N/A 3) 06 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	201	59.92	1	13 May 20	N/A	Radish roots Radish tops with leaves	ND ND	54 54	Mean Recovery
				39.9	211	84.29	1	13 May 20	N/A	Radish roots Radish tops with leaves	ND ND	54 54	Radish roots 87%
				62.7	195	122.34	1	13 May 20	N/A	Radish roots Radish tops with leaves	ND ND	54 54	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Brassicas**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

243 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Cabbage / Capriccio	1) 15 Jun 20 2) N/A 3) 18 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	216	64.58	1	18 Jun 19	N/A	Cabbage	ND	458	Mean Recovery Whole Cabbage 82%
				39.9	206	82.21	1	18 Jun 19	N/A	Cabbage	ND	458	
				62.5	193	120.71	1	18 Jun 19	N/A	Cabbage	ND	458	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

277 days

Study no. / DAS Study ID

CEMS-9009 / 190557

30													
1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Cabbage / Capriccio	1) 15 Jun 20 2) N/A 3) 18 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	208	62.25	1	12 Feb 20	N/A	Cabbage	ND	219	Mean Recovery Whole Cabbage 82%
				40.0	216	86.37	1	12 Feb 20	N/A	Cabbage	ND	219	
				62.6	206	128.87	1	12 Feb 20	N/A	Cabbage	ND	219	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

308 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Cabbage / Dutchman	1) 19 Sep 19 2) N/A 3) 10 Mar 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	193	57.58	1	18 Jun 19	N/A	Cabbage	ND	266	Mean Recovery Whole Cabbage 82%
				40.0	182	72.84	1	18 Jun 19	N/A	Cabbage	ND	266	
				62.5	201	125.61	1	18 Jun 19	N/A	Cabbage	ND	266	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

243 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Cabbage / Capriccio	1) 15 Jun 20 2) N/A 3) 18 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	216	64.58	1	13 May 20	N/A	Cabbage	ND	128	Mean Recovery Whole Cabbage 82%
				39.9	201	80.13	1	13 May 20	N/A	Cabbage	ND	128	
				62.6	206	128.87	1	13 May 20	N/A	Cabbage	ND	128	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

356 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Barley / Olympic	1) 23 Mar 20 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	219	65.36	1	18 Jun 19	N/A	Whole Plant Straw Grain	ND ND ND	331 406 406	Mean Recovery
				40.0	208	83.25	1	18 Jun 19	N/A	Whole Plant Straw Grain	ND ND ND	331 406 406	Whole Plant 92%
				62.6	198	123.98	1	18 Jun 19	N/A	Whole Plant Straw Grain	ND ND ND	331 406 406	Straw 88%
													Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Winter Barley / HORVW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

332 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Barley / KWS Orwell	1) 30 Oct 19 2) N/A 3) 29 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	190	56.80	1	05 Aug 19	N/A	Whole Plant Straw Grain	ND ND ND	249 329 329	Mean Recovery Whole Plant 92%
				39.9	206	82.21	1	05 Aug 19		Whole Plant Straw Grain	ND ND ND	249 329 329	Straw 88% Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

327 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Barley / Olympic	1) 19 May 20 2) N/A 3) 02 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	62.5	197	123.16	1	12 Feb 20	N/A	Whole Plant Straw Grain	ND ND ND	135 203 203	Mean Recovery Whole Plant 92% Straw 88% Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

355 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Barley / Olympic	1) 23 Mar 20 2) N/A 3) 29 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	211	63.03	1	12 Feb 20	N/A	Whole Plant	ND	93	Mean Recovery
										Straw	ND	168	Whole Plant 92%
										Grain	ND	168	
				40.0	216	86.37	1	12 Feb 20	N/A	Whole Plant	ND	93	Straw 88%
										Straw	ND	168	
										Grain	ND	168	Grain 83%
				62.6	206	128.87	1	12 Feb 20	N/A	Whole Plant	ND	93	
										Straw	ND	168	
										Grain	ND	168	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

336 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Oilseed Rape / ES Saoker CL	1) 23 Mar 20 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	201	59.92	1	18 Jun 19	N/A	Whole Plant	ND	358	Mean Recovery
										Seed	ND	406	Whole Plant 85%
										Rest of Plant	ND	406	
				40.0	195	78.05	1	18 Jun 19	N/A	Whole Plant	ND	358	Seed 84%
										Seed	ND	406	
										Rest of Plant	ND	406	Rest of Plant 85%
				62.6	185	115.82	1	18 Jun 19	N/A	Whole Plant	ND	358	
										Seed	ND	406	
										Rest of Plant	ND	406	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

348 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Oilseed Rape / ES Saoker CL	1) 23 Mar 20 2) N/A 3) 28 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	203	60.69	1	30 Oct 19	N/A	Whole Plant	ND	224	Mean Recovery
										Seed	ND	272	Whole Plant 85%
										Rest of Plant	ND	272	
				39.9	206	82.21	1	30 Oct 19	N/A	Whole Plant	ND	224	Seed 84%
										Seed	ND	272	
										Rest of Plant	ND	272	Rest of Plant 85%
				62.7	208	130.50	1	30 Oct 19	N/A	Whole Plant	ND	224	
										Seed	ND	272	
										Rest of Plant	ND	272	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

294 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Oilseed Rape / DK Exclaim	1) 19 Sep 19 2) N/A 3) 29 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.9	190	56.80	1	18 Jun 19	N/A	Whole Plant	ND	290	Mean Recovery
										Seed	ND	377	Whole Plant 85%
										Rest of Plant	ND	377	
				39.9	193	77.01	1	18 Jun 19	N/A	Whole Plant	ND	290	Seed 84%
										Seed	ND	377	
										Rest of Plant	ND	377	Rest of Plant 85%
				62.7	203	127.24	1	18 Jun 19	N/A	Whole Plant	ND	290	
										Seed	ND	377	
										Rest of Plant	ND	377	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

France

Trial location (region):

47370 Saint Georges (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

336 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009D 47370 Saint Georges, France	Oilseed Rape / ES Saoker CL	1) 23 Mar 20 2) N/A 3) 29 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 8 x XR TeeJet AI 110015 VS noz- zles	29.8	214	63.81	1	12 Feb 20	N/A	Whole Plant	ND	119	Mean Recovery
										Seed	ND	168	Whole Plant 85%
										Rest of Plant	ND	168	
				39.9	211	84.29	1	12 Feb 20	N/A	Whole Plant	ND	119	Seed 84%
										Seed	ND	168	
										Rest of Plant	ND	168	Rest of Plant 85%
				62.7	203	127.24	1	12 Feb 20	N/A	Whole Plant	ND	119	
										Seed	ND	168	
										Rest of Plant	ND	168	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Spain

Country:

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

290 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Radish / Murciano	1) 13 Apr 20 2) N/A 3) 08 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	20.0	303	60.48	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	361 361	Mean Recovery
				26.7	305	81.36	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	361 361	Radish roots 87%
				41.7	292	121.68	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	361 361	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

342 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Radish / Murciano	1) 15 Oct 19 2) N/A 3) 20 Feb 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	19.9	307	61.20	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	252 252	Mean Recovery
				26.5	307	81.36	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	252 252	Radish roots 87%
				41.7	295	123.12	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	252 252	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

372 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Radish / Murciano	1) 16 Sep 19 2) N/A 3) 09 Jan 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	19.9	315	62.64	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.007)	210 210	Mean Recovery
				26.7	305	81.36	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND 0.025	210 210	Radish roots 87%
				41.7	292	121.68	1	13 Jun 19	N/A	Radish roots Radish tops with leaves	ND (0.006)	210 210	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

290 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Radish / Murciano	1) 30 Mar 20 2) N/A 3) 08 Jun 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	19.8	323	64.08	1	27 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	102 102	Mean Recovery
				26.5	307	81.36	1	27 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	102 102	Radish roots 87%
				41.8	303	126.72	1	27 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	102 102	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Brassicas**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Responsible body for reporting (name & address):

Head Cabbage / BRSOL

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Spain

Country:

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

232 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Cabbage / Avon Crest	1) 13 Apr 20 2) N/A 3) 06 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	312	312	61.92	1	13 Jun 19	N/A	Cabbage	ND	420	Mean Recovery Whole Cabbage 82%
				303	303	80.64	1	13 Jun 19	N/A	Cabbage	ND	420	
				297	297	123.84	1	13 Jun 19	N/A	Cabbage	ND	420	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

321 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Cabbage / Jupiter	1) 15 Oct 19 2) N/A 3) 10 Mar 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	20.0	313	62.64	1	13 Jun 19	N/A	Cabbage	ND	271	Mean Recovery Whole Cabbage 82%
				26.6	300	79.92	1	13 Jun 19	N/A	Cabbage	ND	271	
				41.8	293	122.4	1	13 Jun 19	N/A	Cabbage	ND	271	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

330 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Cabbage / Jupiter	1) 16 Sep 19 2) N/A 3) 17 Feb 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	19.9	300	59.76	1	13 Jun 19	N/A	Cabbage	ND	249	Mean Recovery Whole Cabbage 82%
				26.7	302	80.64	1	13 Jun 19	N/A	Cabbage	ND	249	
				41.7	290	120.96	1	13 Jun 19	N/A	Cabbage	ND	249	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

232 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Cabbage / Avon Crest	1) 30 Mar 20 2) N/A 3) 06 Aug 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	20.0	320	64.08	1	27 Feb 20	N/A	Cabbage	ND	161	Mean Recovery Whole Cabbage 82%
				26.5	307	81.36	1	27 Feb 20	N/A	Cabbage	ND	161	
				41.8	293	122.4	1	27 Feb 20	N/A	Cabbage	ND	161	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

**Clopyralid
Cereals**

Crop / EPPO code:

Responsible body for reporting (name & address):

Spring Barley / HORVS

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Trial location (region):

Content of active substance (g/kg or g/l):

Formulation number:

Formulation type (e.g. WP):

Spain

Agramon, 02490 Albacete (EU Southern Zone)

720 g ae/L

GF-1966

SG

Commercial Product (name):

Other active substance in the formulation (common name and content):

Producer of commercial product

Study type

Indoor/Glasshouse/Outdoor:

Residues calculated as:

Residue method and LOQ

GF-1966

None

Dow AgroSciences

Residue

Outdoor

Clopyralid

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

Study no. / DAS Study ID

286 days

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Barley / Shakira	1) 13 Apr 20 2) N/A 3) 06 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	19.9	307	61.20	1	13 Jun 19	N/A	Whole Plant Straw Grain	ND 0.012 ND	356 420 420	Mean Recovery
				26.6	308	82.08	1	13 Jun 19	N/A	Whole Plant Straw Grain	ND (0.003) ND	356 420 420	Whole Plant 92%
				41.7	295	123.12	1	13 Jun 19	N/A	Whole Plant Straw Grain	ND 0.036 ND	356 420 420	Straw 88%
													Grain 83%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Winter Barley / HORVW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

360 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Barley / Saratoga	1) 22 Nov 19 2) N/A 3) 08 Jun 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	19.9	308	61.20	1	16 Jul 19	N/A	Whole Plant	ND	241	Mean Recovery
										Straw	ND	328	Whole Plant 92%
										Grain	ND	328	
				26.7	318	84.96	1	16 Jul 19	N/A	Whole Plant	ND	241	Straw 88%
										Straw	ND	328	
										Grain	ND	328	Grain 83%
				41.7	292	121.68	1	16 Jul 19	N/A	Whole Plant	(0.003)	241	
										Straw	ND	328	
										Grain	ND	328	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

272 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Barley / Shakira	1) 06 May 20 2) N/A 3) 19 Sep 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	20.0	320	64.08	1	05 Feb 20	N/A	Whole Plant	0.028	133	Mean Recovery
										Straw	ND	227	Whole Plant 92%
										Grain	ND	227	
				26.6	317	84.24	1	05 Feb 20	N/A	Whole Plant	ND	133	Straw 88%
										Straw	ND	227	
										Grain	ND	227	Grain 83%
				41.7	307	128.16	1	05 Feb 20	N/A	Whole Plant	0.084	133	
										Straw	ND	227	
										Grain	ND	227	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

309 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Barley / Shakira	1) 03 Mar 20 2) N/A 3) 26 Jun 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	19.9	315	62.64	1	05 Feb 20	N/A	Whole Plant	0.018	96	Mean Recovery
										Straw	0.024	142	Whole Plant 92%
										Grain	(0.009)	142	
				26.7	313	83.52	1	05 Feb 20	N/A	Whole Plant	0.029	96	Straw 88%
										Straw	0.015	142	
										Grain	(0.007)	142	Grain 83%
				41.8	312	130.32	1	05 Feb 20	N/A	Whole Plant	0.583	96	
										Straw	0.100	142	
										Grain	0.053	142	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

272 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Oilseed Rape / Jura	1) 13 Apr 20 2) N/A 3) 15 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	20.0	317	63.36	1	13 Jun 19	N/A	Whole Plant	ND	376	Mean Recovery
										Seed	ND	460	Whole Plant 85%
										Rest of Plant	ND	460	
				26.1	303	79.20	1	13 Jun 19	N/A	Whole Plant	ND	376	Seed 84%
										Seed	ND	460	
										Rest of Plant	ND	460	Rest of Plant 85%
				41.8	288	120.24	1	13 Jun 19	N/A	Whole Plant	ND	376	
										Seed	ND	460	
										Rest of Plant	ND	460	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

271 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Oilseed Rape / Albatros	1) 15 Oct 19 2) N/A 3) 10 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x LDC 110° / 110-02 ASJ nozzles	19.9	308	61.20	1	13 Jun 19	N/A	Whole Plant	ND	328	Mean Recovery
										Seed	ND	393	Whole Plant 85%
										Rest of Plant	ND	393	
				26.7	297	79.20	1	13 Jun 19	N/A	Whole Plant	ND	328	Seed 84%
										Seed	ND	393	
										Rest of Plant	ND	393	Rest of Plant 85%
				41.8	293	122.4	1	13 Jun 19	N/A	Whole Plant	ND	328	
										Seed	ND	393	
										Rest of Plant	ND	393	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Agramon, 02490 Albacete (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

271 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Oilseed Rape / Albatros	1) 15 Oct 19 2) N/A 3) 10 Jul 20	Broadcast spraying directed to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	20.0	317	63.36	1	16 Jul 19	N/A	Whole Plant	ND	295	Mean Recovery
										Seed	ND	360	Whole Plant 85%
										Rest of Plant	ND	360	
				26.7	313	83.52	1	16 Jul 19	N/A	Whole Plant	ND	295	Seed 84%
										Seed	ND	360	
										Rest of Plant	ND	360	Rest of Plant 85%
				41.7	285	118.80	1	16 Jul 19	N/A	Whole Plant	ND	295	
										Seed	ND	360	
										Rest of Plant	ND	360	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Crop / EPPO code:

Responsible body for reporting (name & address):

Country:

Trial location (region):

Content of active substance (g/kg or g/l):

Formulation number:

Formulation type (e.g. WP):

**Clopyralid
Oilseeds**

Oilseed Rape / BRSNS

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Spain

Agramon, 02490 Albacete (EU Southern Zone)

720 g ae/L

GF-1966

SG

Commercial Product (name):

Other active substance in the formulation (common name and content):

Producer of commercial product

Study type

Indoor/Glasshouse/Outdoor:

Residues calculated as:

Residue method and LOQ

GF-1966

None

Dow AgroSciences

Residue

Outdoor

Clopyralid

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

Study no. / DAS Study ID

301 days

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009E Agramon, 02490 Albacete, Spain	Oilseed Rape / Jura	1) 03 Mar 20 2) N/A 3) 28 Aug 20	Broadcast spraying di- rected to the ground, knapsack boom sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles	20.0	313	62.64	1	05 Feb 20	N/A	Whole Plant Seed Rest of Plant	ND ND ND	110 205 205	Mean Recovery
				26.5	307	81.36	1	05 Feb 20	N/A	Whole Plant Seed Rest of Plant	ND ND ND	110 205 205	Seed 84%
				41.9	313	131.04	1	05 Feb 20	N/A	Whole Plant Seed Rest of Plant	(0.004) ND 0.015	110 205 205	Rest of Plant 85%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Responsible body for reporting (name & address):

Radish / RAPSR

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Spain

Country:

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

272 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Radish / Mallorca	1) 04 May 20 2) N/A 3) 26 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	20.0	306	61.20	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	374 374	Mean Recovery
				26.7	315	84.24	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	374 374	Radish roots 87%
				41.7	297	123.84	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	374 374	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

363 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Radish / Mallorca	1) 18 Oct 19 2) N/A 3) 30 Jan 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	311	61.92	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	226 226	Mean Recovery
				26.6	300	79.92	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	226 226	Radish roots 87%
				41.7	307	128.16	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	226 226	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

415 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Radish / Mallorca	1) 20 Sep 19 2) N/A 3) 27 Nov 19	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	304	60.48	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	162 162	Mean Recovery
				26.6	295	78.48	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	162 162	Radish roots 87%
				41.6	306	127.44	1	18 Jun 19	N/A	Radish roots Radish tops with leaves	ND ND	162 162	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Crop group:

Clopyralid**Root and tuber vegetables**

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Crop / EPPO code:

Radish / RAPSR

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre

3B Park Square, Milton Park, Abingdon

Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Max frozen storage time prior to analysis

325 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Radish / Mallorca	1) 04 Mar 20 2) N/A 3) 04 May 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	20.0	303	60.48	1	06 Feb 20	N/A	Radish roots Radish tops with leaves	ND (0.004)	88 88	Mean Recovery
				26.7	315	84.24	1	06 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	88 88	Radish roots 87%
				41.9	289	120.96	1	06 Feb 20	N/A	Radish roots Radish tops with leaves	ND ND	88 88	Radish tops with leaves 90%

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

213 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Cabbage / Brunswick	1) 04 May 20 2) N/A 3) 25 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	307	61.20	1	18 Jun 19	N/A	Cabbage	ND	434	Mean Recovery Whole Cabbage 82%
				26.7	307	82.08	1	18 Jun 19	N/A	Cabbage	ND	434	
				41.8	300	125.28	1	18 Jun 19	N/A	Cabbage	ND	434	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

335 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Cabbage / Brunswick	1) 18 Oct 19 2) N/A 3) 25 Feb 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	308	61.20	1	18 Jun 19	N/A	Cabbage	ND	252	Mean Recovery Whole Cabbage 82%
				26.6	306	81.36	1	18 Jun 19	N/A	Cabbage	ND	252	
				41.6	306	127.44	1	18 Jun 19	N/A	Cabbage	ND	252	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

348 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Cabbage / Brunswick	1) 20 Sep 19 2) N/A 3) 30 Jan 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	297	59.04	1	18 Jun 19	N/A	Cabbage	ND	226	Mean Recovery Whole Cabbage 82%
				26.7	307	82.08	1	18 Jun 19	N/A	Cabbage	ND	226	
				41.8	308	128.88	1	18 Jun 19	N/A	Cabbage	ND	226	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Brassicas

Crop / EPPO code:

Head Cabbage / BRSOL

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

245 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Cabbage / Brunswick	1) 04 Mar 20 2) N/A 3) 24 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	20.0	310	61.92	1	06 Feb 20	N/A	Cabbage	ND	169	Mean Recovery Whole Cabbage 82%
				26.6	314	83.52	1	06 Feb 20	N/A	Cabbage	ND	169	
				41.8	296	123.84	1	06 Feb 20	N/A	Cabbage	ND	169	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

279 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Barley / Shakira	1) 04 May 20 2) N/A 3) 20 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	20.0	303	60.48	1	18 Jun 19	N/A	Whole Plant	ND	358	Mean Recovery
										Straw	ND	429	Whole Plant 92%
										Grain	ND	429	
				26.7	310	82.80	1	18 Jun 19	N/A	Whole Plant	ND	358	Straw 88%
										Straw	ND	429	
										Grain	ND	429	Grain 83%
				41.9	301	126.00	1	18 Jun 19	N/A	Whole Plant	ND	358	
										Straw	0.016	429	
										Grain	ND	429	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Winter Barley / HORVW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

357 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha		(d)	(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Barley / Lagalia	1) 10 Dec 19 2) N/A 3) 17 Jun 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	19.9	300	59.76	1	07 Aug 19	N/A	Whole Plant	ND	222	Mean Recovery
										Straw	ND	315	Whole Plant 92%
										Grain	ND	315	
				26.5	296	78.48	1	07 Aug 19	N/A	Whole Plant	ND	222	Straw 88%
										Straw	ND	315	
										Grain	ND	315	Grain 83%
				41.8	308	128.88	1	07 Aug 19	N/A	Whole Plant	ND	222	
										Straw	ND	315	
										Grain	ND	315	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

279 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Barley / Shakira	1) 04 May 20 2) N/A 3) 20 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	20.0	306	61.20	1	06 Feb 20	N/A	Whole Plant	ND	125	Mean Recovery Whole Plant 92% Straw 88% Grain 83%
										Straw	ND	196	
										Grain	ND	196	
				26.6	311	82.80	1	06 Feb 20	N/A	Whole Plant	ND	125	
										Straw	ND	196	
										Grain	ND	196	
				41.7	292	121.68	1	06 Feb 20	N/A	Whole Plant	(0.006)	125	
										Straw	ND	196	
										Grain	ND	196	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

August 2024

EF-243

Part B – Section 7 - Core Assessment

Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Spring Barley / HORVS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Max frozen storage time prior to analysis

320 days

Formulation number:

GF-1966

Study no. / DAS Study ID

CEMS-9009 / 190557

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Barley / Gustav	1) 04 Mar 20 2) N/A 3) 13 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	19.9	307	61.20	1	06 Feb 20	N/A	Whole Plant	(0.004)	84	Mean Recovery
										Straw	0.018	158	Whole Plant 92%
										Grain	(0.006)	158	
				26.6	319	84.96	1	06 Feb 20	N/A	Whole Plant	(0.005)	84	Straw 88%
										Straw	0.027	158	
										Grain	(0.008)	158	Grain 83%
				41.8	286	119.52	1	06 Feb 20	N/A	Whole Plant	0.034	84	
										Straw	0.279	158	
										Grain	0.035	158	

(a) According to EEC and Codex classifications (both) should be used.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(b) Only if relevant.

(f) Minimum number of days after last application

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites
Included, method of storage, storage stability, analysis date and analytical method.

(d) Year must be indicated.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Max frozen storage time prior to analysis

269 days

Formulation type (e.g. WP):

SG

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Oilseed Rape / Katia	1) 04 May 19 2) N/A 3) 10 Sep 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	304	60.48	1	18 Jun 19	N/A	Whole Plant	ND	374	Mean Recovery
										Seed	ND	450	Whole Plant 85%
										Rest of Plant	ND	450	
				26.6	306	81.36	1	18 Jun 19	N/A	Whole Plant	ND	374	Seed 84%
										Seed	ND	450	
										Rest of Plant	ND	450	Rest of Plant 85%
				41.7	307	128.16	1	18 Jun 19	N/A	Whole Plant	ND	374	
										Seed	ND	450	
										Rest of Plant	ND	450	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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Corteva Agriscience version

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Max frozen storage time prior to analysis

300 days

Formulation number:

GF-1966

Study no. / DAS Study ID

CEMS-9009 / 190557

Formulation type (e.g. WP):

SG

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Oilseed Rape / Arsenal	1) 18 Oct 19 2) N/A 3) 11 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.9	307	61.20	1	18 Jun 19	N/A	Whole Plant	ND	294	Mean Recovery
										Seed	ND	289	Whole Plant 85%
										Rest of Plant	ND	389	
				26.6	308	82.08	1	18 Jun 19	N/A	Whole Plant	ND	294	Seed 84%
										Seed	ND	289	
										Rest of Plant	ND	389	Rest of Plant 85%
				41.8	296	123.84	1	18 Jun 19	N/A	Whole Plant	ND	294	
										Seed	ND	289	
										Rest of Plant	ND	389	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNW

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

300 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Oilseed Rape / Arsenal	1) 18 Oct 19 2) N/A 3) 11 Jul 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° / 110-015 VS nozzles	19.8	313	61.92	1	17 Jul 19	N/A	Whole Plant	ND	265	Mean Recovery
										Seed	ND	360	Whole Plant 85%
										Rest of Plant	ND	360	
				26.6	319	84.96	1	17 Jul 19	N/A	Whole Plant	ND	265	Seed 84%
										Seed	ND	360	
										Rest of Plant	ND	360	Rest of Plant 85%
				41.7	318	132.48	1	17 Jul 19	N/A	Whole Plant	ND	265	
										Seed	ND	360	
										Rest of Plant	ND	360	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Oilseeds

Crop / EPPO code:

Oilseed Rape / BRSNS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Lobosillo, 30331 Murcia (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

303 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009F Lobosillo, 30331 Murcia, Spain	Oilseed Rape / Katia	1) 04 Mar 20 2) N/A 3) 20 Aug 20	Broadcast spraying directed to the ground, knapsack sprayer with 6 x XR TEEJET 110° 110-05 V8 nozzles.	20.0	317	63.36	1	06 Feb 20	N/A	Whole Plant	ND	107	Mean Recovery
										Seed	ND	196	Whole Plant 85%
										Rest of Plant	ND	196	
				26.6	308	82.08	1	06 Feb 20	N/A	Whole Plant	ND	107	Seed 84%
										Seed	ND	196	
										Rest of Plant	ND	196	Rest of Plant 85%
				41.7	283	118.08	1	06 Feb 20	N/A	Whole Plant	ND	107	
										Seed	ND	196	
										Rest of Plant	(0.009)	196	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

DAA = Days after application

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RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance (common name):

Clopyralid

Crop group:

Cereals

Crop / EPPO code:

Spring Wheat / TRZAS

Responsible body for reporting (name & address):

Dow AgroSciences, European Development Centre
3B Park Square, Milton Park, Abingdon
Oxon OX14 4RN, UK

Country:

Spain

Trial location (region):

Conil de la Frontera, 11140 Cádiz (EU Southern Zone)

Content of active substance (g/kg or g/l):

720 g ae/L

Formulation number:

GF-1966

Formulation type (e.g. WP):

SG

Commercial Product (name):

GF-1966

Other active substance in the formulation (common name and content):

None

Producer of commercial product

Dow AgroSciences

Study type

Residue

Indoor/Glasshouse/Outdoor:

Outdoor

Residues calculated as:

Clopyralid

Residue method and LOQ

120610 / 0.01 mg/kg

Max frozen storage time prior to analysis

274 days

Study no. / DAS Study ID

CEMS-9009 / 190557

1	2	3	4	5			6		7	8	9	10	11
Trial No. Location (region)	Commod- ity/Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treat- ments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)	DAA	Remarks:
	(a)	(b) – if relevant	(c)	g ae/hL	Water (L/ha)	g ae/ha	(d)		(e)	(a)		(days) (f)	(g)
CEMS-9009G Conil de la Fron- tera 11140 Cádiz, Spain	Wheat / Gazul	1) 15 Jul 20 2) N/A 3) 10 Jun 21	Broadcast spraying directed to the ground, knapsack sprayer with 9 x Anti-drift Flat Fan Nozzles ASJ CFA-01 (Orange)	28.3	218	61.769	1	13 Mar 20	N/A	Whole Plant	ND	185	Mean Recovery
										Straw	ND	454	
										Grain	ND	454	
				38.0	211	80.086	1	13 Mar 20	N/A	Whole Plant	ND	185	Straw 95%
										Straw	ND	454	
										Grain	ND	454	
				59.5	219	130.262	1	13 Mar 20	N/A	Whole Plant	ND	185	Grain 91%
										Straw	ND	454	
										Grain	ND	454	

(a) According to EEC and Codex classifications (both) should be used.

(b) Only if relevant.

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, -type of equipment must be indicated.

(d) Year must be indicated.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-429

(f) Minimum number of days after last application

(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites Included, method of storage, storage stability, analysis date and analytical method.

Residues of less than the LOQ, but greater than 0.003 mg/kg, are shown in parentheses, ND = Not detected (<0.003 mg/kg).

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A 2.1.7 Other/Special Studies

~~No new data are submitted in the framework of this application.~~

Comments of zRMS:	The study was performed according to GLP requirements and relevant guidelines. Study is acceptable. The application rate used in the study was comparable to the proposed use rate for oilseed rape. The residues in honey were 3x <0.01, 0.0274 and 0.0695 mg/kg.
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The applicant provided the following study for determination of residues in honey. The zRMS performed the evaluation of the study:

Data point	Point 7.2.1
Report author	Appeltauer A.
Report year	2021
Report title	Determination of Residues of Clopyralid in Nectar, Pollen, Plants and Honey of Winter Oilseed Rape after One Application of GF-1966 in a Semi-Field Residue Study in Germany, Romania, The Netherlands, Southern France and Spain in 2020
Study code	S20-00871
Study number	DAS 200098
Guidelines followed in study	7029/VI/95 (rev. 5) to Directive 91/414/EEC, Reg. (EU) 283/2013 and 284/2013, SANTE/11956/2016 rev. 9
Major deviations from test guideline	None
Previous evaluation	None
GLP/Officially recognised testing facilities	Yes
Acceptability/Reliability	Yes

Materials and methods:

Materials:

Analytical standards:

Analyte	Clopyralid
Lot/batch	200901001
Purity	99.1%
CAS	1702-17-6
Expiry date	21.6.2023

Test formulation:

Description: GF-1966 / formulation SG

Lot/Batch #: D062EAKA04

Content: 94.7 % w/w clopyralid-olamine (947 g/kg) / 71.9 % w/w acid equivalent (719 g/kg)

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Expiry date: 8.1.2021

Study design:**Test procedure**

The study was conducted as six separate field trials in Northern and Southern Germany, Romania, The Netherlands, Southern France and Spain in 2020. The distance between trials was at least 297 km. The study consisted of two treatment groups per trial: the test item group T (2 replicates- Ta and Tb) and an untreated control C (1 replicate). Each trial consisted of 3 tunnels/plots (Control C, Test item treatment replicate Ta and replicate Tb). The area covered per tunnel was 200 m² for all trials (see Table 3). The approximate dimensions of each tunnel were 40 m length, 5 m width and 3 - 3.5 m height in the center. The tunnels were covered with light plastic gauze (mesh size 1.5 and 1.67 mm). In tunnels C and Ta one colony per tunnel was set up. In tunnel Tb two colonies were set up. The colonies were set up in the tunnels 1-2 days before sampling S6 (equivalent to 9 to 24 days after application). Honeybee colonies (*Apis mellifera* L. (Hymenoptera, Apidae) with a sufficient number of forager bees were used.

There was one application in the test item treatment group at a target rate of 125 g a.e./ha (Ta, Tb; 173.85 g product/ha, analysed) at BBCH 55 for trials -02, -03, -05, -06 and -07 and BBCH 57 for trial -04.

Winter oilseed rape plants, pollen and forager bees for preparation of nectar were collected in the control tunnel and in replicate Tb. Honey was collected in the control tunnel and in replicate Ta. Winter oilseed rape plants were collected six times after application. Sampling of plants for residue analysis was conducted first at 0DAA and last sampling 10-25DAA. Pollen and forager bees were collected six times after application. Sampling of pollen and forager bees for preparation of nectar for residue analysis was conducted first at 10-25DAA and last sampling 17-34DAA.

For plants samples on each sampling day, at least 500 g sample was collected.

From sampling S6 to sampling S11 forager bees were collected for the preparation of nectar from their honey stomachs for residue analysis in replicate Tb. At sampling S6 forager bees were also collected from the control tunnel. On each sampling day an A-sample of at least 300 bees was collected. From sampling S6 to sampling S11 on each sampling day pollen from winter oilseed rape flowers retrieved by the bees was collected using pollen traps in replicate Tb. At sampling S6 forager bees were also collected from the control tunnel. The hives in the tunnel were equipped with pollen traps.

Honey was collected once mature at the end of flowering or if the water content was < 20 % or after comb closure – whatever occurred first - for subsequent residue analysis in replicate Ta. For honey samples an A1- and, where sufficient sample material was available, an R1-sample of preferable 100g was targeted for sampling, with a minimum of at least 10 g honey as a representative sample of the tunnel area, was collected.

Analytical procedures

Prior sample analysis, the analytical methods were validated in all matrices according to SANCO/3029/99, rev. 4 within the analytical phase. Mean recoveries at each fortification level were in the range of 70 - 110 % with relative standard deviation(s) below 20 % for all matrices. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for all matrices with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The method was considered to be acceptably validated and fit for purpose. No ILV for the method was available.

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Hydrolysis of whole plants, honey, nectar and pollen samples were performed based on the analytical method as described in the Sponsor study with ID 120610. Sample workup was modified depending on matrix in the current study and was fully validated for all matrices according to SANCO/3029/99 rev. 4. Quantification was performed by use of LC-MS/MS detection.

Results and discussion:

Residues in honey, nectar, pollen and plants are shown in the table below:

Trial details	Crop	Country	Formulation, Application rate (g a.s./ha)	Crop growth stage2 (BBCH)	DALA1	Residues found (mg/kg)	
						Matrix	clopyralid
Study code: S20-00871 Doc ID: Trial No: 02 GLP: Yes Year: 2020	Oilseed rape	Germany	GF-1966	55	35	honey	<0.01
			SG				
			Ta: 127.7				
			GF-1966	55	0	plant	1.51
			SG		1	plant	1.78
			Tb: 125.5		2	plant	2.15
					4	plant	1.84
					6	plant	1.19
					18	pollen	1.04
						plant	1.04
						nectar	0.0760
					19	pollen	0.808
						nectar	0.0555
					20	pollen	0.620
						nectar	0.0386
Study code: S20-00871 Doc ID: Trial No: 03 GLP: Yes Year: 2020	Oilseed rape	Romania	GF-1966	55	21	honey	0.0179
			SG				
			Ta: 136.1				
			GF-1966	55	0	plant	0.944
			SG		1	plant	0.168
			Tb: 134.8		3	plant	0.218
					4	plant	0.358
					7	plant	0.433
					10	pollen	0.550
						plant	0.337

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Trial details		Crop	Country	Formulation, Application rate (g a.s./ha)	Crop growth stage2 (BBCH)	DALAI	Residues found (mg/kg)	
							Matrix	clopyralid
						11	nectar	0.0675
							pollen	0.453
						12	nectar	0.0333
							pollen	2.61
							nectar	0.120
						14	pollen	0.249
							nectar	0.0255
						16	pollen	0.310
							nectar	0.0325
						17	pollen	0.169
							nectar	0.0253

Trial details		Crop	Country	Formulation, Application rate (g a.s./ha)	Crop growth stage2 (BBCH)	DALAI	Residues found (mg/kg)	
							Matrix	clopyralid
Study code:	S20-00871	Oilseed rape	The NL	GF-1966	57	42	honey	<0.01
Doc ID:				SG				
Trial No:	04			Ta: 127.2				
GLP:	Yes							
Year:	2020			GF-1966	57	0	plant	1.45
				SG		1	plant	0.926
				Tb: 127.2		3	plant	1.06
						5	plant	1.05
						7	plant	0.749
						25	pollen	2.35
							plant	1.25
							nectar	0.019
						26	pollen	1.74
							nectar	0.0510
						27	pollen	1.65
							nectar	0.0422
						29	pollen	0.663
							nectar	0.0800
						31	pollen	0.488
							nectar	0.0960
						34	pollen	0.248
							nectar	<0.01
Study code:	S20-00871	Oilseed rape	France	GF-1966	55	40	honey	0.0695
Doc ID:			(SEU)	SG				
Trial No:	05			Ta: 127.4				
GLP:	Yes							

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Trial details		Crop	Country	Formulation, Application rate (g a.s./ha)	Crop growth stage2 (BBCH)	DALAI	Residues found (mg/kg)	
							Matrix	clopyralid
Year:	2020			GF-1966 SG Tb: 126.4	55	0 1 2 5 6 12 13 14 16 18 20	plant plant plant plant plant pollen plant nectar pollen nectar pollen nectar pollen nectar pollen nectar	2.33 2.30 1.44 3.09 3.02 3.30 2.12 0.479 3.17 0.520 0.260 1.31 1.39 1.70 1.68 1.58 1.30 1.31
Study code:	S20-00871	Oilseed rape	Spain	GF-1966 SG Ta: 124.1	55	49	honey	<0.01
Doc ID:								
Trial No:	06							
GLP:	Yes							
Year:	2020			GF-1966 SG Tb: 133.5	55	0 1 2 4 7 14 15 17 18 19 21	plant plant plant plant plant pollen plant nectar pollen nectar pollen nectar pollen nectar pollen nectar pollen nectar	0.686 1.16 1.48 1.19 2.02 1.72 1.56 0.0169 1.69 0.0860 1.71 0.295 1.52 0.165 1.73 0.358 0.855 0.157
Study code:	S20-00871	Oilseed rape	Germany	GF-1966 SG	55	17	honey	0.0274
Doc ID:								

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Trial details		Crop	Country	Formulation, Application rate (g a.s./ha)	Crop growth stage ² (BBCH)	DALAI	Residues found (mg/kg)	
							Matrix	clopyralid
Trial No:	07			Ta: 126.1				
GLP:	Yes							
				GF-1966	55	0	plant	1.49
				SG		1	plant	1.69
				Tb: 126.4		3	plant	1.52
						5	plant	1.07
						7	plant	1.29
						11	pollen	1.33
							plant	1.16
							nectar	0.338
						12	pollen	1.14
							nectar	2.05
						13	pollen	0.610
							nectar	2.71
						15	pollen	0.530
							nectar	0.815
						17	pollen	0.360
							nectar	0.0585
						19	pollen	0.408
							nectar	0.0690

1 Days after last application

2 At last application

Underlined values were used for MRL calculation

The residues in honey were 3x <0.01, 0.0179, 0.0274, 0.0695 mg/kg. Calculated STMR is 0.014 mg/kg and unrounded MRL 0.117 mg/kg (rounded 0.15 mg/kg). Current MRL for clopyralid in honey is 0.05 mg/kg and thus potentially exceeded.

No residues of clopyralid were detected above LOD (0.003 mg/kg) in untreated plant, pollen, nectar and honey specimen, with one exception: In untreated honey specimen of trial -02, residues of clopyralid were determined at 0.0179 mg/kg.

Storage stability

Maximum storage of samples were following:

Honey samples: 222 days; honey extracts 1 day

Pollen samples: 194 days; pollen extracts 3 days

Nectar samples: 15 days; nectar extracts 1 day

Whole plant samples: 188 days; plant extracts 6 days

Maximum storage time of the samples in the test facility was 187 days before dispatch. This should be added to the storage times. Storage times are acceptable when compared to the demonstrated stability of clopyralid in honey (18 months – approx. 540 days).

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Stability of residues in extracts of pollen, nectar, whole plant and honey was shown to be at least 12 days in the dark for pollen, and 34 days for whole plants, 8 days for honey and 12 days for nectar.

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Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI:					Exposure resulting from		
	Calculated exposure (% of ADI)	MS-Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	42.3%	NL toddler	63.42	9.4%	Maize/corn	7.9%	Wheat	3.6%	Apples	0.1%	25.3%
	27.0%	GEMS/Food G06	40.56	14.5%	Wheat	2.1%	Rice	1.7%	Maize/corn	0.1%	18.2%
	26.1%	DK child	39.17	11.0%	Rye	8.8%	Wheat	0.8%	Potatoes	0.1%	21.0%
	24.9%	NL child	37.28	8.2%	Wheat	5.6%	Sugar beet roots	1.9%	Apples	0.1%	15.8%
	23.8%	DE child	35.64	8.4%	Wheat	4.2%	Apples	1.6%	Rye	0.1%	11.6%
	20.9%	RO general	31.29	10.1%	Wheat	2.9%	Head cabbages	1.3%	Maize/corn	0.1%	15.5%
	20.3%	GEMS/Food G15	30.41	9.1%	Wheat	1.6%	Head cabbages	1.2%	Potatoes	0.1%	14.0%
	20.0%	FR child 3-15 yr	30.05	9.2%	Wheat	2.4%	Sugar beet roots	1.1%	Oranges	0.1%	13.3%
	19.8%	GEMS/Food G08	29.63	8.2%	Wheat	1.3%	Potatoes	1.2%	Barley	0.1%	13.1%
	19.4%	GEMS/Food G10	29.13	7.8%	Wheat	1.7%	Rice	1.1%	Soyabeans	0.1%	11.4%
	18.4%	IT toddler	27.67	13.3%	Wheat	2.0%	Other cereals	0.5%	Tomatoes		13.6%

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	18.1%	GEMS/Food G07	27.22	8.4%	Wheat	1.3%	Potatoes	0.8%	Barley	0.1%	11.3%
	18.1%	IE adult	27.10	4.6%	Wheat	2.4%	Sweet potatoes	2.0%	Linseeds	0.0%	9.0%
	17.1%	GEMS/Food G11	25.71	7.2%	Wheat	1.3%	Potatoes	1.2%	Soyabeans	0.1%	9.4%
	16.7%	UK toddler	25.12	7.8%	Wheat	2.1%	Sugar beet roots	1.2%	Potatoes	0.0%	10.8%
	16.0%	FR toddler-2 3-yr	23.95	6.2%	Wheat	1.9%	Sugar beet roots	1.3%	Milk: Cattle	0.1%	9.2%
	15.6%	UK infant	23.43	5.2%	Wheat	1.7%	Milk: Cattle	1.4%	Maize/corn	0.1%	9.0%
	15.2%	PT general	22.77	7.8%	Wheat	1.8%	Potatoes	1.0%	Rice		9.0%
	15.1%	ES child	22.63	8.9%	Wheat	0.7%	Oranges	0.6%	Rice	0.1%	9.8%
	15.0%	SE general	22.54	6.4%	Wheat	1.4%	Potatoes	1.3%	Head cabbages	0.0%	8.9%
	14.2%	DE women 14-50-yr	21.31	4.3%	Wheat	3.1%	Sugar beet roots	1.0%	Rye	0.1%	9.6%
	13.8%	DE general	20.76	3.8%	Wheat	2.8%	Sugar beet roots	1.2%	Rye	0.1%	9.5%
	12.1%	IT adult	18.12	8.3%	Wheat	0.9%	Other cereals	0.4%	Tomatoes		8.6%
	11.9%	NL general	17.86	3.9%	Wheat	1.9%	Sugar beet roots	0.8%	Potatoes	0.1%	7.6%
	10.7%	FI 3-yr	16.07	2.4%	Wheat	1.6%	Potatoes	1.3%	Rye	0.0%	5.7%
	9.4%	ES adult	14.04	4.7%	Wheat	0.7%	Barley	0.4%	Oranges	0.1%	5.9%
	9.1%	FR adult	13.62	4.4%	Wheat	0.8%	Wine grapes	0.5%	Sugar beet roots	0.1%	5.7%
	8.5%	LT adult	12.81	2.2%	Rye	2.1%	Wheat	1.1%	Potatoes	0.1%	5.4%
	8.4%	FI 6-yr	12.55	1.9%	Wheat	1.3%	Potatoes	1.2%	Rye	0.0%	4.5%
	8.3%	UK-vegetarian	12.51	4.1%	Wheat	0.5%	Rice	0.5%	Potatoes	0.0%	5.3%
	7.1%	FR infant	10.68	1.6%	Wheat	0.9%	Sugar beet roots	0.7%	Milk: Cattle	0.0%	3.6%
	6.9%	UK adult	10.38	3.4%	Wheat	0.5%	Rice	0.5%	Potatoes	0.0%	4.3%
	6.7%	FI adult	9.98	1.9%	Coffee beans	1.4%	Rye	0.6%	Wheat		2.8%
	6.3%	DK adult	9.44	2.2%	Wheat	1.1%	Rye	0.4%	Potatoes	0.0%	3.6%
	4.1%	PL general	6.17	1.1%	Potatoes	0.7%	Head cabbages	0.7%	Apples		1.2%
	3.8%	IE child	5.69	2.3%	Wheat	0.4%	Rice	0.2%	Potatoes	0.0%	2.6%
Conclusion:	The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.										
	The long-term intake of residues of Clopyralid is unlikely to present a public health concern.										

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IESTI calculations—Raw commodities

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	45.64%	Swedes/rutabagas	1.5 / 1.5	77.59	30.13%	Swedes/rutabagas	1.5 / 1.5	51.23
	33.57%	Beetroots	1 / 1	57.06	22.51%	Head cabbages	3 / 0.91	38.27
	31.70%	Turnips	1.5 / 1.5	53.88	14.83%	Wheat	3 / 3	25.21
	28.97%	Cauliflowers	3 / 0.85	49.24	13.54%	Beetroots	1 / 1	23.02
	25.50%	Wheat	3 / 3	43.35	11.92%	Broccoli	1.5 / 0.85	20.26
	23.68%	Head cabbages	3 / 0.91	40.26	11.59%	Cauliflowers	3 / 0.85	19.71
	20.80%	Broccoli	1.5 / 0.85	35.36	11.12%	Chards/beet leaves	1 / 1	18.90
	13.29%	Spinaches	1 / 1	22.60	9.83%	Turnips	1.5 / 1.5	16.71
	12.60%	Linseeds	20 / 20	21.42	8.56%	Rye	3 / 3	14.56
	11.16%	Rye	3 / 3	18.97	5.69%	Barley	2 / 2	9.67
	9.18%	Chards/beet leaves	1 / 1	15.60	5.65%	Linseeds	20 / 20	9.60
	7.92%	Maize/corn	2 / 2	13.47	4.37%	Onions	0.5 / 0.5	7.43
	6.69%	Onions	0.5 / 0.5	11.37	2.55%	Maize/corn	2 / 2	4.34
	6.60%	Barley	2 / 2	11.22	2.35%	Spinaches	1 / 1	4.00
	6.46%	Spring onions/green onions and Welsh onions	0.7 / 0.7	10.98	1.85%	Spring onions/green onions and Welsh onions	0.7 / 0.7	3.15
	Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

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A 3.2 IESTI calculations - Processed commodities

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	64.8%	Sugar beets (root) / sugar	1 / 12	110.15	25.8%	Sugar beets (root) / sugar	1 / 12	43.80
	44.7%	Turnips / boiled	1.5 / 1.5	76.07	22.88%	Beetroots / boiled	1 / 1	38.89
	39.4%	Broccoli / boiled	1.5 / 0.85	66.96	20.83%	Cauliflowers / boiled	3 / 0.85	35.41
	34.8%	Cauliflowers / boiled	3 / 0.85	59.17	16.84%	Turnips / boiled	1.5 / 1.5	28.63
	27.4%	Maize / oil	2 / 50	46.57	14.94%	Maize / oil	2 / 50	25.40
	26.1%	Beetroots / boiled	1 / 1	44.33	12.04%	Broccoli / boiled	1.5 / 0.85	20.46
21.3%	Wheat / milling (flour)	3 / 3	36.27	8.47%	Barley / beer	2 / 0.4	14.40	
18.3%	Chards/beet leaves / boiled	1 / 1	31.12	7.75%	Wheat / bread/pizza	3 / 3	13.17	
9.8%	Wheat / milling (wholemeal)-baking	3 / 3	16.63	7.36%	Chards/beet leaves / boiled	1 / 1	12.52	
8.2%	Spinaches / frozen; boiled	1 / 1	13.91	6.73%	Wheat / pasta	3 / 3	11.44	
6.4%	Rye / boiled	3 / 3	10.88	6.17%	Wheat / bread (whole-meal)	3 / 3	10.48	
6.4%	Oat / boiled	3 / 3	10.88	4.87%	Spinaches / frozen; boiled	1 / 1	8.28	
6.2%	Rye / milling (wholemeal)-baking	3 / 3	10.53	2.77%	Onions / boiled	0.5 / 0.5	4.71	
5.3%	Oat / milling (flakes)	3 / 3	9.00	2.68%	Oat / boiled	3 / 3	4.56	
4.8%	Shallots / boiled	0.5 / 0.5	8.11	1.82%	Shallots / boiled	0.5 / 0.5	3.10	
Expand/collapse list								
Conclusion:								

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of Clopyralid is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.3 TMDI calculations

IESTI calculations - Raw commodities

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
			MRL / input for RA (mg/kg)	Exposure (µg/kg bw)			MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	Highest % of ARfD/ADI	Commodities			Highest % of ARfD/ADI	Commodities		
	48.39%	Cauliflowers	3 / 1.42	82.26	37.60%	Head cabbages	3 / 1.52	63.92
	45.64%	Swedes/rutabagas	1.5 / 1.5	77.59	30.13%	Swedes/rutabagas	1.5 / 1.5	51.23
	39.56%	Head cabbages	3 / 1.52	67.25	19.37%	Cauliflowers	3 / 1.42	32.92
	33.57%	Beetroots	1 / 1	57.06	14.89%	Chinese cabbages/pe-tsai	1 / 1	25.31
	31.70%	Turnips	1.5 / 1.5	53.88	14.83%	Wheat	3 / 3	25.21
25.50%	Wheat	3 / 3	43.35	14.27%	Rye	5 / 5	24.26	
18.90%	Chinese cabbages/pe-tsai	1 / 1	32.13	13.54%	Beetroots	1 / 1	23.02	
18.59%	Rye	5 / 5	31.61	11.12%	Chards/beet leaves	1 / 1	18.90	
17.86%	Broccoli	1.5 / 0.73	30.37	10.24%	Broccoli	1.5 / 0.73	17.40	
13.29%	Spinaches	1 / 1	22.60	9.83%	Turnips	1.5 / 1.5	16.71	
12.60%	Linseeds	20 / 20	21.42	5.69%	Barley	2 / 2	9.67	
9.18%	Chards/beet leaves	1 / 1	15.60	5.65%	Linseeds	20 / 20	9.60	

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	7.92%	Maize/corn	2 / 2	13.47	4.37%	Onions	0.5 / 0.5	7.43
	6.69%	Onions	0.5 / 0.5	11.37	2.55%	Maize/corn	2 / 2	4.34
	6.60%	Barley	2 / 2	11.22	2.35%	Spinaches	1 / 1	4.00
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations - Processed commodities

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	64.8%	Sugar beets (root) / sugar	1 / 12	110.15	34.8%	Cauliflowers / boiled	3 / 1.42	59.16
	58.1%	Cauliflowers / boiled	3 / 1.42	98.84	25.76%	Sugar beets (root) / sugar	1 / 12	43.80
	44.7%	Turnips / boiled	1.5 / 1.5	76.07	22.88%	Beetroots / boiled	1 / 1	38.89
	33.8%	Broccoli / boiled	1.5 / 0.73	57.51	16.84%	Turnips / boiled	1.5 / 1.5	28.63
	27.4%	Maize / oil	2 / 50	46.57	14.94%	Maize / oil	2 / 50	25.40
	26.1%	Beetroots / boiled	1 / 1	44.33	10.34%	Broccoli / boiled	1.5 / 0.73	17.57
	21.3%	Wheat / milling (flour)	3 / 3	36.27	8.47%	Barley / beer	2 / 0.4	14.40
	18.3%	Chards/beet leaves / boiled	1 / 1	31.12	7.75%	Wheat / bread/pizza	3 / 3	13.17
	10.7%	Rye / boiled	5 / 5	18.13	7.36%	Chards/beet leaves / boiled	1 / 1	12.52
	10.3%	Rye / milling (wholemeal)-baking	5 / 5	17.55	6.73%	Wheat / pasta	3 / 3	11.44

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—	9.8%	Wheat / milling (wholemeal)-baking	3 / 3	16.63	6.17%	Wheat / bread (wholemeal)	3 / 3	10.48
—	8.2%	Spinaches / frozen; boiled	1 / 1	13.91	4.87%	Spinaches / frozen; boiled	1 / 1	8.28
—	6.4%	Oat / boiled	3 / 3	10.88	2.77%	Onions / boiled	0.5 / 0.5	4.71
—	5.3%	Oat / milling (flakes)	3 / 3	9.00	2.68%	Oat / boiled	3 / 3	4.56
—	4.8%	Shallots / boiled	0.5 / 0.5	8.11	1.82%	Shallots / boiled	0.5 / 0.5	3.10
<p>Conclusion:</p> <p>No exceedance of the toxicological reference value was identified for any unprocessed commodity.</p> <p>A short term intake of residues of Clopyralid is unlikely to present a public health risk.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>								

Appendix 4 Additional information provided by the applicant

There are two separate processes in which the applicant (Dow AgroSciences, DAS, now Corteva Agriscience), the RMS (FI) and EFSA have communicated to address identified data gaps in the metabolism data package. These are (i) the renewal of approval of clopyralid and (ii) an Article 6 MRL evaluation report, submitted 31 May 2018, updated 14 November 2018, 25 January 2019, 03 May 2019, 14 November 2019 and 17 August 2020.

Additional information on metabolism of clopyralid in plants (RAR, Finland, revised May 2019)

Upon the framework of Art.6 MRL review for clopyralid, the applicant submitted further explanation and data on the metabolism in plants due to requests of EFSA to clarify the nature of the “polar clopyralid” / “metabolite A” detected in OSR and sugar beet metabolism studies. It was specifically requested that an explanation should be provided why in mature samples of sugar beet and oilseed rape ‘polar clopyralid’ and clopyralid were observed, while ‘polar clopyralid’ was not observed in immature samples, as the analytical procedure used was always the same within one study. In addition, EFSA requested further clarification on the nature of the unknown “metabolite B” in the plant metabolism studies, and explanation whether it is identical with the “polar form of clopyralid” or “clopyralid conjugates”.

Metabolite A / “polar clopyralid”

The applicant explained that “polar clopyralid” is the same throughout these studies and is also known as “unknown A” and “unknown 1”. It is observed only in mature OSR straw and seed and mature sugar beet shoots (foliage) and roots. It is the same in both studies where it has been identified as such. Although the extraction procedures are identical, the mature samples were concentrated and reconstituted in 1:1 ACN:H₂O, which would be less likely to retain clopyralid than the 28-d immature samples which were not concentrated and would contain water and therefore contain >50% water in the injected sample. Between the higher organic content and the weaker acid used in HPLC system 1, clopyralid would be less likely to be retained.

The analytical conditions were further explained by the applicant:

“Although the extraction analytical procedures were identical within a study, and similar between OSR and sugar beet metabolism studies, the chromatography was different between immature and mature samples. The samples analyzed by HPLC were of the same general composition, nominally 50/50, ACN/H₂O (v/v). However, after carefully reviewing the raw data of these studies (finalized in 2002), it was determined that a major, and very important difference, was that the HPLC injection volume was 100 µL for the immature samples, versus 200 µL injected for the mature samples. There was sufficient radioactivity in the immature samples for detection of 100 µL, however, a larger volume of 200 µL was needed for the mature samples.

As previously provided, column “break-through” resulting in radioactivity eluting near the solvent front, or peak splitting of a compound, can occur when samples are injected with a high percentage of organic (50% acetonitrile) in a larger injection (200 µL). This is particularly true for a polar compound such as clopyralid.

Evidence of this effect was observed during analysis of the mature samples. On the same day that the mature acetonitrile/water extracts were analyzed and shown to contain 30-70% as “polar clopyralid”, additional analyses were made. These additional analyses combined day 0 acetonitrile/water extract with mature sugar beet shoot, or mature oilseed rape straw acetonitrile/water extracts, in each study. Keep in

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mind that the day 0 extracts contained 100% clopyralid, and that clopyralid is stable to hydrolysis and stable in crops for >13 months (EFSA 2018;16(7):5389). For sugar beet shoots, 700 µL of Day 0 extract (40,550 dpm/mL, 28,385 dpm, entirely clopyralid, 100 µL injection) plus 800 µL mature shoot extract (10,448 dpm/mL, 8358 dpm, 69.8% “polar clopyralid”, 200 µL injection) were combined (total 36,743 dpm). Based on these results, mathematically, the combined sample would contain ca 16% polar compounds, while at least 77% of the radioactivity should elute with clopyralid. The sample was combined less than 2 months after individually analyzing the day 0 extract.

Rather, upon injection of 200 µL of the combined sample, nearly 86% of the radioactivity eluted near the solvent front, with only 14% of the radioactivity eluting with clopyralid. Similar results were obtained for the mature oilseed rape straw acetonitrile/water extract combined with the Day 0 oilseed rape acetonitrile/water extract, where too much polar material eluted when 200 µL of the combined extract was analyzed. Since the day 0 fraction had recently demonstrated that the combined sample should contain a majority of clopyralid, and clopyralid is stable, yet the combined samples did not chromatograph as clopyralid, these data clearly demonstrate that injecting too much of a 50/50 acetonitrile/water extract onto the HPLC prompts early elution of clopyralid; clopyralid is not fully retained.

Furthermore, there was additional chromatography of the mature oilseed rape straw and mature sugar beet shoots acetonitrile/water extracts, in which the organic solvent was removed, and the samples made entirely aqueous (acetate buffer, pH 5.01), then the samples were heated to 37 °C for 18 hours. This heating cannot be considered significant, due to the low temperature. The slightly acidic pH (pH 5.01) is a very minor modification, and above the pKa of clopyralid (2.3), therefore, not protonating clopyralid. HPLC of the processed sample demonstrated less than 2% polar material in both samples. There were similarly low levels of polar material in sugar beet tubers made entirely aqueous and heated to 60 °C for 1 hour. These data demonstrate that the “polar clopyralid” is an artefact of the sample preparation/ chromatography.

To support this explanation of “polar clopyralid appearing near the solvent front, additional lab work was recently conducted at the Dow AgroSciences Indianapolis lab to confirm the previously reported results above, using non-radiolabeled clopyralid reference standard. Clopyralid was dissolved in 50/50 acetonitrile/water (v/v) at a concentration of ca 1 mg/mL. An HPLC system was set-up similar to the system used for the oilseed rape and sugar beet NORs above. The prepared standard was analyzed, in varying injection volumes of 10, 100, 200, and 250 µL. The clopyralid peak shape was sharp for the 10 µL injection, and gradually broadened, splitted, and included a more polar peak when at least 200 µL was injected. To confirm that the standard had not degraded, another 10 µL injection was made, resulting in sharp peak shape indicating no degradation. These results clearly indicate that although the majority of clopyralid is retained upon injection of larger volumes of acetonitrile/aqueous mixtures, there is peak broadening/splitting as well as an earlier eluting portion of clopyralid. These data clearly demonstrate that the “polar clopyralid” is an artefact of the sample preparation and/or chromatography.”

“metabolite B”

Metabolite B/ Unknown B" (also reported as "Unknown II") in the sugar beet and oilseed rape metabolism studies was stated to be identical to ‘clopyralid conjugates’. Unknown B is a temperature-labile conjugate of clopyralid forming clopyralid at elevated temperatures (60 °C, 1 h). Unknown B was characterized as less polar than clopyralid. The exact identity of the conjugate was not clarified in the studies and can possibly include more than one compound.

The applicant gave following explanation:

“Unknown B was only observed in the neutral-organic extract (ACN:H₂O). The levels in the sugar beets were too low to warrant further identification. A subsample of oilseed rape ACN:H₂O (1:1 v/v) extract was reduced to dryness under a stream of nitrogen and reconstituted in water. An aliquot (1 mL) of the

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concentrated extract was combined with an equal volume of 6 M HCl. A separate aliquot of the concentrated extract was combined with an equal volume of water (control). Both were incubated in a shaking water bath at 60 °C for 1 hour, neutralized and analyzed by HPLC system 2. HPLC revealed no unknown B was present in either the acidified or the control (heated only) extract, therefore Unknown B is a temperature-labile conjugate of clopyralid. Unknown B remained following treatment with glucosidase, indicating it is unlikely to be a glucose conjugate of clopyralid, i.e., no evidence for glucose deconjugation.”

“Metabolite B is a mixture of conjugates of clopyralid that are less polar than clopyralid, that easily release clopyralid upon treatment with caustic solution. This has been proven in both the pasture and cabbage NORs (DAS study IDs GH-C 4289 and GH-C 1424), as well as radiovalidation of the caustic extraction that quantitatively extracts clopyralid, as reported in the 30-d CRC (DAS study ID 130733). Therefore, the analytical methods (e.g., 120610) quantitatively measure clopyralid, free and conjugated, as clopyralid, thus allowing a worst-case residue level for consumer risk assessment purposes.”

RMS conclusions: RMS FI concluded, based on the further data provided by the applicant, that it has been sufficiently demonstrated that “polar clopyralid” / “metabolite A” is indeed an artefact of the sample preparation (content of organic solvent) / chromatography (injection volume), and cannot thus be considered to originate from plant metabolism. In case of “metabolite B”, clopyralid conjugates are a plausible explanation although their nature has not been confirmed. The caustic methanol extraction method used NOR studies and majority of MOR studies can be expected to sufficiently quantitate the conjugates in plant material.

ER, Art.6 MRL application on the setting of MRL(s) in various commodities; 31 May 2018, updated 14 November 2018, 25 January 2019, 3 May 2019, 14 November 2019 and updated for wheat NOR & MOR 17 August 2020

EFSA:

Clarification on the nature of the ‘unknown metabolite B’ in the plant metabolism studies and whether it is identical with the ‘polar form of clopyralid’ and ‘clopyralid conjugates’ should be provided. Furthermore, an explanation should be provided why in mature samples of sugar beet and oilseed rape ‘polar clopyralid’ and clopyralid were observed, while ‘polar clopyralid’ was not observed in immature samples, as the analytical procedure used was always the same within one study.

Reply from EFSA (26.11.2018):

Clarification on the nature of the ‘unknown metabolite B’ in the plant metabolism studies was provided by the applicant as follows: „The author’s OSR NOR conclusions were that “it is more likely that the acidic conditions of the sample optimise retention of clopyralid on the chromatography column...and that this component represents free clopyralid.” Similarly, the sugar beet NOR concluded that “Unknown A represents unchanged clopyralid which is in some way excluded from association with the C18 solid phase. There was no evidence for any deconjugation.

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It is understood that the argumentation is meant to clarify the nature of 'unknown A'¹. Although it sounds logic, for transparency reasons the details of the sample preparation and chromatographic conditions for the NOR studies with OSR and sugar beet should be listed, compared and analysed systematically and to substantiate this argument. It should be also confirmed that the term 'polar clopyralid' is referring always to a single structure (and not different polar compounds) and that these structure of 'polar clopyralid' is identical across all metabolism studies where identified.

In the same way facts and arguments should be systematically listed and analysed to substantiate the claim that "unknown B" is a clopyralide conjugate.

The argumentation / explanation provided by the applicant why in mature samples of sugar beet and oilseed rape 'polar clopyralid' and clopyralid were observed while 'polar clopyralid' was not observed in immature samples seems not to be coherent with the observation/interpretation of the RMS. Please clarify.

Reply from EFSA (18.3.2019):

The applicant provided in a tabulated format a summary of the extraction and analysis conditions of the samples of the OSR and sugar beet metabolism studies (Table S1).

From this summary it is understood, that the same extraction (ACN:H₂O, 1:1) and analysis conditions (HPLC system 1 with 2% acetic acid) were applied to immature and mature OSR and sugar beet plant parts resulting in the occurrence of the "unknown metabolite A" in mature sample extracts only whereas clopyralid was detected in both mature and immature plant material.

The argumentation that "unknown metabolite A" represents a protonated form of clopyralid seems not logic as it was only demonstrated with the mature sample material that a shift in pH resulted in disappearing of the unknown metabolite A. If a protonation of clopyralid occurred during analysis, the "unknown metabolite A" should have also been observed under the same analytical conditions (ACN:H₂O, 1:1) in the chromatograms of the immature plant extracts which also contained clopyralid.

The change in the sample workup and analytical conditions for mature sample parts resulted in the disappearance of the "unknown metabolite A". The conclusion that it was converted into clopyralid can be challenged without further identification, e.g. by MS. Another explanation could also be the co-elution of any compound with clopyralid due to the pH change.

The applicant is invited to provide further clarification on the nature of "unknown metabolite A".

RMS:

RMS considered Applicants' responses.

RMS concluded that the 'polar form of clopyralid' does seem to easily convert to protonated free clopyralid. Thus, it is probable, that the "polar form" represents either the non-protonated form or some other matrix effect-derived easily transformed form (such as chelates). In such case the form would not

¹ It should be noted that the "unknown A" refers to a polar form, whereas "unknown B" is referred to as clopyralide conjugate in the NOR with sugar beet. In the OSR NOR study the "unknown B" is referred to as clopyralide conjugate.

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originate from plant metabolism but would indeed be an artefact of sample preparation protocol. The current analytical methods as well as those used in the magnitude of residue trials can be considered to effectively analyze also the “polar form” provided that they sufficiently take into account possible matrix effects and the low pKa of clopyralid. RMS does not consider that the identity of the “polar form” needs to be studied any further, nor is there need to change the definition of residue suggested in the active substance review.

The applicant DAS stated that the metabolite ‘unknown B’ is a temperature-labile conjugate of clopyralid forming clopyralid at elevated temperatures. Unknown B was characterized as less polar than clopyralid. The exact identity of the conjugate was not clarified in the studies and can possibly include more than one compound. As all conjugates are included in the residue definition for monitoring and risk assessment this explanation is considered sufficient, provided that the analytical method for monitoring includes caustic methanol or other equivalent hydrolyzing extraction step capable of releasing clopyralid.

Based on the further clarification (9.1.2019), the identity of Unknown B still cannot be concluded. The plausible conjugate compound/compounds is/are fully degraded to clopyralid with either heat treatment or acid treatment but not with glucosidase enzyme treatment. Based on the data, only clopyralid-glucose conjugates are excluded as possible compounds.

After further explanations by the applicant on **09.01.2019**, EFSA commented on the metabolite issue in the following manner:

The applicant provided in a tabulated format a summary of the extraction and analysis conditions of the samples of the OSR and sugar beet metabolism studies (Table S1). From this summary it is understood, that the same extraction (ACN:H₂O, 1:1) and analysis conditions (HPLC system 1 with 2% acetic acid) were applied to immature and mature OSR and sugar beet plant parts resulting in the occurrence of the “unknown metabolite A” in mature sample extracts only whereas clopyralid was detected in both mature and immature plant material.

The argumentation that “unknown metabolite A” represents a protonated form of clopyralid seems not logic as it was only demonstrated with the mature sample material that a shift in pH resulted in disappearing of the unknown metabolite A. If a protonation of clopyralid occurred during analysis, the “unknown metabolite A” should have also been observed under the same analytical conditions (ACN:H₂O, 1:1) in the chromatograms of the immature plant extracts which also contained clopyralid.

The change in the sample workup and analytical conditions for mature sample parts resulted in the disappearance of the “unknown metabolite A”. The conclusion that it was converted into clopyralid can be challenged without further identification, e.g. by MS. Another explanation could also be the co-elution of any compound with clopyralid due to the pH change. The applicant is invited to provide further clarification on the nature of “unknown metabolite A”.

The applicant responded on **30.4.2019** after going through the material of OSR and beet studies.

“Although the extraction analytical procedures were identical within a study, and similar between studies (DAS study IDs GHE-P 9938 and GHE-P-9939), the chromatography was different between immature and mature samples. The samples analyzed by HPLC were of the same general composition, nominally 50/50, ACN/H₂O (v/v). However, after carefully reviewing the raw data of these studies (finalized in 2002), it was determined that a major, and very important difference, was that the HPLC injection volume was 100 µL for the immature samples, versus 200 µL injected for the mature samples. There

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was sufficient radioactivity in the immature samples for detection of 100 μL , however, a larger volume of 200 μL was needed for the mature samples.

As previously provided, column “break-through” resulting in radioactivity eluting near the solvent front, or peak splitting of a compound, can occur when samples are injected with a high percentage of organic (50% acetonitrile) in a larger injection (200 μL). This is particularly true for a polar compound such as clopyralid.

Evidence of this effect was observed during analysis of the mature samples. On the same day that the mature acetonitrile/water extracts were analyzed and shown to contain 30-70% as “polar clopyralid”, additional analyses were made. These additional analyses combined day 0 acetonitrile/water extract with mature sugar beet shoot, or mature oilseed rape straw acetonitrile/water extracts, in each study. Keep in mind that the day 0 extracts contained 100% clopyralid, and that clopyralid is stable to hydrolysis and stable in crops for >13 months (EFSA 2018;16(7):5389). For sugar beet shoots, 700 μL of Day 0 extract (40,550 dpm/mL, 28,385 dpm, entirely clopyralid, 100 μL injection) plus 800 μL mature shoot extract (10,448 dpm/mL, 8358 dpm, 69.8% “polar clopyralid”, 200 μL injection) were combined (total 36,743 dpm). Based on these results, mathematically, the combined sample would contain ca 16% polar compounds, while at least 77% of the radioactivity should elute with clopyralid. The sample was combined less than 2 months after individually analyzing the day 0 extract.

Rather, upon injection of 200 μL of the combined sample, nearly 86% of the radioactivity eluted near the solvent front, with only 14% of the radioactivity eluting with clopyralid. Similar results were obtained for the mature oilseed rape straw acetonitrile/water extract combined with the Day 0 oilseed rape acetonitrile/water extract, where too much polar material eluted when 200 μL of the combined extract was analyzed. Since the day 0 fraction had recently demonstrated that the combined sample should contain a majority of clopyralid, and clopyralid is stable, yet the combined samples did not chromatograph as clopyralid, these data clearly demonstrate that injecting too much of a 50/50 acetonitrile/water extract onto the HPLC prompts early elution of clopyralid; clopyralid is not fully retained.

Furthermore, there was additional chromatography of the mature oilseed rape straw and mature sugar beet shoots acetonitrile/water extracts, in which the organic solvent was removed, and the samples made entirely aqueous (acetate buffer, pH 5.01), then the samples were heated to 37 $^{\circ}\text{C}$ for 18 hours. This heating cannot be considered significant, due to the low temperature. The slightly acidic pH (pH 5.01) is a very minor modification, and above the pKa of clopyralid (2.3), therefore, not protonating clopyralid. HPLC of the processed sample demonstrated less than 2% polar material in both samples. There were similarly low levels of polar material in sugar beet tubers made entirely aqueous and heated to 60 $^{\circ}\text{C}$ for 1 hour. These data demonstrate that the “polar clopyralid” is an artefact of the sample preparation/chromatography.

The majority of data cited above were not included in the final report, however were found upon thorough review of the raw data. These data support the conclusions of the authors: that Unknown A is an artefact and is really unchanged clopyralid.

To support this explanation of “polar clopyralid appearing near the solvent front, additional lab work was recently conducted at the Dow AgroSciences Indianapolis lab to confirm the previously reported results above, using non-radiolabeled clopyralid reference standard. Clopyralid was dissolved in 50/50 acetonitrile/water (v/v) at a concentration of ca 1 mg/mL. An HPLC system was set-up similar to the system used for the oilseed rape and sugar beet NORs above. The prepared standard was analyzed, in varying injection volumes of 10, 100, 200, and 250 μL . The clopyralid peak shape was sharp for the 10

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µL injection, and gradually broadened, splitted, and included a more polar peak (5-7% of the Region of Interest eluting ca 4.7 minutes) when at least 200 µL was injected. To confirm that the standard had not degraded, another 10 µL injection was made, resulting in sharp peak shape indicating no degradation. These results clearly indicate that although the majority of clopyralid is retained upon injection of larger volumes of acetonitrile/aqueous mixtures, there is peak broadening/splitting as well as an earlier eluting portion of clopyralid. These data clearly demonstrate that the “polar clopyralid” is an artefact of the sample preparation and/or chromatography.”

The applicant gave further explanation also on the “metabolite B”:

“Metabolite B is a mixture of conjugates of clopyralid that are less polar than clopyralid, that easily release clopyralid upon treatment with caustic solution. This has been proven in both the pasture and cabbage NORs (DAS study IDs GH-C 4289 and GH-C 1424), as well as radiovalidation of the caustic extraction that quantitatively extracts clopyralid, as reported in the 30-d CRC (DAS study ID 130733). Therefore, the analytical methods (e.g., 120610) quantitatively measure clopyralid, free and conjugated, as clopyralid, thus allowing a worst-case residue level for consumer risk assessment purposes.”

RMS FI concluded, based on the further data provided by the applicant, that it has been sufficiently demonstrated that polar clopyralid / “metabolite A” is indeed an artefact of the sample preparation (content of organic solvent) / chromatography (injection volume), and cannot thus be considered to originate from plant metabolism. In case of “metabolite B”, clopyralid conjugates are a plausible explanation although their nature has not been confirmed. The caustic methanol extraction method used in NOR studies and majority of MOR studies can be expected to sufficiently quantitate the conjugates in plant material.

In response to EFSA’s comments on **June 3rd 2019**, the applicant submitted amended study reports of the sugar beet and oilseed rape metabolism studies (study reports 397619 (GHE-P-9939) and 397624 (GHE-P-9938)), and a non-GLP study on behavior of clopyralid chemical standard in the analytical HPLC conditions described in these NoR studies. Detailed evaluation of the submitted study reports were performed and can be found in this report (page 115). Based on the studies, EMS concluded following:

The “polar clopyralid”, also termed as Unknown A, was observed in the new study performed using analytical clopyralid standard. As the standard compound was shown to be stable, the appearance of the compound seems to be an artefact of the HPLC system. Unknown A appeared when high injection volume and high proportion of organic solvent was used.

Compared to the injection volumes, solvents and HPLC systems used in the sugar beet and oilseed rape metabolism studies, the above findings can be mostly confirmed with few exceptions. These exceptions could be explained by other matrix effects in the extract samples. It is possible, that Unknown A is a form of clopyralid that is sensitive to pH changes, especially in complex extracts. The increase of its relative amount in mixing two ACN:H₂O extracts (described in the sugar beet study) also indicates that it can form in situ in extracts, and thus would not be a plant metabolite.

Unknown B was hypothesised to be either heat-labile conjugate(s) or an artefact of the HPLC system. The component was found in the ACN:H₂O extracts of oilseed rape 28 DAT and mature straw and seed samples and at very low level in mature sugar beet shoots. The appearance of the component was not dependent on the HPLC system used or solvent change, while it seemed to be easily converted to

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clopyralid by heat treatment or long storage. It is thus not clearly resolved if the component is a labile clopyralid conjugate or similar component, or an artefact of the analysis system.

Unknown A and B were only detected in the neutral ACN:H₂O extracts while they were not detected in the caustic methanol (NaOH:MeOH) extracts. Thus, the compounds are degraded/transferred to clopyralid by caustic methanol extraction and can be reliably analysed as clopyralid.

The applicant stated that “the revised oilseed rape and sugar beet NORs, plus the HPLC analyses report, indicate that in all samples, Unknowns A and B were free or conjugated clopyralid, not a new/unidentified metabolite. The elution time may vary due to injection of too much organic and/or matrix effects and/or HPLC conditions (e.g., pH), but the results consistently indicate the entirety of the radioactive residue in immature and mature crop fractions is directly related to clopyralid.”

Further information was provided in **June 2020** by the applicant:

Furthermore, we have completed a **new wheat Nature of Residue study** (*Reference: The Metabolism of [¹⁴C]-Clopyralid in Wheat, 19 June 2020. GLP, unpublished. Dow AgroSciences Study: Study No: 191200*).

This Wheat Nature of Residue (NoR) study has been conducted after applying clopyralid at 125 g/ha (BBCH 39) and confirms the pathway observed in other crops, supporting the residue definition in all crops, especially cereals and pasture grass due to similarity with wheat forage.

No “polar clopyralid” was observed, because proper sample preparation was performed including limiting the amount of organic solvent injected onto the HPLC.

The study confirms the previous NORs in that “free” clopyralid is only detected in the neutral extracts, along with a broad peak similar to the previously reported clopyralid conjugates (“unknown B”). The radioactive residues are completely extracted (same general procedures as used in the original NORs), primarily with neutral followed by mild base; the mild base extracts contain only clopyralid. When the neutral extract containing the clopyralid conjugates is exposed to a mild base (5% ammonium hydroxide) for less than 1 hour, the residue becomes completely clopyralid. Formation of “conjugates” was replicated using clopyralid standard spiked onto control wheat grain – the “conjugates” were observed before treating with caustic, and disappeared after mild, quick caustic treatment. Since true conjugates cannot form so quickly with a frozen, milled tissue, it has been concluded that the “conjugates” are actually weak chromatographic interactions between the clopyralid and the matrix, that are easily interrupted with mild caustic. Any sort of light manipulation of the sample (SPE, changing the pH, etc.) removed the “unknown B” region. Therefore, this region can be identified as base labile-clopyralid. In total, 92.6-97.2% of the residue (normalized) was identified as clopyralid.

In conclusion, the additional evidence from existing plant metabolism studies including a new wheat plant metabolism study confirm that polar clopyralid (also called unknown A and unknown 1) is an artefact of the sample preparation (content of organic solvent)/ chromatography (injection volume) and is clopyralid. Unknown B is mild caustic-labile conjugates of clopyralid. The majority (>90%) of the residue can be considered to be clopyralid, which is fully quantitated using the existing field trial analytical method. The EFSA proposed plant residue definition for risk assessment and monitoring (clopyralid common moiety as sum of clopyralid, its salts and conjugates expressed as clopyralid) is justified and can be adopted.

RMS comments:

The results of the new wheat metabolism study indicate that the detected wide, less polar region eluting after the main clopyralid peak is composed of clopyralid that is loosely bound to or interacting with coextracted plant material where it is easily released from. The ease of release of this “base-labile” clopyralid does not support the presence of covalently bound clopyralid conjugates or other similar compound that could be regarded as plant metabolite.

EMS considers the new wheat metabolism study as acceptable and it can be used to confirm the previously suggested residue definitions.

The new study does not answer to the questions raised on metabolite A detected in the sugar beet and OSR studies as no such polar clopyralid was detected in the wheat metabolism study. The possible reasons were the use of optimized analytical methods and lower solvent use at injection, assuming that the more polar region is an artefact of the analytical method.

Note that “polar clopyralid” was not observed in the current oilseed rape metabolism study (2021) nor the on-going sugar beet metabolism study. The Sponsor still considers the more polar regions to be an artefact of the analytical procedures.