REGISTRATION REPORT
Part A
Risk Management

Product code: EF-243

Product name(s): Lontrel 300

Chemical active substance:

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

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(Renewal of Authorization under Art.43)

Applicant: Corteva Agriscience

Submission date: 20/12/2021

MS Finalisation date: 05/12/2022

After commenting: 22/02/2023

zRMS evaluation following Applicant's amendment: November 2023

zRMS correction: January 2024

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

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

zRMS – update of the report at the request of the applicant: June 2024

zRMS – update of GAP and Appendix 2 – September 2024

Correction of Appendix 4 – October 2024

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
November 2023	zRMS evaluation following Applicant's amendment
January 2024	zRMS correction
February 2024	zRMS - update of the report in terms of additional onion and honey study study submitted by Applicant
April 2024	Update of the report in terms of honey study (national approach)
June 2024	zRMS – update of the report at the request of the applicant
September 2024	zRMS – update of GAP and Appendix 2 Applicant replaced Appendix 4 "List of data submitted by the applicant and relied on" to remove duplications of studies and multiplication error of table.
October 2024	Correction of Appendix 4

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Corteva Agriscience in December 2021.

The application is for the renewal of authorization under Art.43 of the formulation EF-243, a soluble concentrate (SL) containing Clopyralid – olamine (395 g/L (300 g ae/L)) active substance for use as a herbicide.

zRMS is Poland for this application and cMS are Czech Republic and Slovakia.

1.2 Letters of Access

Access to the data relied on in the active substance renewal: Letter of access are not necessary for the application. Corteva Agriscience is the owner of the clopyralid Annex I Renewal data and was the only notifier.

Corteva Agriscience is the producer of Clopyralid technical. This application refers to the same technical source that has been assessed during the EU active substance renewal process. In addition, a letter of access is provided for the other sources not evaluated during the EU active substance renewal evaluation process.

1.3 Justification for submission of tests and studies

The studies submitted are necessary for authorization in Central Zone and are in accordance with Reg. (EU) No. 284/2013.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	EF-243 (Lontrel 300 SL)

Product name in MS	Lontrel 300 SL
Authorization number	R - 88/2010
Function	Herbicide
Applicant	Corteva Agriscience
Active substance(s) (incl. content)	Clopyralid – olamine; 395 g/L (300 g ae/L)
Formulation type	Soluble concentrate [SL]
Packaging	Bottles/Jerrican 0.05, 0.10, 0.15,0.25, 0.5, 1, 2, 3, 5, 10 L, 15 L and 20 L - PET
Coformulants of concern for national authorizations	None
Restrictions related to identiy	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for Lontrel 300 SL resulted in the decision to grant the authorization for beets, cereals and onion.

Noticed data gaps are:

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.

The applicant provided the honey study report. The zRMS found the study acceptable however the current MRL for clopyralid in honey is potentially exceeded. 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, it is proposed to raise the 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.

No national monitoring data are available by the applicant.

2.3 Classification and labelling

2.3.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Chronic 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard symbol(s)

GHS09

Signal word Warning

Hazard statement(s)

Aquatic chronic 1	H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P280 Wear protective gloves and protective clothing.
P391 Collect spillage.P501 Dispose of contents/container in accordance with applicable regulations.

EU specific statement(s)
EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

See Part C for justifications of the classification and labelling proposals.

2.3.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.3.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None required.

2.4 Risk management

2.4.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Wear protective gloves and protective clothing.

Worker protection:	
respective code if available	national PPE requirements
Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
respective code if available	buffer zones or other national risk mitigation
Other specific restrictions	
respective code if available	are there any other national requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

2.4.2 Specific restrictions linked to the intended uses

No specific restrictions are required.

2.5 Intended uses (only NATIONAL GAP)

			GAP rev. 1, date: 2021-December-
PPP (product name/code):	EF-243	Formulation type:	SL [a, b]
Active substance 1:	Clopyralid-olamine	Conc. of as 1:	395.26 g a.s/L (300 g ae/L) [c]
Safener:	NA	Conc. of safener:	NA [c]
Synergist:	NA	Conc. of synergist:	NA [c]
Applicant:	Corteva Agriscience	Professional use:	☒
Zone(s):	Central zone[d]	Non professional use:	☐
Verified by MS:	yes		

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 1st)	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 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 Not requested
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 Not requested
16	Maize (grain, forage) EU MRL Code:	CEU	EF-243	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 30-32	1	-		100-400	0.102	60 (forage) 90 (grain)	A Not requested

	0500030				spp.)											
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 arv-ense, Matricaria spp.)	SL	395.26 g as/L (300 g ae/L)	Foliar	BBCH 11-16	1	-		100-400	0.120	42	A

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of hazy, pale yellow liquid. It is not explosive, has no oxidising properties. The product has a flash point of >100 °C. It has a self ignition temperature of greater than 400°C. In aqueous solution, it has a pH value around 7.38 at 21.6 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PET. Its technical characteristics are acceptable for a SL formulation.

No application is being made for the authorisation of the combined use of the preparation with any other product. However the product is expected to be compatible (physically/chemically) in mixtures with other commercial products in agitated spray tanks.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

This core assessment concerns the renewal of authorisation of the field uses of the herbicide EF-243, which is currently authorised under product name Lontrel 300 SL in the Czech Republic, Poland and Slovakia according to Art. 43 of Regulation (EC) No. 1107/2009, following the renewal of active substance clopyralid. EF-243 is formulated as a Soluble Liquid concentrate (SL-formulation) and contains 300 g a.e./L clopyralid. The product is currently authorised for use as a post-emergence herbicide for the control of broadleaf weeds in a range of crops: sugar beet (BEAVA), fodder beet (BEAVC), red beet (BEAVD), mangel (BEAVC) winter oilseed rape (BRSNW), maize (ZEAMX), winter and spring barley (HORVW, HORWS), winter and spring oat (AVESW, AVESP), winter and spring wheat (TRZAW, TRZAS), winter and spring rye (SECCW, SECCS), winter and spring (TTLWI, TTLSO), flax/linseed (LIUUT), grass for seeds (YGRAS), lawn (NNNZW), onion for seeds (ALLCE/ALLXS) and gladiolus (1GLAG).
The renewal is based on an unchanged product, and product formulation remains the same, whereas for grass for seeds, lawn, maize, winter and spring cereals and sugar beet uses, the GAP table has been revised by dose rate reduction and or application timing. The applicant states that these changes were caused by new risk assessment endpoints and were implemented to align with the residue data package.
To support reduced dose rates as a result of new regulatory endpoints, the applicant presented bridging data of other registered clopyralid formulations to demonstrate their equivalence and use them as support of EF-243. Thus, the conclusions drawn from the efficacy evaluation concern uses where the GAP was changed.

For the following intended uses PL as zRMS would accept the efficacy of the applied data:
- cereals, grass for seeds and lawn uses.

For the following application, PL as zRMS would not accept the data provided:
- sugar beet - split dose application use (NE region).

For the following intended uses the concerned Member States are kindly asked to decide themselves whether to accept provided data or not:
- maize, sugar beet - split dose application use (Southeast and Maritime EPPO regions).

In the framework of Article 43 the applicant submitted an updated analysis of the resistance risk (following EPPO guideline PP 1/213 (1) "Resistance risk analysis") which is required for the renewal of Lontrel 300 SL containing 300 g a.e./L of the active substance clopyralid. Based on the updated resistance risk analysis, zRMS concluded that the resistance risk for the active substance clopyralid within Lontrel 300 SL can be considered acceptable.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The method, described in Part B Section 5 (Methods) has been sufficiently validated for the determination of clopyralid in EF-243. For further information, please refer to Part B Section 5 (Methods) of the current dRR.

3.4.2 Analytical methods for residues

Adequate methods are available for the determination of clopyralid, its salts and conjugates in plants, plant products, foodstuff (of plant origin) and in foodstuff (of animal origin). Appropriate LC-MS/MS methods have been validated with a limit of quantitation (LOQ) of 0.01 mg/kg in representative matrices, in accordance with the respective residue definitions and also have been verified by independent laboratory validation (ILV).

Adequate method is available for the determination of clopyralid in soil. An appropriate LC-MS/MS method was validated with an LOQ of 0.5 µg/kg.

Adequate methods are available for the determination of clopyralid in surface and drinking water. An LC-MS/MS method was validated with an LOQ of 0.05 µg/L in surface and drinking water and verified by an appropriate independent laboratory validation (ILV).

An Adequate method is available for the determination of clopyralid in air. An LC-MS/MS method was validated with an LOQ of 4.5 µg/m^3 in air.

3.5 Mammalian toxicology (Part B, Section 6)

Acute studies were conducted with EF-243. Overall, EF-243 has very low toxicity profile. The results were summarized below.

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 401)	(>) 5000 mg/kg bw	None	Guest, R. L., 1990
LD_{50} oral, rat (None)	(>) 5000 mg/kg bw	None	Vosvenieks, D. J., 1981
LD_{50} dermal, rat (OECD 402)	(>) 2000 mg/kg bw	None	Guest, R. L., 1990

LC_{50} inhalation, rat (OECD 403)	(>) 4.27 mg/L air	None	Guest, R. L., 1990
Skin irritation, model system (OECD 404)	Non-irritant	None	Guest, R. L., 1990
Eye irritation, model system (OECD 405)	Non-irritant	None	Guest, R. L., 1990
Skin sensitisation, guinea pig/mouse (OECD 406)	Non-sensitising	None	Guest, R. L., 1990

3.5.1 Acute toxicity

Acute studies were conducted with EF-243. Overall, EF-243 has very low toxicity profile. Specifically, oral LD50 is greater than 5000 mg/kg, dermal LD50 is greater than 2000 mg/kg, LC50 is great than 4.27 mg/L. Additionally, EF-243 is not an eye and skin irritant and it does not cause skin sensitization. For detailed information, please refer to B6.

3.5.2 Operator exposure

Grassland and Lawn application had the worst-case exposure for operators in the EFSA model, while for workers, residents, and bystanders, bulb vegetables had the worst-case exposure scenario for all supported applications. This is due to the crop-specific differences in working hours, worker task activity and the concentration of the active in-use dilution for liquid application.

Estimated exposures (acute and longer term) from the proposed uses of EF-243 have been evaluated using the EFSA Calculator and do not present a risk for operators. Chronic operator exposure to clopyralid from grasslands and lawns was estimated to be 10% of the AOEL with the use of gloves during mixing/loading only and standard work wear. Acute operator exposure to clopyralid from grasslands and lawns was estimated to be 68% of the AAOEL, also based on standard work wear and gloves worn during mixing/loading.

3.5.3 Worker exposure

For supported re-entry worker activities, bulb vegetables had the worst-case exposure scenario for all supported applications. No unacceptable risk for workers from the supported uses (reaching and picking; 8 hr/day) of EF-243 was identified based on exposure estimates from the EFSA Model. The predicted worker exposure to clopyralid was 40% of the AOEL, based on normal work wear and no additional PPE. There are currently no acute re-entry worker exposure data/scenarios in the EFSA Model.

3.5.4 Bystander and resident exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

During the clopyralid renewal process the AOEL was revised and an AAOEL established. Both resident and bystander assessments are, therefore, relevant to EF-243 and are presented below.

One application scenario was considered appropriate to assess resident and bystander exposure (worst-case scenario based on the highest supported application rate and the lowest supported application water volume). The maximum predicted all route resident (child) mean exposure was at 12% of the AOEL. For bystanders the maximum individual route of exposure (bystander child; spray drift) was at 22% of the AAOEL. Assessments are based on default approaches.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

The formulated product EF-243 is a soluble concentrate formulation (SL) containing the active substance clopyralid (300 g ae/L; formulated as clopyralid – olamine (395.26 g/L)). EF-243 is proposed for use as an herbicide on pasture, maize, onion, winter and spring cereals, sugar beet (fodder beet and red beet), and winter oilseed rape in the central EU regulatory zone. New magnitude of the residue, processing, and field rotational crop studies have been submitted in the framework of this application, and adequate residue trials are available to support the proposed uses. The residue data show that no exceedances of the current EU MRLs will occur.

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 all Article 43 uses presented in this submission (including consideration of rotational residues). The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.
In Poland, the requested use, according to the label submitted by the applicant, included beets (sugar, red and fodder), oilseed rape and onion for seeds. In the case of oilseed rape and beet, when plant metabolism studies assessed at EU level are published, it will be necessary to verify the assessment performed.

3.6.2 Consumer exposure

Chronic and acute dietary assessments conducted for clopyralid using the EFSA PRIMO (rev. 3.1) indicate no risks of concern for the consumer. The chronic risk assessment is based on current MRLs from Reg. 2018/1514, apart from indicated animal products, wheat, and oat which considered MRLs adopted in the Article 6 MRL Evaluation Report (EFSA Journal 2021; 19(1):6389). The acute dietary assessments are performed only for the commodities for which GAPs are notified. The assessments are highly conservative and assume no dissipation of residues.

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.

3.7 Environmental fate and behaviour (Part B, Section 8)

The formulated product EF-243 contains the active substances clopyralid (300 g ae/L; formulated as clopyralid – olamine (395.26 g/L)). Concentrations of the active substance clopyralid in various environmental compartments are predicted following use of EF-243 according to the proposed risk envelope for each individual active substance.

Based on data evaluated in the EU review for clopyralid, appropriate endpoints were used to calculate PEC values for formulation EF-243 and for active substance clopyralid in soil, surface water and ground water for the intended use patterns. No major metabolites of clopyralid were formed in soil (*i.e.* those >10% AR, >5% AR at sequential sampling intervals or >5% AR and increasing at the end of the study) and are thus not considered further in the risk assessment

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The predicted environmental concentration of each active substance in soil (PECsoil) was calculated following the recommendations of the FOCUS Soils Group (FOCUS, 1997). Calculations assume that any of the applied active substance reaching the soil surface is distributed uniformly to a depth of 5 cm (with no mechanical incorporation). The bulk density of soil is assumed to be 1.5 g/cm^3. The results for PECsoil for the active substance were used for the ecotoxicological risk assessment.

Clopyralid

Based on the risk envelope, the maximum initial predicted environmental concentration in soil (PEC_{soil}) of clopyralid will be 0.144 mg/kg.

Formulation EF-243

Based on the use rate of 0.667 L EF-243 / ha (equivalent to 760.9 g/ ha), the maximum initial predicted environmental concentration in soil (PEC_{soil}) of the formulation EF-243 will be 0.913 mg/kg.
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3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC_{GW} of active substance clopyralid in ground water has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO and FOCUS PEARL (tier 1) and FOCUS MACRO (tier 2) models using the input parameters established in the EU review. No calculations were performed for the formulation EF-243, since its components, other than the active substance, will dissipate rapidly after application.

Clopyralid

The predicted environmental concentrations (PEC_{GW}) at 1 m depth for clopyralid following annual, biennual or triennial application to various crops were no greater than 0.036 µg/L for relevant GAP scenarios at tier 2 using FOCUS MACRO. Unacceptable leaching of clopyralid after application of EF-243 within the GAP is therefore unlikely to occur.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PECs of the active substance clopyralid in surface water (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW models and the parameters established in the 2018 EU review. Based on the GAPs, the maximum PEC values for surface water and sediment have been calculated using the FOCUS Steps 1 to 3 tools (clopyralid) and the FOCUS spray drift calculator (EF-243).

The results for PEC surface water for the active substance were used for the ecotoxicological risk assessment.

Clopyralid

The maximum PEC_{SW} values for clopyralid applications to various crops are 68.4 µg/L at Step 1 and 12.6 µg/L at Step 2.

The maximum PEC_{SED} values for clopyralid applications to various crops are 0.964 µg/kg at Step 1 and 0.178 µg/kg at Step 2.

No major metabolites of clopyralid were formed and are thus not considered further in the risk assessment.

Formulation EF-243

The initial predicted environmental concentration of the formulated product EF-243 has been calculated using the FOCUS SWASH Drift calculator. The maximum PEC_{SW} for EF-243 was calculated to be 4.04 µg/L with 0% drift reducing nozzle and FOCUS default spray drift buffer zone.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance clopyralid is estimated to be > 10^{-4} Pa (7.07×10^{-4}; calculated with EVA 3). Hence the active substance clopyralid is regarded as semi-volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the clopyralid due to volatilisation with subsequent deposition should be considered. The low Henry's Law Constant indicates that partitioning into air is negligible. Therefore the risk of long range transport of clopyralid is acceptable.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Avian toxicity studies have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of EF-243 were not evaluated as part of the latest EU assessment of clopyralid. New data has generated for EF-243. New data submitted with this application is listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in **Błąd! Nie można odnaleźć źródła odwołania.** in the Core dossier Section B9. The risk assessment was based on the active substance endpoints.
An acceptable acute and long-term risk to birds at screening level is expected from the proposed uses of EF-243 without the need of any refinement

Mammalian toxicity studies have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of EF-243 were not evaluated as part of the EU assessment of clopyralid. However, the provision of further data on the EF-243 is not considered essential, because the toxicity can be predicted on the basis of the data for the active substance due to the fact that EF-243 is an aqueous soluble concentrate of clopyralid with no additional co-formulants.
An acceptable acute and long-term risk to mammals is expected from the intended uses of EF-243 without the need of any refinement

3.8.2 Effects on aquatic species

Studies on the toxicity to aquatic organisms have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on aquatic organisms of EF-243 were not evaluated as part of the last EU assessment of clopyralid. Data on EF-255, EF-243, GF-2895 and GF-1966 is available. EF-255/EF-243 are a dilution of clopyralid (as monoethanolamine salt) in water. GF-1966 is a granule formulation of clopyralid (as monoethanolamine salt) containing a small amount of water. GF-2895 is a dilution of clopyralid (as dimethylamine salt) in water. EF-1136 a soluble concentrate (SL) formulation containing 100 g clopyralid ae/L Following dilution with water within the spray tank, immediately prior to application, the resulting spray solutions are equivalent for purposes of ecotoxicology. New data submitted with this application is listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in **Błąd! Nie można odnaleźć źródła odwołania.** in the Core dossier Section B9.
An acceptable risk for aquatic organisms is concluded for all the intended uses of EF-243 without the need of any mitigation.
Effects

3.8.3 Effects on bees

Studies on the toxicity to bees have been carried out with clopyralid Full details of these studies are provided in the respective EU DAR and related documents. New data submitted with this application is listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in **Błąd! Nie można odnaleźć źródła odwołania.** in the Core dossier Section B9.
Effects on bees of EF-243 were not evaluated as part of the last EU assessment of clopyralid. However, the provision of further data on the EF-243 is not considered essential, because the toxicity can be predicted on the basis of the data for the active substance due to the fact that EF-243 is an aqueous soluble concentrate of clopyralid with no additional co-formulants.
An acceptable risk to bees is expected from the proposed uses of EF-243 without the need of any risk mitigation.

3.8.4 Effects on other arthropod species other than bees

Studies on the toxicity to non-target arthropods have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of EF-243 were not evaluated as part of the EU assessment of clopyralid. Data is available for EF-1136. Following dilution with water within the spray tank, immediately prior to application, all formulations are equivalent. Therefore, all will have equivalent toxicological properties to arthropods and thus additional testing with EF-243 is not necessary for the purposes of risk assessment.
An acceptable risk for non-target arthropods is concluded for all the intended uses of EF-243 without the need of any mitigation.

3.8.5 Effects on soil organisms

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on earthworms of EF-243 were not evaluated as part of the EU assessment of clopyralid. The DT_{90f} of clopyralid has a mean value of 38 days. Furthermore, the HQs for arthropods were less than 2. Due to the lack of effects and clopyralid not being persistent in soils, further data on other non-target soil organisms (meso- and macrofauna) are deemed unnecessary. However, for completeness data on other non-target soil organism (springtail and soil mite) has been generated for GF-1966. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 in the Core dossier Section B9.
Following dilution with water within the spray tank, immediately prior to application, all LONTREL formulations are equivalent. Therefore, all will have equivalent toxicological properties to arthro-pods. Therefore, additional testing with EF-243 is not necessary for the purposes of risk assessment.
An acceptable risk to earthworms and soil macro-organisms is expected from the proposed uses of EF-243 for all the intended uses without the need of any risk mitigation

Studies on effects soil microorganisms have been carried out with clopyralid. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on soil microorganisms of EF-243 were not evaluated as part of the EU assessment of clopyralid. Data is available for EF-1136. Following dilution with water within the spray tank, immediately prior to application, all formulations are equivalent. Therefore, all will have equivalent toxicological properties to soil microorganisms and thus additional testing with EF-243 is not necessary for the purposes of risk assessment
An acceptable risk to soil micro-organisms is expected from the proposed uses of EF-243 without the need of any risk mitigation.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants of EF-243 were not evaluated as part of the EU assessment of clopyralid. New data for GF-1966 is submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** summarised in **Błąd! Nie można odnaleźć źródła odwołania.** in the Core dossier Section B9. The new studies for GF-1966 follow the OECD plant density recommendations and include the ER_{50} based on visual injury. Following dilution with water within the spray tank, immediately prior to application, all LONTREL formulations are equivalent. Therefore, additional testing with EF-243 is not necessary for the purposes of risk assessment.
An acceptable risk to non-target plants is expected from the proposed uses A-E and G (max application rate 120 g ae/ha) of EF-243 without the need of any risk mitigation measurement.
For Group F (established grassland >1 year; max application rate 200 g ae/ha) an acceptable risk to terrestrial non-target plants can be anticipated following uses of EF-243 with the following mitigation measurements:

- 1 m distance to the treated field when 50% drift reducing nozzles are used during terrestrial applications or
- 5 m distance to the treated field without drift reducing nozzles

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No effects on other terrestrial organisms are anticipated if the previously proposed risk mitigations are implemented during applications of EF-243 in all the intended uses.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant. There are no metabolites of clopyralid predicted to occur in groundwater (see Part B8).

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance Clopyralid is not the candidate for substitution therefore the national comparative assessment is not required.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

When the results of the plant metabolism studies in oilseed rape and sugar beet, evaluated at UE level are available, it will be necessary to verify the evaluation performed. The holder of authorization shall be required to confirm that the product can be used in the abovementioned applications.

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.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Załącznik do decyzji MRiRW nr
zmieniającej zezwolenie MRiRW nr R - 88/2010 z dnia 15.12.2010 r.

Posiadacz zezwolenia:
Corteva Agriscience Poland Sp. z o.o. ul. Józefa Piusa Dziekońskiego 1, 00-728 Warszawa,
+48 22 548 73 00, +48 22 548 73 09, e-mail: biuro@corteva.com, www.corteva.pl

Lontrel 300 SL

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej: chlopyralid (substancja z grupy pochodnych kwasu karboksylowego) - 300 g/l

Zezwolenie MRiRW nr R - 88/2010 z dnia 15.12.2010 r.
ostatnio zmienione decyzją MRiRW nr R -

UWAGA !

H410 - Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe zmiany

EUH 401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia

P280 – Stosować rękawice ochronne i odzież ochronną.

P391 – Zebrać wyciek.

OPIS DZIAŁANIA

Lontrel 300 SL jest środkiem chwastobójczym w formie koncentratu do sporządzania roztworu wodnego, stosowanym nalistnie, w rzepaku ozimym, buraku cukrowym i cebuli.
Środek Lontrel 300 SL przeznaczony jest do stosowania przy użyciu opryskiwaczy polowych.

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liście chwastów. Powoduje blokadę auksyn tj. hormonów roślinnych odpowiedzialnych za wzrost roślin. Unieczynnienie hormonów wzrostu powoduje w efekcie wstrzymanie syntezy aminokwasów, ponadto środek zakłóca proces oddychania na poziomie komórkowym.
Najskuteczniej niszczy młode, intensywnie rosnące chwasty, od fazy 2-3 liści do fazy rozety.

Chwasty wrażliwe: chaber bławatek, maruna bezwonna, ostrożeń polny, psianka czarna, rdest plamisty, rumian polny, rumianek pospolity, żółtlica drobnokwiatowa.
Chwasty średnio wrażliwe: **komosa biała**.
Chwasty średnio odporne: szarłat szorstki.
Chwasty odporne: **bodziszek drobny, fiołek polny, gwiazdnica pospolita, mak polny, przytulia czepna, tasznik pospolity, tobołki polne oraz** chwasty jednoliścienne.

STOSOWANIE ŚRODKA

RZEPAK OZIMY
Termin stosowania środka:
a) jesienią - w fazie 4-6 liści rzepaku.
b) wiosną - w momencie ruszenia wegetacji, jednak nie później, niż do rozpoczęcia tworzenia przez rośliny rzepaku pąków kwiatowych.

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0,3-0,4 l/ha
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1
Zalecana ilość wody: 200-300 l/ha.
Zalecane opryskiwanie: średniokropliste.

BURAK CUKROWY Termin stosowania środka: w fazie 2-4 liści buraka.

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0,3-0,4 l/ha Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1 Zalecana ilość wody: 200-300 l/ha.
Zalecane opryskiwanie: średniokropliste.

CEBULA Z SIEWU
Termin stosowania środka: w fazie wyraźnie widocznych 3 liści.

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0,3-0,4 l/ha Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1 Zalecana ilość wody: 200-300 l/ha.
Zalecane opryskiwanie: średniokropliste.

NASTĘPSTWO ROŚLIN

Po zbiorze można uprawiać warzywa kapustne, liściaste, korzeniowe, zboża oraz nasiona oleiste. Pozostałe rośliny można uprawiać po upływie 30 dni od zastosowania środka.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Na cebuli środek Lontrel 300 SL powoduje przemijające objawy fitotoksyczności tj. lekkie chlorozy lub skręcanie liści i ich wyłożenie. Objawy te mijają po około 2 tygodniach i nie mają wpływu na plon cebuli.
2. W celu niedopuszczenia do powstania odporności chwastów nie stosować dawek ani wyższych ani niższych od zalecanych, środek stosować przemiennie z herbicydami o różnym mechanizmie działania
3. Podczas stosowania środka nie dopuścić do:

− znoszenia cieczy użytkowej na sąsiadujące rośliny uprawne (szczególnie zioła i niektóre warzywa),
− nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

4. Środka nie stosować na roślinach mokrych oraz uszkodzonych przez choroby i szkodniki, w mieszaninach z nawozami.
5. 5. Materiału roślinnego, który opryskano środkiem nie wolno używać do kompostowania ani ściółkowania.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać.
W przypadku stosowania środka w mieszaninach z innymi środkami przestrzegać ściśle zaleceń dotyczących sporządzania cieczy użytkowej tych środków.
W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub – unieszkodliwić w inny sposób, zgodny z przepisami o odpadach. Po pracy aparaturę dokładnie wymyć.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić ani nie palić podczas używania produktu. Nosić odpowiednią odzież ochronną.

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.
W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Rzepak ozimy: Nie dotyczy
Burak cukrowy: 42 dni
Cebula z siewu: 42 dni

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):
Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następczo: Należy uwzględnić następstwo roślin

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą.

Przechowywać w temperaturze 0 ^{o}C - 30^{o}C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

The letter of access is confidential information and it has been submitted separately.

Appendix 4 Lists of data considered for national authorization

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	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 2.1 KCP 2.3.1 KCP 2.4.2 KCP 2.5.1 KCP 2.6.1	Croffie, J.	2019	Determination of Color, Odor, Physical State, pH, Density, Flashpoint and Viscosity for EF-243 191215 Dow Agrosciences GLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 2.2.2 KCP 2.3.3 KCP 2.5.2	Cowlyn, N.	2019	Determination of Oxidising Properties, Auto-Ignition Tem-perature and Surface Tension of EF-243 191214 Covance CRS Limited GLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 2.2.1 KCP 2.5.2	Turner, B.	2005	Determination of Surface Tension and Explosive Properties for EF-243 NAFST-04-872 Huntingdon Life Sciences Ltd. GLP Unpublished	N	N		Corteva Agrisci-ence
KCP 2.7.4	Koors, B.	2010	One Week Low Temperature Storage of EF-243 NAFST-10-67 Dow Agrosciences Not GLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 2.4.2 KCP 2.7.2 KCP 2.7.5 KCP 2.8.2	Stock, M.	2007	Storage Stability and Package Corrosion Characteristics of EF-243; Accelerated and Two-Year Ambient Study FOR-05-003 Dow Agroscience	N	N		Corteva Agrisci-ence

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 2.8.4			GLP Unpublished				
KCP 4.2	Huby, JP.	2019	GF-1966 Tank Clean Out Study Following EPPO 1/292 guid-ance 191711 Corteva Agriscience nonGLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 5.1.1	O'Connor, B.J.	2019	EF-243: Analytical Method Validation for the Determination of the Active Ingredient (Clopyralid) Content AM-191198 Covance CRS Research Limited GLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 5.1.2 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	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 5.1.2 KCA 6.1	Teasdale, R.	1996	Frozen Storage Stability of Clopyralid Residues in Strawber-ries Corteva Report No. GHE-P-4832 Study No. CEMS-235 CEM Analytical Services Ltd. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland If previously submitted in this MS: Data protection started with: R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 5.1.2 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) GLP Unpublished	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence
KCP 5.1.2 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	N	Y	Data/study report never submit-ted before to <Poland>	Corteva Agrisci-ence

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Straw), following One Application of GF-3488, Northern Europe - 2015 DAS Report No. 150534 Study No. RDE-15-20400 Staphyt GLP Unpublished			If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	
KCP 5.1.2 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 Unpublished	N	Y	Data/study report never submitted before to <Poland>	Corteva Agriscience
KCP 5.1.2 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	Y	Data/study report never submitted before to Poland If previously submitted in this MS: Data protection started with: R - 88/2010, 15.12.2010	Corteva Agriscience
KCP 5.1.2 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	Y	Data/study report never submitted before to <Poland>	Corteva Agriscience
KCP 5.1.2 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-10605	N	N		Corteva Agriscience

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			CEM Analytical Services Ltd (CEMAS) GLP Unpublished				
KCP 5.1.2 KCA 6.3.5/03	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–2546 DAS Report No. GHL-P-4108I CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	N		Corteva Agriscience
KCP 5.1.2 KCA 6.3.5/03	Devine, H.C.	2005	Residues of Clopyralid in Onions at Intervals Following Two Applications of Lontrel 100 (EF–1136), Northern Europe - 2005 Study No. CEMS–2595 DAS Report No. GHL-P-4127I CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	N		Corteva Agriscience
KCP 5.1.2 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. GHL-P-5280I CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 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	Y	Data/study report never submitted before to Poland If previously submitted in this MS: Data protection started with: R - 88/2010, 15.12.2010	Corteva Agriscience

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2 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	Y	Data/study report never submitted before to <POLAND>	Corteva Agriscience
KCP 5.1.2 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	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.2	Arnie, J.R., Zhao, J., Aufderheide, J.A., Zhang, L., Fierman, L.A.	2020	EF-243: A 72-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata) DAS Study ID 200843 Eurofins EAG Agroscience LLC GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.2	Arnie, J.R., Zhao, J., Aufderheide, J.A., Zhang, L	2020	GF-2895: A 72-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata) DAS Study ID 191747 Eurofins EAG Agroscience LLC GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.2	Banman, C. S. and S. Moore	2015	GF-1966: Toxicity to the Aquatic Macrophyte, Myriophyllum spicatum. DAS Study ID 150051 SynTech Research Laboratory Services GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience

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KCP 5.1.2 KCP 10.2	Gonsior G.	2018	GF-2895: Growth Inhibition of Myriophyllum spicatum in a Water/Sediment System DAS Study ID 170354 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.2	[redacted]	2020	EF-243: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss) [redacted] GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.2	Ross, T. L., Zhao, E., Zhang, L., Schneider, S.Z.;	2020	EF-243: A 48-Hour Static Acute Toxicity Test With the Cladoceran (Daphnia magna) DAS Study ID 200842 Eurofins EAG Agroscience LLC GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCA 8.3.1	Tänzler, V., Kowalczyk, F.	2019	Clopyralid: Effects (Acute Contact and Oral) on Bumblebees (Bombus terrestris L.) in the Laboratory DAS Study ID 190300 ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.6	Stead, A.	2019	GF-1966: Seedling Emergence and Seedling Growth Test Terrestrial Non-Target Plants DAS Study ID 190288 Stockbridge Technology Centre Ltd GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.1.2 KCP 10.6	Davies, C.	2019	GF-1966: Vegetative Vigour Test Terrestrial Non Target Plants DAS Study ID 190287 Stockbridge Technology Centre Ltd GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Sahvorost, N.	2020	Title: Extraction Efficiency Assessment of Clopyralid in High Oil Content Plants Study No.: 200353 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.2	Fears, S.L.	2019	Assessment of the Extraction Efficiency of the Analytical Method for Determining Residues of Clopyralid in Animal Matrices Study No.: 190543 Dow AgroSciences LLC GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.2	Forbes, T.	2018	Validation of an Analytical Method for the Determination of Clopyralid in Pollinator Matrices Study Number: 171332 CEM Analytical Services Ltd GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 5.2	Bendig, P., Przybylek, A.	2018	Summary of Independent Laboratory Validation (ILV) of an Analytical Method for the Determination of Clopyralid in Honey and Pollen Matrices Study Number: 180870 EAG Laboratories GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 6.1.1-01 KCP 6.4.1-01	Mavrotas, Costas	2007	What ios the efficacy of Lontrel 400 agianst ANTAR in wheat, ELANCO HELLAS SACI. GR, GR07A2A003CM01C, not GEP, Unpublished	N	Y	If previously submitted in this MS: Data protection started with: R - 88/2010, 15.12.2010	Corteva Agriscience
KCP 6.1.1-02 KCP 6.2.2-01 KCP 6.4.1-02	Mezei, Imre	2008	What is the efficacy of Lontrel 720SG compared to Lontrel 300 in cereals, Dow AgroScience, HU08A2A085IM01C,	N	Y	Data protection started with: R - 88/2010, 15.12.2010	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
			GEP, Unpublished				
KCP 6.1.1-03 KCP 6.2.2-02 KCP 6.4.1-03	Mezei, Imre	2008	What is the efficacy of Lontrel 720SG compared tp Lontrel 300 in cereals, Dow AgroScience, HU08A2A085IM02C, GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence
KCP 6.2.2-03 KCP 6.4.1-04	Mezei, Imre	1998	Efficacy of normal stored DAS Herbicides in comparison to samples stored at frozen conditions, Eastern Europe 1998, Dow AgroScience, E81018H1, Not GEP, Unpublished	N	Y	Data protection started with R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 6.2.2-04 KCP 6.4.1-05	Mezei, Imre	2002	Efficacy of Mustang on CIRAR in comparison to commercial standards in Cereal, Europe, Dow AgroScience, H2700201, GEP, Unpublished	N	Y	Data protection started with R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 6.2.2-05 KCP 6.4.1-06	Mezei, Imre	2002	Efficacy of Mustang on CIRAR in comparison to commercial standards in Cereal, Europe, Dow AgroScience, H2700202, GEP, Unpublished	N	Y	Data protection started with R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 6.2.2-06 KCP 6.4.1-07	Mezei, Imre	2003	Mustang + (increased 2-4,D) Combination partners against CIRAR, Dow AgroScience, M3F00101, Not GEP, Unpublished	N	Y	Data protection started with R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 6.2.2-07 KCP 6.4.1-08	Kerekes, Gabor	2018	Efficacy of clopyralid in winter cereals when applied at B23-30 and B33-39. Hungary, 2018, Agropass Hungaria Kft.	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence

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			HU18A2A004GK01C, GEP, Unpublished				
KCP 6.1.1-04 KCP 6.4.1-09	Mezei, Imre	2008	Formulation change of Lontrel in Onion NTSZ Nograd Megye. HU HU08A2A088IMO1C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-05 KCP 6.4.1-10	Mezei, Imre	2008	Formulation change of Lontrel in Maize NTSZ Nograd Megye. HU HU08A2A088IMO2C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-06 KCP 6.4.1-11	Bernhard, Uli	2008	Bekämpfung von Ackerkratzdisteln in Mais Efficacy of GF-1633 and GF-1966 against CIRAR in maize, registration tri-als, Germany 2008 LVLF VS Nuhnen, DE DE08A2A001AZ02C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-07 KCP 6.4.1-12	Bernhard, Uli	2009	Unkrautbekämpfung in Silomais Efficacy of GF-1633 against CIRAR and other dycot.- weeds in maize, registration trials, Germany 2008 LWK Niedersachse, Hannover, DE DE08A2A001AZ03C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-08 KCP 6.4.1-13	Bernhard, Uli	2009	Unkrautbekämpfung in Silomais Efficacy of GF-1633 against CIRAR and other dycot.- weeds in maize, registration trials, Germany 2008 LWK Niedersachse, Hannover, DE DE08A2A001AZ04C GEP Unpublished	N	N		Corteva Agrisci-ence

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 6.1.1-09 KCP 6.4.1-14	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyra-lid+clopyra-lid+picloram) AGRARTEST, DE DE08A2A003UB01C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-10 KCP 6.4.1-15	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyra-lid+clopyra-lid+picloram) AGRO-CHECK, DE DE08A2A003UB02C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-11 KCP 6.4.1-16	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyra-lid+clopyra-lid+picloram) AGRARTEST, DE DE08A2A003UB03C GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-12 KCP 6.4.1-17	Schulz, Thomas	2008	Efficacy and selectivity of GF-1633 (aminopyra-lid+clopyra-lid+picloram) applied for BLW control in maize. Germany 2008. Dow AgroScience, DE08A2A004TS01 GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-13 KCP 6.4.1-18	Schneider, Frank	2008	Efficacy and selectivity of GF-1633 (aminopyra-lid+clopyra-lid+picloram) applied for BLW control in maize. Germany 2008. Dow AgroScience, DE08A2A004FS02 GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.2.2-08 KCP 6.4.1-19	Lourdet, Yves	1998	WHAT IS THE BEST RATIO OF CLOPYRALID + CAR-FENTRAZONE TO ACHIEVE COMMERCIAL CONTROL OF CIRSIUM ARVENSIS IN MAIZE ?	N	N		Corteva Agrisci-ence

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
			Dow Agroscience F9B01301 GEP Unpublished				
KCP 6.2.2-09 KCP 6.4.1-20	Kiraly, E	2000	EFFICACY OF CLOPYRALID + CARFENTRAZONE AGAINST CIRSIUM ARVENSE IN MAIZE -EUROPE 1999 Corteva Agroscience, E9B013H1 GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.2.2-10 KCP 6.4.1-21	Kiraly, E	2000	EFFICACY OF CLOPYRALID + CARFENTRAZONE AGAINST CIRSIUM ARVENSE IN MAIZE -EUROPE 1999 Corteva Agroscience, E9B013H2 GEP Unpublished	N	N		Corteva Agrisci-ence
KCP 6.1.1-14 KCP 6.2.2-11 KCP 6.4.1-22	Toth, F	2012	EFFICACY EVALUATION OF CLOPYRALID 600 SL AP-PLIED ON MAIZE CROP 2012 Staphyt, FPT-12-13443-SK04 GEP Unpublished	N	Y	Data/study report never submit-ted before to Poland	UPL
KCP 6.1.1-15 KCP 6.2.2-12 KCP 6.4.1-23	Toth, F	2012	EFFICACY EVALUATION OF CLOPYRALID 600 SL AP-PLIED ON MAIZE CROP 2012 Staphyt, FPT-12-13443-SK05 GEP Unpublished	N	Y	Data/study report never submit-ted before to Poland	UPL
KCP 6.1.1-16 KCP 6.4.1-25	Karel Sikora	2010	What is the efficacy of GF-1966 in comparison to existing formulations of clopyralid, Zemedelsky Vyzkumny Ustav Kromeriz, S.R.O. CZ, CZ10A2A019KS01C, GEP	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence

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			Unpublished				
KCP 6.1.1-17 KCP 6.4.1-26	Karel Sikora	2010	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE NECHANICE, CZ10A2A019KS02C GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 6.1.1-18 KCP 6.4.1-27	Karel Sikora	2010	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY, CZ10A2A019KS03C GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 6.1.1-19 KCP 6.4.1-28	Karel Sikora	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY CZ11A2A022KS01C GEP Unpublished	N	Y	Data/study report never submitted before to Poland I	Corteva Agriscience
KCP 6.1.1-20 KCP 6.4.1-29	Karel Sikora	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE NECHANICE, CZ11A2A022KS02C GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 6.1.1-21 KCP 6.2.2-14 KCP 6.4.1-30	Michel Luras	2008	Efficacy of two different formulation of clopyralid LONTREL 100 and GF-1966 (sg) against Cirsium arvensis to sugar beet - spring 2008 Staphyt, FR08A2A066ML01C GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 6.1.1-22 KCP 6.2.2-15 KCP 6.4.1-31	Michel Luras	2008	Efficacy of two different formulation of clopyralid LONTREL 100 and GF-1966 (sg) against Cirsium arvensis to sugar beet - spring 2008	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
			Staphyt, FR08A2A066ML02C, GEP, Unpublished				
KCP 6.1.1-23 KCP 6.4.1-32	Vojtko, Jan	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, SK11A2A022JV01C, Not GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence
KCP 6.1.1-24 KCP 6.4.1-33	Vojtko, Jan	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, SK11A2A022JV02C, Not GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence
KCP 6.2.2-16 KCP 6.4.1-34	Touzet, Francis	2007	EFFICACY OF LONTREL 100 AGAINST CIRAR IN SUGAR BEETS INCLUDING OIL, Dow Agroscience, FR07A2A037FT01, GEP, Unpublished	N	Y	Data protection started with R - 88/2010, 15.12.2010	Corteva Agrisci-ence
KCP 6.2.2-17 KCP 6.4.1-35	Olivier, Francoise	2015	Interest of GF-2607 in mixture with Lontrel SG when ap-plied against CIRAR in BEAVA. FR-2015, Dow AgroScience, FR15H2B017FO01, GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence
KCP 6.2.2-18 KCP 6.4.1-36	Olivier, Francoise	2015	Interest of GF-2607 in mixture with Lontrel SG when ap-plied against CIRAR in BEAVA. FR-2015, Dow AgroScience, FR15H2B017FO02, GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	Corteva Agrisci-ence

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protec-tion is claimed	Owner
KCP 6.2.2-19 KCP 6.4.1-37	Schmidt, Ingo	2012	Efficacy evaluation of clopyralid 600 SL applied on Winter oilseed rape crop Germany 2011/2012 Staphyt, FPT-12-9761-DE01 GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	UPL
KCP 6.2.2-20 KCP 6.4.1-38	Laêtitia VANELLE	2012	Efficacy evaluation of clopyralid 600 SL applied on Winter oilseed rape crop France 2011/2012 Staphyt, FPT-12-9761-FR03 GEP, Unpublished	N	Y	Data/study report never submit-ted before to Poland	UPL
KCP 6.2.2-21 KCP 6.4.1-39	Zaremba, Mag-delena	2012	Efficacy evaluation of clopyralid 600 SL applied on Spring oilseed rape crop – Poland 2011/12. Staphyt, FPT-12-9761-PL05, GEP Unpublished	N	Y	Data/study report never submit-ted before to Poland	UPL
KCP 7.1.1/1	[redacted]	1990	EF-243: Acute Oral Toxicity (Limit Test) in the Rat [redacted] GLP Unpublished	Y	N		Corteva Agrisci-ence
KCP 7.1.1/2	[redacted]	1981	EF-243: Acute Oral Toxicity Study (LD50) in the Rat [redacted] GLP Unpublished	Y	N		Corteva Agrisci-ence
KCP 7.1.2/1	[redacted]	1990	EF-243: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] GLP Unpublished	Y	N		Corteva Agrisci-ence
KCP 7.1.3/1	[redacted]	1990	EF-243: Acute Inhalation Toxicity Study Four-Hour Expo-sure (Nose-Only) in the Rat	Y	N		Corteva Agrisci-ence

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			[redacted] GLP Unpublished				
KCP 7.1.4/1	[redacted]	1990	EF-243: Acute Dermal Irritation Test in the Rabbit [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 7.1.5/1	[redacted]	1990	EF-243: Acute Eye Irritation Test in the Rabbit [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 7.1.6/1	[redacted]	1990	EF-243: Modified Nine-Induction Buehler Contact Sensitisation Study in the Guinea Pig [redacted] GLP Unpublished	Y	N		Corteva Agriscience
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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 9.1.3 KCP 9.2.4 KCP 9.2.5	Anagu, I. & González Camarero, P	2021	Predicted environmental concentrations of clopyralid in soil, groundwater, surface water and sediment following application to various crops – a modelling assessment for Europe	N	N		Corteva Agriscience

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			Dr Knoell consult Report No. 109738-1 non GLP Unpublished				
KCP 10.1.1	[redacted]	2020	EF-243: An Acute Oral Toxicity Study with the Northern Bobwhite Using a Sequential Testing Procedure [redacted] GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 10/4	Pavić, B.	2020	GF-1966: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil DAS Study ID 201708 ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience
KCP 10/4	Pavić, B.	2020	GF-1966: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil DAS Study ID 201709 ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Corteva Agriscience

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	Hastings, M.	2002	Determination of Residues of Clopyralid on Agriculture Crops by Gas Chromatography with Negative-Ion Chemical ionization Mass Spectrometry GRM 01.16 Study Number: GH-C-5439	N	N		Corteva Agriscience

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			Dow AgroSciences LLC GLP Unpublished				
KCP 5.1.2	Clements, B. Harring-ton, R.	1997	Determination of Residues of MCPA, Clopyralid, and Fluroxypyr in Grass and Cereal Grain and Straw DAS Study No.: ERC 97.10 Dow AgroSciences, LLC GLP Unpublished	N	N		Corteva Agriscience
KCP 5.1.2	Hastings, M.J.	2003	Determination of Residues of Clopyralid and Picloram in Canola by Gas Chromatography with Negative-Ion Chemical Ionization Mass Spectrometry DAS Study Number: 021200 (GRM 00.19) Dow AgroSciences, LLC GLP Unpublished	N	N		Corteva Agriscience
KCP 5.1.2	Hastings, M.J.	2002	Determination of Residues of Clopyralid in Animal Tissues by Gas Chromatography with Negative-Ion Chemical Ionization Mass Spectrometry Study Number: GRM 02.14 Dow AgroSciences, LLC GLP Unpublished	N	N		Corteva Agriscience
KCP 5.1.2	Vincent, T.	2013	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Soil by LC-MS/MS Study Number: 120612 ABC Laboratories, Inc GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	Shaffer, S.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Drinking Water, Ground Water and Surface Water by LC-MS/MS Study Number: 120611 GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.1.2 KCP 5.2	Vogl, E.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Agricultural Commondities by LC-MS/MS Study Number: 120610 ABC Laboratories, Inc GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Austin, R.	2012	Independent Laboratory Validation of Dow AgroSciences Method 120610, "Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Agricultural Commodities by LC-MS/MS" Study Number: 120614 Battelle UK Ltd GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Hall, L.R.	2013	14C-Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval	N	Y	Active substance data submitted for the Active Substance Renewal	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Study Number: 130733 ABC Laboratories, Inc GLP Unpublished			Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	
KCP 5.2	Shaffer, S.	2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection Study Number: 120483 ABC Laboratories, Inc GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Gemrot, F.	2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices Study Number: 120484 Eurofins Agroscience Services Chem GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Lindner, M., Giesau, A.	2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin Study Number: 130729	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU)	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Eurofins Agroscience Services Chem GmbH GLP Unpublished			2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	
KCP 5.2	Austin, R., Turner, R.	2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin Study Number: 130728 Battelle UK Ltd GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Austin, R, Turner, R.	2014	Independent Laboratory Validation of a Dow AgroSciences Method for the Determination of Residues of Clopyralid and Picloram in Soil by LC-MS/MS Study Number: 140079 Battelle UK Ltd. GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Shaffer, S.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Drinking Water, Ground Water and Surface Water by LC-MS/MS Study Number: 120611 ABC Laboratories, Inc. GLP	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	
KCP 5.2	Austin, R, Turner, R.	2013	Independent Laboratory Validation of Dow AgroSciences Method 120611, "Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Drinking Water, Ground Water, and Surface Water by LC-MS/MS" Study Number: 120613 Battelle UK Ltd. GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Bacher, R.	2012	The Development and Validation of a Method for the Analysis of Clopyralid in Air Study Number: 120601 PTRL Europe GmbH GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 5.2	Senciuc, M.	2014	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluid(s) Study Number: 130727 PTRL Europe GmbH GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
						registration or re-registration of a PPP where this study is relied upon.	
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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	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	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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
						registration or re-registration of a PPP where this study is relied upon.	
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
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	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	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	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	N	N		Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Non-GLP (pre-GLP) Unpublished				
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
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	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	N		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	N		Corteva Agriscience
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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]	Y	N		Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Non-GLP Unpublished				
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	N		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	N		Corteva Agriscience
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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	N		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	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU)	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished			2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCA 6.5.3 (IIA 6.5.2/06)	Day, SR	1987	Clopyralid Residues in Rape Plant, Straw, Seed and Oil, Follow-ing Application of LONTREL 100, Germany 1985 and 1986 Study No. GHE-P-1740 Non-GLP Unpublished	N	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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

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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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	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	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	N		Corteva Agriscience
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	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 Lo-cations in Sweden, 1975. Cooperator – Astra Ewos Study No. GHE-P-350 Non-GLP	N	N		Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
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	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	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	N		Corteva Agriscience
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	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Implementing Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 10.1.1	[redacted]	1980	Acute Oral LD_{50} – Mallard Duck – DOWCO 290 [redacted]. GLP Unpublished	Y	N		Corteva Agriscience

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KCP 10.1.1	[redacted]	1985	Lontrel Herbicide: A One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*) - Final Report. [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 10.2	Aufderheide, J.	2014	Clopyralid Technical: Growth Inhibition Test with the Freshwater Diatom, *Navicula pelliculosa* DAS Study ID 140515 ABC Laboratories, Inc. GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 10.2	Banman, C. S., Moore, S	2015	Clopyralid: Toxicity to the Aquatic Macrophyte, *Myriophyllum spicatum* DAS Study ID 140735 SynTech Research Laboratory Services LLC GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 10.2	Barrett, K	2001	Clopyralid Technical Toxicity to the Sediment Dwelling Phase of the Midge *Chironomus riparius* DAS Study ID GHE-T-1122 Huntingdon Research Centre Ltd. GLP Unpublished	N	N		Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2	[redacted]	1989	Lontrel 100: Determination of acute toxicity (LC_{50}) to rainbow trout (96h, static). [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 10.2	Caley, C.Y., Cam-eron, B.D., Chapleo, S. & Wright, J.G.	1989	Lontrel 100: Determination of acute toxicity (LC_{50}) to Daphnia (48h, static). DAS Study ID IRI 140464 & IRI 140731 Inveresk Research International GLP Unpublished	N	N		Corteva Agriscience
KCP 10.2	Caley, C.Y., Cam-eron, B.D., Chapleo, S. & Wright, J.G.	1990	Lontrel 100: Daphnia reproduction test (20 day, semi-static) DAS Study ID IRI 140553 Inveresk Research International GLP Unpublished	N	N		Corteva Agriscience
KCP 10.2	Caley, C.Y., Cam-eron, B.D. & Chapleo, S	1989	Lontrel 100: Alga, growth inhibition test (72h EC_{50}). DAS Study ID IRI 140490 & IRI 140731 Inveresk Research International GLP Unpublished	N	N		Corteva Agriscience
KCP 10.2	Cowgill, U. M. ; Milazzo, D. P. ; Potter, R. B.	1990	The Fourteen Day Toxicity of Lontrel T to *Lemna gibba* L G-3 (Duckweed) DAS Study ID ES-2243 Toxicology & Environmental Research and Consulting Laboratory (TERC) GLP Unpublished	N	N		Corteva Agriscience
KCP 10.2	Kirk, H. D.; Gilles, M. M.; McClymont, E. L. ; McFadden, L.G.,	2000	Clopyralid: Growth Inhibition Test with the Freshwater Green Alga, *Selenastrum capricornutum* Printz DAS Study ID 001040 Toxicology & Environmental Research and Consulting Laboratory (TERC) GLP Unpublished	N	N		Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2	[redacted]	2000	Clopyralid: An Acute Toxicity Study with the Rainbow Trout, *Oncorhynchus mykiss* Walbaum [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 10.2	[redacted]	2000	Clopyralid: Toxicity to the Early Life Stages of the Fathead Minnow, *Pimephales Promelas* Rafinesque. [redacted] GLP Unpublished	Y	N		Corteva Agriscience
KCP 10.2	Marino, T. A. ; McClymont, E. L. ; Staley, J. L.,	2000	Clopyralid: An Acute Toxicity Study with the Daphnia, *Daphnia magna* Straus DAS Study ID 001025 Toxicology & Environmental Research and Consulting Laboratory (TERC) GLP Unpublished	N	N		Corteva Agriscience
KCP 10.2	Douglas, M. T. ; Bell, G. ; Macdonald, I. A.	1992	An Assessment of the Effects of Lontrel T on the Reproduction of *Daphnia magna* DAS Study ID DWC 615/911087 Huntingdon Research Centre Ltd. GLP Unpublished	N	N		Corteva Agriscience
KCP 10.3.1	Leonard, J. and Moore, S.	2017	Clopyralid: A laboratory study to determine the chronic oral toxicity to the adult worker honey bee *Apis mellifera* L. (Hymenoptera: Apidae) DAS Study ID 170098 SynTech Research, LLC GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
						registration or re-registration of a PPP where this study is relied upon.	
KCP 10.3.1	Leonard, J. and Moore, S.	2017	Clopyralid: A repeated-exposure laboratory toxicity study in larvae, pupae and emergent adults of the honey bee *Apis mellifera* Linnaeus. (Hymenoptera: Apidae) DAS Study ID 170099 SynTech Research, LLC GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 10.3.1	Wainwright, M.	2001	Clopyralid Technical Acute Toxicity To Honey Bees DAS Study ID GHE-T-1091 Huntingdon Life Sciences Ltd GLP Unpublished	N	N		Corteva Agriscience
KCP 10.3.1	Wainwright, M.	2001	EF-1136: Acute toxicity to honey bees (*Apis mellifera*). DAS Study ID DOS 166/004732 Huntingdon Life Sciences Ltd GLP Unpublished	N	N		Corteva Agriscience
KCP 10.3.2	Halsall, N.	2005	A laboratory rate response test to determine the effects of EF-1136 on the parasitic wasp, *Aphidius rhopalosiphi* DAS Study ID 050171 Insect Investigations Services GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2	Sankanu A.	2000	A laboratory study to evaluate the effects of clopyralid (EF-1136, an SL formulation containing 100 g/L clopyralid) on *Typhlodromus pyri* (Acari: Phytoseiidae). DAS Study ID GHE-P-8416 Ecotox Limited GLP Unpublished	N	N		Corteva Agriscience
KCP 10.3.2	Sankanu A.	2000	laboratory study to evaluate the effects of clopyralid (EF-1136, an SL formulation containing 100 g/L clopyralid) on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae). DAS Study ID GHE-P-8725 Ecotox Limited GLP Unpublished	N	N		Corteva Agriscience
KCP 10.4	Hayward, J. C.	2001	The Effects of EF-1136 on Reproduction and Growth in the Earthworm *Eisenia fetida* DAS Study ID GHE-T-1135 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	N		Corteva Agriscience
KCP 10.5	Hayward, J.C. & Morgan, A.J.	2003	EF-1136: Effects on Soil Microflora Activity. DAS Study ID 031001 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	N		Corteva Agriscience
KCP 10.5	Schöbinger, U.	2003	Clopyralid: Effects on the Activity of the Soil Microflora under Laboratory Conditions (Nitrogen and Carbon Transformation) DAS Study ID 130283 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a	Corteva Agriscience

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						PPP where this study is relied upon.	
KCP 10.6	Rockliff, C.	2013	EF-797 (clopyralid potassium, 750 g a.e/kg, SG) GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plants (based on OECD Guideline 208) – China, 2013 DAS Study ID 130095 Stockbridge Technology Centre Ltd GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience
KCP 10.6	Rockliff, C.	2013	EF-797 (clopyralid potassium, 750 g a.e/kg, SG) GLP Vegetative Vigour Test Terrestrial Non Target Plants (based on OECD Guideline 227) – China 2013 DAS Study ID 130094 Stockbridge Technology Centre Ltd GLP Unpublished	N	Y	Active substance data submitted for the Active Substance Renewal Clopyralid (Commission Imple-menting Regulation (EU) 2021/1191) applied 1st October 2021. Data protection for a period of 30 months to be initiated at the national level following the first registration or re-registration of a PPP where this study is relied upon.	Corteva Agriscience

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	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to Poland If previously submitted in **this** MS: Data protection started with: <insert authorization number of first au-thorization>	Owner

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	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to Poland If previously submitted in **this** MS: Data protection started with: <insert authorization number of first au-thorization>	Owner