

REGISTRATION REPORT

Part A

Risk Management

Product code: ADM.01851.H.1.A

Product name(s): TAXATUM

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: ADAMA Polska Sp. z o.o.

Submission date: August 2024, update March 2025

MS Finalisation date: March 2025 (initial National Assessment)

June 2025, updated August (final National Assessment)

Version history

When	What
August 2024	dRR version 1 submitted by applicant
March 2025	The applicant: update of the label phrase concerned with succeeding crops.
March 2025	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern ~~is struck through~~ and shaded.
June 2025	Final report (National Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
August 2025	Final report (National Assessment updated after the correction of Appendix 4 prepared by the Applicant) In order to facilitate tracking of changes in the Lists of data considered for national authorization (Appendix 4), amendments are highlighted in turquoise. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application under article 33 of regulation 1107/2009 submitted by the applicant in August 2024 is for the first authorisation of the product ADM.01851.H.1.A, a suspension concentrate containing 500 g/L ethofumesate and 75 g/L clopyralid for use in sugar beets and fodder beets, with a maximum application rate of 0.66 L/ha and at latest BBCH of 19.

The zRMS for this central zone dossier is Poland. There are no further concerned member states (cMS) in the CZ.

An application to the Southern Zone (zRMS France) is planned in April 2025.

1.2 Letters of Access

This is business confidential information. If needed, the Letters of Access are provided separate to this submission.

1.3 Justification for submission of tests and studies

This application was submitted in order to allow the authorization of ADM.01851.H.1.A in accordance to the data requirements laid down in Regulation (EC) No. 284/2013.

The reference list included in Part A Appendix 4 defines the list of studies and reports, submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the authorisation.

1.4 Data protection claims

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company, the Applicant claims data protection for the studies submitted with this application. The list of the studies for which the applicant requests data protection are reported in the Appendix 4 of Part A. The Applicant confirms that no period of data protection has previously been granted in respect of the study or has been granted and not yet expired.

2 Details of the authorization decision

2.1 Product identity

Product code	ADM.01851.H.1.A
Product name in MS	TAXATUM
Authorization number	new product
Function	herbicide
Applicant	ADAMA Polska Sp. z o.o.
Active substance(s) (incl. content)	ethofumesat, 500 g/L clopyralid, 75 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	1 L, 5 L and 10 L HDPE, professional user

Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	Not applicable

2.2 Conclusion

The authorisation of ADM.01851.H.1.A for the uses specified in 2.6 of this document can be granted.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **ADM.01851.H.1.A** does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product **ADM.01851.H.1.A** meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of **Regulation (EU) 2023/574** can be found in annex to Part C of this submission.

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

2.4.1 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:	Skin irritation cat 2 (H315) Eye irritation cat 1 (H318) Chronic aquatic cat 1 (H410)
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS05 GHS09
Signal word:	Danger
Hazard statements:	H315 - Causes skin irritation H318 - Causes serious damage to the eye H410 - Very toxic to aquatic life with long lasting effects
Precautionary statements:	P102 - Keep out of reach of children P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/eye protection/face protection P302 + P352 - IF ON SKIN: Wash with plenty of water and soap P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313 - If skin irritation occurs: Get medical advice/attention. P310 - Immediately call a POISON CENTER/ doctor/... P501 - Dispose of contents/ container to an approved waste disposal plant
Additional labelling phrases:	EUH401 - To avoid risks to human health and the environment, comply with the instructions for use

	EUH208 - Contains (1,2-Benzisothiazolin-3-one). May produce an allergic reaction
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2.4.2 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).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Refer to national product label.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
respective code if available	none
Worker protection:	
respective code if available	none
Integrated pest management (IPM)/sustainable use:	
respective code if available	none
Environmental protection	
respective code if available	SP1 - 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) SPe 1 To protect groundwater, do not apply this or any other product containing ethofumesat or clopyralid more than every second year .

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	none	
Environmental Protection		

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1 ~~0~~, date: March 2025
~~August 2024~~

PPP (product name/code): ADM.01851.H.1.A

Active substance 1: ethofumesat

Active substance 2: clopyralid

Safener/Synergist: not relevant

Applicant: ADAMA Polska Sp. z o.o.

Zone(s): central

Verified by MS: yes ~~no~~

Field of use: herbicide

Formulation type: SC

Conc. of as 1: 500 g/L

Conc. of as 2: 75 g/L

Conc. of synergist: not relevant

Professional use: X

Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. (e)	Mem ber state (s)	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests con- trolled (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. g saf- ener/syner- gist per ha (i)	zRMS comments							
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. to- tal rate per crop/sea- son	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate and behavior	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Sugar beet BEAVA Fodder-beet BEAVG	F	annual dicot weeds and annual grass-weeds	foliar spraying, overall	BBCH 10- 19/ March- June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesa te/ha 49.5 g clopyralid/ ha	100- 400	n.a.	Total rate per season 2 L/ha Max rate of ethofumesate should not exceed 1.0 kg/ha every 2	A	A	A	A	R Biennial applica- tion	A	A	A

										b) 990 g ethofumesate/ha 148.5 g clopyralid/ha			3 years Max. rate of clopyralid should not exceed 150 g/ha every 2 years							N fodder beet possible authorization based on the art. 51 – minor uses	
2	PL	Sugar beet BEAVA Fodder-beet BEAVG	F	annual dicot weeds and annual grass-weeds	foliar spraying, overall	BBCH 10-19/ March-June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/ha 49.5 g clopyralid/ha b) 990 g ethofumesate/ha 148.5 g clopyralid/ha	100-400	n.a.	Band application applied to 50% of the surface, along the plant rows. Total rate / season = 1 L/ha (500+75 g ai/ha) Max rate of ethofumesate should not exceed 1.0 kg/ha every 2 years Max. rate of clopyralid should not exceed 150 g/ha every 2 years	A	A	A	A	R Biennial application	A	A	A N fodder beet possible authorization based on the art. 51 – minor uses

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	1	2	3	4	5	6	7	8	9	10	11	12	13	14
columns:	1	Numeration necessary to allow references						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					
	2	Use official codes/nomenclatures of EU Member States							8	The maximum number of application possible under practical conditions of use must be provided.				
the	3	For crops, the EU and Codex classifications (both) should be used; when relevant, use situation should be described (e.g. fumigation of a structure)							9	Minimum interval (in days) between applications of the same product				
	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							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.				
	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.							11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).				
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench							12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.				
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.							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 an oyster white opaque homogeneous liquid with characteristic odour. It is not explosive, has no oxidising properties. The product does not flash in the range tested from 10 to 110°C. It has a self-ignition temperature of 485°C. The pH value of the neat formulation is 7.2 and the pH value of a 1% dilution is 7.3 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the content of the active ingredients or impurities nor the technical properties were changed. The 2 years shelf-life study is on-going at the time of sub-mission of this dossier. Based on the accelerated storage stability study, the data confirms the formulation meets the regulatory requirements and the shelf life is expected to be at least 2 years when stored at ambient temperature in HDPE/PA commercial containers. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.165% to 0.66%.
The product will not be used in tank mixtures.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Experimental results on the product ADM.01851.H.1.A with regard to product classification and labelling:

Studies	Method	Findings			Classification acc. to Regulation (EC) No. 1272/2008
Explosive prop- erties	EC A.14	Not explosive			None
Oxidising prop- erties	EC A.21	Not oxidizing			None
Flammability	--	Not applicable for SC-formulation			--
Flash point	EC A.9	No flash in the range tested from 10 to 110°C			None
Auto-flammabil- ity	EC A.15	Self-ignition temperature = 485°C			None
pH	CIPAC MT 75.3	7.2			None
Viscosity	CIPAC MT 192, OECD 114	Shear rate (s ⁻¹)	Mean viscosity at 20°C	Mean viscosity at 40°C	None
		Dynamic viscosity (cP = mPa*s)			
		0.1	21695.3	10964.7	
		0.2	12947.0	7148.3	
		0.5	6305.7	3765.7	
		1.0	3632.3	2256.7	
		2.0	2190.0	1400.0	
		4.1	1320.0	856.5	
		10.2	706.5	462.6	
		20.4	455.4	302.1	
		Kinematic viscosity (cSt = mm²/s)			
		0.1	18784	-	
		0.2	11210	-	

		0.5	5459.5	-	
		1.0	3144.8	-	
		2.0	1896.1	-	
		4.1	1142.9	-	
		10.2	611.7	-	
Surface tension	EEC A.5	42.2 mN/m for 0.84% (v/v) solution of the test item in de-ionized water at 20.0°C			None
Relative density	EEC A.3	1.155 (Batch U3311B)			None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications:

The product ADM.01851.H.1.A has not FAO specifications..

3.2 Efficacy (Part B, Section 3)

ADM.01851.H.1.A is an herbicide containing two active ingredients: 500 g/L of ethofumesate and 75 g/L of clopyralid (SC formulation). This application under article 33 of Regulation (EC) No. 1107/2009 submitted by the applicant is for first authorisation of the product ADM.01851.H.1.A Poland (Central Regulatory zone).

The aim of this dossier is to provide data on the efficacy and crop safety in support of the registration of ADM.01851.H.1.A in Poland (EU Central Registration zone / North-East EPPO climatic zone) for use as an herbicide in sugar beet (post-emergence applications).

3.3 Efficacy data

Total of 11 trials were conducted in growing season 2022-2023 in Poland – 9 trials (North East EPPO zone) and in Germany – 2 trials (Maritime EPPO zone).

Trials in this dossier were carried out by contractor companies, all of which following the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

• Preliminary tests (KCP 6.1)

ADM.01851.H.1.A is a new and innovative co-formulation product that combines the complementary and overlapping selective post-emergence herbicidal activities of ethofumesate and clopyralid to provide growers with an effective control of weed plants in sugar beets.

Whilst products containing either ethofumesate or clopyralid alone are approved for use in sugar beets, ADM.01851.H.1.A offers the convenience and benefits associated with the use of two complementary and overlapping activities of two active ingredients in a single product.

Efficacy of ADM.01851.H.1.A is higher than that of the equivalent rates of ethofumesate and clopyralid products applied alone against some of the main target weed species (LAMP, CHEAL, POLPE, MATIN, POLCO, SOLNI and RAPRA), which proves the synergistic effect of both substances in the formulation of ADM.01851.H.1.A.

Evidently, the combination of both substances in ADM.01851.H.1.A formulation, resulted in better effectiveness in weed control than the effectiveness observed in the case of straight products as well as a wider range of weed species controlled resulting from the complementary effects of both substances .

Based on presented data, the combination of ethofumesate and clopyralid in ADM.01851.H.1.A is therefore

fully justified on the basis of higher efficacy, compared to active substance applied alone, against major target weed species for which label claims are supported for proposed uses in sugar beets.

- **Minimum effective dose tests (KCP 6.2)**

All efficacy trials presented in this dossier included, in treatment list, dose rates lower than proposed target dose rate. In total 11 efficacy trials were available to evaluate the minimum effective dose of ADM.01851.H.1.A for the control of target uses.

Trials were conducted in: Poland (North East EPPO zone) – 9 and Germany (Maritime EPPO zone) - 2

ADM.01851.H.1.A was tested at dose rates:

0,26 l/ha - 40 % of the target dose rate

0,33 l/ha - 50 % of the target dose rate

0,53 l/ha - 80 % of the target dose rate

0,66 l/ha – 100 % of the target dose rate

The rates reflect the proposed label rate and 40%; 50%; 80% of the full recommended rate of ADM.01851.H.1.A in accordance with the EPPO standard PP 1/225 'Minimum effective dose'.

Total of 9 trials were conducted in North East EPPO climatic zone (Poland) between 2022-2023.

Data generated in trials carried in the North East EPPO climatic zone clearly show the efficacy of ADM.01851.H.1.A applied at 3*0,66 l/ha against annual broadleaved weed species in sugar beets like CHEAL, LAMPU, POLCO, MATIN, SOLNI, STEME, POLPE, THLAR to be generally higher and more consistent compared to that of lower rates of product/ha and rate response was evident with all three rates. Based on the presented data, it is therefore reasonable to conclude that the maximum proposed label rate of 3*0,66 L product/ha is fully justified as the minimum effective dose for the control of annual broadleaved weed species in sugar beets by ADM.01851.H.1.A under conditions in countries in the North-east EPPO climatic zones.

Total of 2 trials were conducted in Maritime EPPO climatic zone (Germany) in 2023.

The rates reflect the proposed label rate and 40%; 50%; 80% of the full recommended rate of ADM.01851.H.1.A in accordance with the EPPO standard PP 1/225 'Minimum effective dose'.

Dose response is evident for all weed plant species.

- **Efficacy tests (KCP 6.2)**

A total of 11 efficacy trials, conducted in: Poland (North East EPPO zone) – 9 and Germany (Maritime EPPO zone) - 2 between 2023-2024, tested the efficacy of ADM.01851.H.1.A applied 3 times at 0.66 L/ha (i.e. the maximal total target dose rate of 1.98 L/ha for Poland and Germany).

In all trials ADM.01851.H.1.A was compared to the zonal standard herbicide FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L) applied at registered rate. In the efficacy part, only results of the total intended dose rate (i.e. a total of 1.98 L/ha of formulated product for Poland) are presented.

North-East EPPO zone 2022-2023

Results from a total of 9 trials carried out in Poland in 2022-2023 are presented in Table 3.2-13 of the BAD. The evaluation focused on A4 (25-30 DAC) BBCH 31-42.

The efficacy of ADM.01851.H.1.A was compared to the standard product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L).

Results of 9 trials conducted in Poland in 2022 and 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha gave a satisfactory level of control against the key weeds Galium aparine (GALAP), Stellaria media (STEME), Matricaria inodora (MATIN), Lamium purpureum (LAMPU) which are of economical importance in sugar beet in the Central zone of Europe.

Maritime EPPO zone 2023

Results from a total of 2 trials carried out in Germany in 2023 are presented in Table 3.2-14 of the BAD.

The evaluation focused on A4 (25-27 DAC) BBCH 19-39.

The efficacy of ADM.01851.H.1.A was compared to the standard product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L).

Results of 2 trials conducted in Germany in 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha gave a satisfactory level of control against the key weeds Chenopodium album (CHEAL), Galium aparine (GALAP), Polygonum convolvulus (POLCO), Solanum nigrum (SOLNI) which

are of economic importance in sugar beet in the Central zone of Europe.

Due to consistency of level of control on the key weeds in both North-East and Maritime EPPO zones, a global mean is presented for all efficacy trials testing ADM.01851.H.1.A at 3*0.66 L/ha. In addition, the EPPO Maritime zone results are comparable to results in the EPPO North-East zone as in Germany the agronomic conditions and cultural practices in beet crops are very close to what is encountered in Poland, and thus no direct impact on the efficacy of the product is expected. Furthermore, the climatic conditions at application (air temperature and relative moisture) were globally homogeneous from a climatic zone to another.

Data from 11 efficacy trials were used to evaluate the efficacy of ADM.01851.H.1.A applied post-emergence of the crop against annual weeds in sugar beet. ADM.01851.H.1.A was applied 3 times at 0.66 L/ha (i.e. a total of 1.98 L/ha corresponding to the maximum total recommended dose rate for Poland and Germany) and compared to the standard FSG 01095 H (metamitron + ethofumesate, SC, 350 + 150 g/L) applied at registered rate.

Evaluation of efficacy focused at A4 (25-30 DAC) BBCH 19-42 when the sugar beet is near row close.

Results of 9 trials conducted in Poland in 2022-2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha, gave a satisfactory level of control against the key weeds *Galium aparine* (GALAP), *Stellaria media* (STEME), *Matricaria inodora* (MATIN), *Lamium purpureum* (LAMPU) which are of economic importance in sugar beet in the Central zone of Europe.

Results of 2 trials conducted in Germany in 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha controls a number of key weeds of economic importance in sugar beet in the Central zone of Europe, especially against *Chenopodium album* (CHEAL), *Galium aparine* (GALAP), *Polygonum convolvulus* (POLCO), *Solanum nigrum* (SOLNI).

All results support the intended GAP, application in all surface or application applied to 50% of the surface along the plant rows, since weeds receive the same quantity of product.

Weed spectrum of ADM.01851.H.1.A at 3*0.66 L/ha - A4 (25-30 DAC) BBCH 19-42 - Maritime and North-East EPPO zones 2022-2023, 11 trials.

Highly susceptible (HS)	STEME (4)
Susceptible (S)	GALAP(6), MATIN(4)
Moderately Susceptible (MS)	CHEAL (10), THLAR(2), LAMPU(3)
Moderately Tolerant (MT)	POLAV(3), POLCO(7)
Tolerant (T)	No weeds were identified as tolerant

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The product ADM.01851.H.1.A is suspension concentrate (SC) containing two active ingredients: ethofumesate – 500 g/l and clopyralid – 75 g/l. intended for professional use as herbicide for the control of grassweeds and broadleaved weed species in sugar beets.

Ethofumesate belongs to the chemical group of benzofurans. The general mode of action is the inhibition of the fatty acid and lipid biosynthesis. Ethofumesate is a selective systemic herbicide. It is an inhibitor of elongases, enzymes leading to long chain of fatty acids (over 18 C), precursors of waxy cuticle and sobering. It acts as an inhibitor of cell division and lipid synthesis in the seedling shoot leading to retardation of meristem growth. The selectivity of the beet can be explained by its ability to metabolize this active substance, rendering it inactive. Whilst the exact target site of HRAC Group 15 herbicides is unknown, it involves inhibition of enzymes involved in the biosynthesis of very long chain fatty acids (VLCFAs) and prevention of cell division. Cases of resistance to HRAC group 15 herbicides are quite rare.

Clopyralid is classified by HRAC within group O (synthetic auxins). It belongs to the chemical group of 6-Chloropicolinates. Other chemical classes classified as group O herbicides are: benzoic acids phenoxy-carboxylic-acids, pyridine carboxylic acids and quinoline carboxylic acids.

Clopyralid is a selective, systemic herbicide used primarily in the control of broadleaf weeds. Clopyralid mode of action is that it operates as a plant growth regulator by imitating natural plant hormones: auxins, altering the plant's metabolism and growth characteristics and often causing a proliferation of abnormal growth that interferes with the transport of nutrients.

Detailed evidence of resistance in Europe and world-wide is specified in BAD section 3.3.

Worldwide, resistance to HRAC group 15 is known in 10 different weeds species, populations of ethofumesate-resistant *Amaranthus palmeri* were found in cotton and soybean fields in Arkansas. These *Amaranthus palmeri* populations evolved multiple resistance to S-metolachlor. So far, no resistance of other dicotyledonous weeds to ethofumesate was reported worldwide.

Worldwide, resistance to HRAC group 4 is known in 44 different weeds, in Europe several cases of resistance to herbicides containing active substances belonging to HRAC 4 have been found, mainly 2,4 D, MCPA, mecoprop belonging to the family of phenoxy-carboxylates, one of dicamba (Poland) from family of benzoates and aminopyralid from family of 6-Chloropicolines. Populations of clopyralid-resistant broadleaved weed species were found in corn fields (*Chenopodium album*), golf courses and turf (*Soliva sessilis*), rangelands (*Centaurea stoebe* ssp. *micranthos*) and Christmas tree plantation (*Ambrosia artemisiifolia*). So far, no resistance of other dicotyledonous weeds to clopyralid was reported worldwide.

Determination of inherent risk of resistance for target weeds

A lot of plants, especially weeds, have a wide range of genetic variability, which gives them an enormous adaptability and survival capability under various conditions.

The following factors influence the resistance risk of species:

- Family and life-form
- Genetic variability and mode of heredity
- Density of individuals and seed production
- Paths of propagation
- Dormancy and lifetime of seeds in soil
- Capacity of metabolism
- Resistant biotypes already known
- Fitness of the resistant species

The inherent risk is classified according to the number of resistant biotypes already recorded in the weeds. Due to the fact that only few cases of resistance against HRAC group 4 and HRAC group 15 herbicides were reported in Europe until now, a low to medium risk for the development of resistance is determined for Clopyralid and ethofumesate (detailed classification is presented in BAD in Table 3.3-11).

Determination of inherent risk of resistance for the active substance

Considering the fact that one case of ethofumesate resistance in dicotyledonous weeds worldwide with no documented cases of resistance in dicotyledonous weeds in Europe and 4 cases of clopyralid-resistant dicotyledonous weeds in Europe, with only one weed being discussed in the presented dossier (*Stellaria media*) we can assume that the inherent risk of resistance to formulation is low.

Determination of inherent agronomic risk for resistance development

The risk results from pressure applied to a population of weeds over several years. However, the key strategy to manage the resistance development is the reduction of pressure on populations by using combined techniques (HRAC guideline):

Cultivation

Cultivation does not exert a chemical selection pressure and limit the soil seed bank. One of the most efficient for annual weeds is ploughing or deep till prior to control emerged plants. Ploughing and deep till bury also new seeds (15-20 cm for ploughing).

Crop rotation

Crop rotation avoids successive crops in the same field which require herbicides with the same mode of action for control of the same weed species.

Different crops will allow rotation of herbicides having a different site of action and can interrupt the growth season of the weed.

A strongly competitive crop in the rotation can give a better chance to restrict weed seed production. Including autumn and spring sown crops within a rotation increases the range of weed species and reduces overall numbers. This makes easier the weeding.

Generally, sugar beets are cultivated exclusively in crop rotations with an interval of at least 3 years and it is common practice to apply sugar beet herbicides either as tank mixtures or as sequential applications using different herbicides.

Number of application

In practice, the registered rate of ADM.01851.H.1.A is split into 3 applications. ADM.01851.H.1.A formulation consist of 2 actives representing different mode of action to broaden the spectrum and control the risk of resistance. This minimizes at the maximum the selection pressure.

Alternating herbicides

Alternating herbicides with different modes of action used in the frame of herbicide programs is an excellent tool to limit the resistance development.

Conclusions for inherent agronomic risk

It can be concluded that the inherent agronomic risk is low.

Determination of the combined risk of resistance with ADM.01851.H.1.A

- Inherent risk of resistance for target weeds: low to medium
- Inherent risk of resistance for the active substance: low
- Inherent agronomic risk for resistance development: low

In conclusion, even if the inherent risk for the target weeds can be high, considering the fact that the inherent risk of resistance for the active substance is very low and that the inherent agronomic risk for resistance development is low, it can be concluded that the risk of resistance with ADM.01851.H.1.A used according to the GAP is low.

3.3.2 Adverse effects on treated crops

A total of 10 specific selectivity trials in weed free conditions were carried out in sugar beet. Trials were conducted in 2022 and 2023, 8 in the North-East EPPO zone (Poland), and 2 in the Maritime EPPO zone (Germany) in order to assess the adverse effects of ADM.01851.H.1.A on sugar beets.

For the North-East EPPO zone, in addition to the results from trials carried out in Poland, the German results are used as complementary data.

ADM.01851.H.1.A was applied at N rate (i.e. a total dose rate of 1.98 L/ha: 3*0,66 L/ha in Polish trials and German trials) and at 2N rate (i.e. a total dose rate of 3.96 L/ha: 3*1,32 L/ in Polish trials and German trials). The standard FSG 01095 H was also applied at N and 2N rates.

Crop selectivity was visually assessed at various intervals after application, in the form of a percentage relative to untreated plots. It was measured on a scale of phytotoxicity (%), 0 to 100.

Yield assessments were done, alongside with quality measurements such as sugar content (%), sugar yield (T/ha), sodium, potassium and amino-nitrogen contents (mmol/100g or mmol/1000g).

Results for North-East EPPO zone

Selectivity trials - 8 Polish trials:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials conducted in 2022 -2023 on the following crop varieties:

Eliska KWS, Doppler, Viola KWS, Orlik, Kujavia, BTS1985, BTS3865, KWS Smart Janninka

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 8 selectivity trials, at any assessment date and for any treatment.

Efficacy trials - 9 Polish trials:

ADM.01851.H.1.A was applied up to 3*0.66 L/ha (N rate for Poland) in 9 trials efficacy implemented in 2022 and 2023 on the following crop varieties:

Smart Latoria KWS, Graciana KWS, Viola KWS, Mazovia, BTS1985, Jadwiga Rh, BTS SMART 9635 , Eliska, KWS Smart Janinka.

No phytotoxicity symptoms were observed with ADM.01851.H.1.A applied at 3*0.66 L/ha. Acceptable (<15%) and transient phytotoxicity symptoms were observed in 1 out of 9 trials with the standard FSG 01095 H (TORERO 500 SC) applied at 1N dose rate. Phytotoxicity symptoms observed on treatments had disappeared at the end of the trials.

Results of the Maritime EPPO zone

Selectivity trials - 2 German trials:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha in 2 selectivity trials implemented in 2023 on the following crop varieties: Smart Manja KWS, BTS 6000 RHC.

Very slight and transient phytotoxicity symptoms were observed in 1 out of 2 selectivity trials with the 2N (1,32 L/ha; 1,0 L/ha) rate of ADM.01851.H.1.A at 7 DA-A (A1) and 13 DAA/3 DAB (A2); also phytotoxicity symptoms were observed on standard product's treatments for both 1N and 2N. In all trials, these symptoms were equivalent to those of the reference products. The symptoms had disappeared at the end of the trials. A slight loss of crop vigor was observed in trial but was no longer observed when the phytotoxicity symptoms disappeared.

Efficacy trials – 2 German trials:

ADM.01851.H.1.A was applied up to 3*0.66 L/ha (N rate for Germany and Poland) in 2 trials efficacy implemented in 2023 on the following crop varieties: Cabriana, Calledia.

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 2 efficacy trials, at any assessment date and for any treatment.

According to the results of 8 selectivity trials and 9 efficacy trials carried out in the North-East EPPO zone (Poland) in 2022 and 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (i.e. a total rate of 1.98 L/ha) is safe to sugar beet.

According to the results of 2 selectivity trials and 2 efficacy trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (i.e. a total rate of 1,98 L/ha) is safe to sugar beet.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) is very close to what is encountered in Poland (North-East EPPO zone). More-over, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany is considered as supportive to evaluate the selectivity of ADM.01851.H.1.A on sugar beet in Poland.

- **Effect on the yield of treated plants or plant product (KCP 6.4.2)**

The yield of crop was evaluated in the 11 selectivity trials.

Results for North-East EPPO zone - 8 Polish trials 2022-2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials implemented in 2022 -2023.

Complementary results in Maritime EPPO zone - 2 German trials 2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland and Germany) in 2 selectivity trials implemented in 2023.

According to the results of 8 selectivity trials carried out in the North-East EPPO zone (Poland) in 2022-2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.98 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 2 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1,98 L/ha) has no negative impact on the yield of the treated beets.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) is very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of ADM.01851.H.1.A on the yield of treated beets in Poland.

- **Effects on the quality of plants or plant products (KCP 6.4.3)**

The following quality parameters of the treated roots were evaluated in the 10 selectivity trials: sugar content (%), sugar yield (T/ha), sodium content, potassium content and amino-nitrogen content.

Results for North-East EPPO zone - 8 Polish trials, 2022-2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials implemented in 2022-2023.

Complementary results in Maritime EPPO zone - 2 German trials, 2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Germany and Poland) in 2 selectivity trials implemented in 2023.

According to the results of 8 selectivity trials carried out in the North-East EPPO zone (Poland) in 2022-2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.98 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 2 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.98 L/ha) has no negative impact on the quality of the treated roots.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) are very close to what is encountered in Poland (North-East EPPO zone). More-over, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of ADM.01851.H.1.A on the quality of the treated roots in Poland.

3.3.3 Observations on other undesirable or unintended side-effects

3.4.4 Effects on transformation processes (KCP 6.4.4)

Not relevant for sugar beet - sugar extraction from beet roots is not transformation process as defined in EPPO guideline PP 1/243 (2).

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

ADM.01851.H.1.A is not intended for protection of seed plantations in any phase of seed production (neither in autumn nor in spring).

3.4.6 Impact on succeeding crops (KCP 6.5.1)

For the absence of the relevant data the issue of replacement crops remains unresolved, for the time being. Currently the label phrase has been proposed preventing cultivation, as replacement crops, of plants other than sugar beet.

3.4.7 Impact on other plants including adjacent crops (KCP 6.5.2)

No risk to other plants including adjacent crops has been concluded based on Toxicity / Exposure quotient (TER) calculation.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The analysis of clopyralid and ethofumesate in the plant protection product ADM.01851.H.1.A (Clopyralid 75 + Ethofumesate 500 SC) was done by high performance liquid chromatography (HPLC) coupled with UV-DAD detection using external standard technique.

3.4.2 Analytical methods for residues

The applicant provided several analytical methods for risk assessment. The validity criteria for the analytical methods according to SANTE/2020/12830 have been met. All new methods are acceptable. More details can be found in Appendix 2 of Part B5.

Proposed uses for ADM.01851.H.1.A: sugar beet, fodder beet.

Residues definition for monitoring for plants for ethofumesate:

According to the EFSA Journal 2016;14(1):4374 and Regulation 2017/1016: Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate (their sum expressed as ethofumesate)

The value of MRL (Regulation 2017/1016):

- 0.2 mg/kg for sugar beet roots

Sufficient analytical method for the determination of ethofumesate (according to the residue definition) residues in crops (Schulte, G.; Diehl, P.; 2014; Method 01392) and its ILV (Betson, S.; 2014) is available (RAR, 2015). The method has been validated with LOQ=0.01mg/kg by LC-MS/MS for ethofumesate, NC 9607 as NC 20645 and NC 20645 separately in high water content, dry, fatty, acidic and no group (hop) commodities. As the method is highly specific (two mass transitions), confirmatory method is not required. Extraction efficiency of the method and efficiency of the acidic hydrolysis have been demonstrated for high water content commodities in the RAR of ethofumesate (2015). No additional data are required.

Validated methods for the generation of post-authorisation data for ethofumesate

Component of residue definition: Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate (their sum expressed as ethofumesate)				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content High acid content High oil content High protein/high starch content (dry)	Primary (Method 01392)	0.01 mg/kg Ethofumesate NC 9607* NC 20645*	LC-MS/MS	Schulte, G., Diehl, P., 2014 MR-13/101 <i>EU agreed (EFSA Journal 2016;14(1):4374)</i>
	ILV	0.01 mg/kg Ethofumesate NC 9607* NC 20645*	LC-MS/MS	Betson, S., 2014, Report No. M-475932-01-1 <i>EU agreed (EFSA Journal 2016;14(1):4374)</i>
	Confirmatory (if required)	-	Not required, highly specific detection system was used (LC-MS/MS).	

* determined as NC 20645 and calculated as ethofumesate

Residues definition for monitoring for plant origin for clopyralid:

- Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid” (EFSA, 2018);
- Clopyralid (Regulation (EU) 2024/2612)

The value of MRL (Regulation 2024/2612):

- 1 mg/kg for sugar beet roots

An analytical method for enforcement analysing for clopyralid, its salts and conjugates was assessed during the EU pesticides peer review (EFSA, 2018). The method (based on LC–MS/MS) is sufficiently validated for the determination of residues of clopyralid, its salts and conjugates in the four main plant matrices. The enforcement method quantifies residues at or above the LOQ of 0.01 mg/kg for the total residue (sum of clopyralid, its salts and conjugates) in the four main plant matrices.

According to the EFSA Journal 2018;16(8):5389 – “Peer review of the pesticide risk assessment of the active substance clopyralid”: *Clopyralid, its salts and conjugates can be monitored in food and feed of plant origin by liquid chromatography with tandem mass spectrometry (LC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in each commodity group.*

(...) In addition, there is a validated multiresidue quick, easy, cheap, effective and safe (QuEChERS) method using LC–MS/MS which can be used for monitoring of the clopyralid residues in high water and high acid content plant commodities and fat and milk with a LOQ of 0.01 mg/kg.

According to the EFSA Journal 2021;19(1):6389:

The method (based on LC-MS/MS) is sufficiently validated for the determination of residues of clopyralid, its salts and conjugates in the crops under consideration. It allows quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (sum of clopyralid, its salts and conjugates) in crops with dry/high starch, high water, high acid and high oil content.

Note: This method involves a hydrolysis step that releases free clopyralid from its conjugates.

EFSA stated (DOI: 10.2903/j.efsa.2024.8546) that *The assessment of extraction efficiency in plant matrices could be further investigated for the plant matrices of concern under the future MRL review. It is recommended to verify whether the sample preparation conditions are expected to release free clopyralid from its various conjugated forms and to confirm the extraction efficiency according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 GD (European Commission, 2023).*

No additional data are required.

Validated methods for the generation of post-authorisation data for clopyralid

Component of residue definition: Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid” (EFSA, 2018)				
Clopyralid (Regulation (EU) n°2024/2612)				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Wet Crops –Wheat Forage Dry Crops – Wheat Grain Acidic Crops – Orange Oily Crops – Canola Seed	Primary (Method 120610)	0.01 mg/kg	LC/MS/MS	CA 4.2 (a)/1, Vogl, E. (2012), 120610 <i>EU agreed (RAR 2017)</i>
Wet Crop – Wheat Whole Plant Oily Crop – Oilseed Rape Seed	ILV	0.01 mg/kg	LC-MS/MS	Austin R., 2012 120614 <i>EU agreed (RAR 2017)</i>
	Confirmatory (if required)	-	Not required, highly specific detection system was used (LC-MS/MS).	
Dry crop – Rye Grain Wet crop - Lettuce Oily crop - Oilseed Rape Seed Acidic crop - Lemon	Primary (Method 130729)	0.01 mg/kg	LC-MS/MS (QuEChERS)	Lindner, M., Giesau, A., 2013 130729 <i>EU agreed (RAR 2017)</i>
Wet Crop - Lettuce Acidic Crop - Lemon	ILV	0.01 mg/kg	LC-MS/MS (QuEChERS)	Austin, R., Turner, R., 2014 130728 <i>EU agreed (RAR 2017)</i>
	Confirmatory (if required)	-	Not required, highly specific detection system was used (LC-MS/MS).	

Noticed data gaps are:

- A method for clopyralid in body fluids with an LOQ of 0.01 mg/L;
- Verification of the efficiency of the extraction procedures used in monitoring methods for clopyralid for animal products (EFSA, 2018);
- Analytical method for clopyralid used in the developmental toxicity study in rats (EFSA, 2018).

The above methods for clopyralid are considered a data gap and should be addressed at the active substance and product renewal.

3.5 Mammalian toxicology (Part B, Section 6)

No experimental acute toxicity data are available. To assess the acute toxicity and the classification of ADM.01851.H.1.A the CLP calculation method according to Regulation (EC) No 1272/2008 was applied. For these calculation toxicity data of individual ingredients were considered. Details are provided in Part C.

3.5.1 Acute toxicity

The acute oral, dermal and inhalation toxicity estimates for ADM.01851.H.1.A are > 2000 mg/kg bw and > 5 mg/L, respectively. No classification for acute dermal and/or inhalation toxicity is required according to Regulation (EC) No 1272/2008.

The formulation ADM.01851.H.1.A was considered to be irritant to skin and to cause serious damage to the eye. According to Regulation (EC) No 1272/2008 ADM.01851.H.1.A is required to be classified for skin irritation (H315, cat 2, causes skin irritation) and eye irritation (H318, cat 1, causes serious damage to the eye).

The formulation ADM.01851.H.1.A is not considered to be sensitizing to the skin. According to Regulation (EC) No 1272/2008 no classification for skin sensitization is required.

3.5.2 Operator exposure

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, online calculator version: 1.0.2

The estimated operator exposures for an operator wearing work wear (arms, body and legs covered), gloves and faceshield during mixing/loading and work wear (arms, body and legs covered) during application were below the established (A)AOEL. Thus, it is concluded that the use of ADM.01851.H.1.A is at an acceptable risk for the operator.

3.5.3 Worker exposure

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, online calculator version: 1.0.2

For workers removing bolting sugar beets, the estimated exposure was below the established AOEL when the worker was wearing work wear (arms, body and legs covered) and gloves. After a re-entry period of 6 days, it was sufficient for a worker removing bolting sugar beets to wear work wear only (arms, body and legs covered, no gloves) for the estimated exposure being below the established AOEL.

For workers performing inspection/irrigation tasks, the estimated exposure was below the established AOEL when the worker was wearing work wear only (arms, body and legs covered, no gloves).

Thus, it is concluded that the use of ADM.01851.H.1.A is at an acceptable risk for the worker.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, online calculator version: 1.0.2

The calculated total systemic exposure for bystanders was below the established AAOEL for the child and adult scenario in the case of clopyralid. For ethofumesate, no AAOEL is established, and therefore, bystander exposure is covered by resident exposure. The calculated total systemic exposure for residents was below the established AOEL for the child and adult scenario for both active substances, i.e., ethofumesate and clopyralid. Thus, it is concluded that the use of ADM.01851.H.1.A is at an acceptable risk for residents and bystanders.

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

This dossier is presented to support the product ADM.01851.H.1.A for the use in sugar beet and fodder beet. The supported uses which are relevant in respect of residues and consumer exposure are summarised below:

Ethofumesate:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2	Sugar beet	Yes	Yes (36 trials)	n.a.	Yes	Yes	No	Not relevant, no ARfD set
1, 2	Fodder beet	Yes	Yes (extrapolated from sugar beet)	n.a.	Yes	no MRL set		

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a.: not applicable, the PHI is covered by the time remaining between application and harvest

Clopyralid:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2	Sugar beet	Yes	Yes (10 trials)	n.a.	Yes	Yes	No	No
1, 2	Fodder beet	Yes	Yes (extrapolated from sugar beet)	n.a.	Yes	no MRL set		Not relevant, only for animal feed

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a.: not applicable, the PHI is covered by the time remaining between application and harvest

3.6.1 Residues

Sugar beet is a major crop in the EU (SANTE/2019/12752 rev. 1) and therefore 8 trials per zone are required. Residue data for sugar beet covers also application on fodder beet and thus the residues are taken into account for the livestock dietary burden calculation.

Ethofumesate:

The intended GAP for ethofumesate (ADM.01851.H.1.A) for sugar and fodder beets in northern Europe is 3 x 0.33 kg a.i./ha with interval between applications of 5 days at BBCH 10-19 with PHI as not applicable, the PHI is covered by the time remaining between application and harvest with remark: max. rate of active must not exceed 1.0 kg/ha every 3 years.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application.

Sufficient trials are available to support the proposed use in sugar beet (EFSA, 2016).

In EFSA Journal 2016;14(1):4374 it is stated that “In residue trials in the primary crop and in rotational crops residues of ethofumesate and by turns of free NC 9607, free and conjugated NC 20645 and NC 8493 were determined. When the occurrence of residues in the primary or rotational crop (food and feed items) at harvesting stage is considered, the residue definition for risk assessment is appropriately defined as the sum of ethofumesate, NC 9607, NC20645 and its conjugate, expressed as ethofumesate. The same residue

definition was proposed for monitoring purposes and MRL setting.”

Sufficient residue trials were conducted in NEU. According to the RMS-Austria conclusion (DRAR for Ethofumesate, 2015): “Between 1972 and 2012, numerous residue trials were conducted to support the presented “representative use” (pre-emergence and post-emergence use) of ethofumesate in *Beta vulgaris*, the trials were conducted in different growing areas in the northern and southern European residue region. The vegetation period in sugar and fodder beet ranges between 5 and 9 months and the studies indicate that the variation within the vegetation period is much higher than the time period between pre- and post-emergent treatment. The final residues were at or slightly above the LOQ levels.”

Residues of ethofumesate (Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate) in samples of sugar beet roots (applications post-emergence up to BBCH 18) were $8x < 0.02$, $15x < 0.06$, 0.06, 0.09, $11x < 0.1$ mg/kg.

The trials are supported by valid storage stability data for sugar beet and validated analytical methods.

The residues arising from the proposed uses will not exceed the MRL established for ethofumesate (as Sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate) for sugar beet roots (0.2 mg/kg) in Reg. (EC) No 2017/1016.

No additional data are required.

Clopyralid:

The intended cGAP for ADM.01851.H.1.A in sugar beet and fodder beet is less critical than the EU cGAP GAP on which EU a.s. assessment is based: $1 \times 0.1 + 1 \times 0.2$ kg as/ha, 21 days interval, BBCH 10-39, outdoor; intended cGAP for ADM.01851.H.1.A is: 3×0.0495 kg as/ha, 5d interval, BBCH 10-19.

No new studies are submitted by the Applicant. All studies have been evaluated during the first approval of clopyralid and were considered acceptable.

A total of 10 supervised residue trials with clopyralid have been carried out on sugar beet in open field conditions in Northern. The majority of trials have been conducted by using EF-1136 formulation containing 100 g/L clopyralid. **The trials are overdosed and are considered to represent a worst-case.**

Residues of clopyralid found in the treated sugar beet roots samples ranged from 0.12 to 0.80 mg/kg (10 NEU trials: 0.12, 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80 mg/kg).

Residues of clopyralid found in the treated sugar beet tops samples ranged from 0.13 to 1.05 mg/kg (10 NEU trials: 0.13, 0.14, 0.23, 0.36, 0.46, 2×0.47 , 0.57, 0.62, 1.05 mg/kg).

According to the SANTE/2019/12752 the residue trials on sugar beets (0900010) may be extrapolated to fodder beets.

It should be noted that the MRL value was recalculated in this dossier with the OECD MRL Calculator from 2020 which was not applicable at the time of first approval of clopyralid. The current MRL of 1 mg/kg for sugar beet was set based on the residue trials summarised in this table and the Rber/Rmax calculation approach and therefore does not need to be increased. All residues of clopyralid in sugar beet roots were below the MRL. Thus, MRL compliance is concluded.

Conclusion:

Available results show that the in force MRL of clopyralid on sugar beets of 1 mg/kg (Reg. (EU) 2024/2612) will not be exceeded. The current EU MRLs for clopyralid are sufficient to support the proposed use.

Therefore, sufficient residue trials are available to support the intended GAP uses on sugar beets and fodder beets.

During the commenting period Applicant submitted additional explanations:

“EFSA 2024 (EFSA Journal 2024.8546) concluded: “Regarding the potential residue uptakes in cereals and root crops, the need for deriving MRLs or implementing risk mitigation measures (as proposed by EMS) should be assessed in the framework of the MRL review to be carried out under Article 12 of Reg (EU) 396/2005”

New rotational crop residue trials have been submitted in this dossier. In leafy vegetables and oilseeds,

residues of clopyralid were <0.01 mg/kg in all food commodities, thus there is no impact on the existing MRLs for these commodities. In root and tuber vegetables, the HR of clopyralid was 0.042 mg/kg in radish root. This value is only 8.4% of the lowest MRL for root and tuber vegetables (0.5 mg/kg), thus no exceedance of the MRL is expected and no PBI is needed. The HR in cereal grain was 0.17 mg/kg that is only 8.5% of the lowest MRL for cereals (2 mg/kg), thus no exceedance of the MRL is expected and no PBI is needed. Furthermore, residues found in rotational crop feed commodities were considered in dietary burden calculation. The calculated dietary burden for livestock did not increase compared to the most recent EFSA calculation. Thus, there is no impact on MRLs for animal commodities. Therefore, no plant-back restriction is needed to manage residues and no planting prior to 30 days in a crop failure situation is feasible in any case. The exception to this is sugarcane where the MRL is set at the default LOQ and therefore the applicant agrees with the 125-day restriction in this instance."

According to available data, specific mitigation measures should apply:

Ethofumesate:

- Do not grow root vegetables (except sugar or fodder beet) in case of crop failure;
- According to the EFSA Journal 2016;14(1):4374 for ethofumesate the maximum annual rate must not exceed 1 kg a.s./ha every 3 years.

Clopyralid:

- ~~— a 30-day PBI is supported for leafy and brassica vegetables, oilseeds and for all other food and feed commodities except sugar canes;~~
- sugar canes not be planted for 125 days after application of clopyralid.

Remark for clopyralid:

- In accordance with national harmonization arrangements, for products containing clopyralid, after completing the procedure under Article 12 of Regulation No 396/2005, it will be necessary to verify the assessment performed in terms of the established residues definition for the accepted uses.

3.6.2 Consumer exposure

Ethofumesate:

Dietary risk assessment for the active substance ethofumesate was carried out using EFSA PRIMo revision 3.1. The results are presented in Point B7.2.8. The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 2017/1016 led to a utilisation of the ADI of 0.5% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 0.2% of the ADI.

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

As no ARfD has been set for ethofumesate, an acute risk assessment was not conducted.

Clopyralid:

Dietary risk assessment for the active substance clopyralid was carried out using EFSA PRIMo revision 3.1. The results are presented in Point B7.3.8.

The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs values for all plant and animals commodities according to Regulation (EU) 2024/2612 led to a utilisation of the ADI of 43% for NL toddler diet with the highest value. For this diet, the highest contributor is Maize/corn with 9% of the ADI.

Additionally, the evaluator performed an acute consumer risk assessment using MRLs for intended uses and MRLs for animal commodities and using a value of ARfD of 0.17 mg/kg bw.

The highest International Estimated Short-Term Intake (IESTI) is at 5% and 2% of the ARfD for the consumption of Milk:Cattle by children and Bovine: Kidney by adults respectively and for processed commodities at 62% and 25% of the ARfD from the consumption of sugar beets (root)/sugar by children and by adults, respectively.

The proposed uses of clopyralid in the product ADM.01851.H.1.A do not represent unacceptable acute and chronic risks for the consumer.

3.7 Part B, Section 8)

The appropriate endpoints regarding Polish requirements were used to calculate PECs for the active substances and their relevant metabolites in soil, groundwater and surface water/sediment for the multiple applications on sugar beet.

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

The PEC_{soil} have been assessed according to guidance given by FOCUS together with the FOCUS groundwater interception values. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{GW})

Predicted concentration in groundwater for ethofumesate and its relevant metabolites, NC8493 and NC20645, and clopyralid were calculated using FOCUS PELMO 5.5.5, FOCUS PEARL 6.6.4 and MACRO 5.5.4 with the respective FOCUS groundwater scenario for sugar beet. PEC_{GW} values were calculated for annual, biennial and triennial applications with plant uptake factors of 0 for both active substances, ethofumesate and clopyralid.

The PEC_{GW} for ethofumesate and its relevant metabolites, NC8493 and NC20645 were $\leq 0.1 \mu\text{g/L}$ for all scenarios relevant to Poland: Châteaudun, Hamburg and Kremsmünster for applications carried out every second year. Please note that the maximum cumulative rate of ethofumesate on the treated field from all used products with this substance cannot exceed 1000 g a.s. every second year.

The PEC_{GW} for clopyralid were $\leq 0.1 \mu\text{g/L}$ for all scenarios relevant to Poland: Châteaudun, Hamburg and Kremsmünster for applications carried out every second year. Please note that the maximum cumulative rate of clopyralid on the treated field from all used products with this substance cannot exceed 150 g a.s. every second year.

Overall, in order to protect groundwater uses of ADM.01851.H.1.A must be restricted to biennial application to sugar beet at the rate of 0.66 L product/ha by considering 3 applications with 5 days interval.

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

Predicted environmental concentrations in surface water and sediment for ethofumesate were calculated using FOCUS Steps 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3 and SWAN v5.01. PEC_{SW} values for ethofumesate metabolite NC8493 were calculated up to FOCUS Step 2. PEC_{SW} values for ethofumesate metabolite NC20645 and clopyralid were calculated up to FOCUS Step 3. All calculations used the respective FOCUS surface water/sediment scenarios for sugar beet.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Effects on birds of ADM.01851.H.1.A were not evaluated as part of the EU assessment of ethofumesate or clopyralid. However, the provision of further data on the formulation is not considered essential, because the active substance data available in the EU reviews are considered adequate to predict the toxicity and related risk assessment to birds.

An assessment of combined toxicity is required as there are two active substances in the formulated product ADM.01851.H.1.A.

Acceptable acute risk is presented with all TERs for dietary exposure of birds towards the active substances and the product exceeding the trigger based on screening evaluations. Likewise, an acceptable reproductive risk is presented for dietary exposure based on Tier 1 evaluations.

Detailed drinking water assessments are not triggered. Assessments of the potential risks to earthworm-eating birds and fish-eating birds from indirect exposure due to secondary poisoning are not triggered as the log Pow of ethofumesate amounts to 2.7 and the log P_{ow} of clopyralid amounts to -2.63, thus do not exceed the trigger value of 3.

Terrestrial vertebrates (other than birds)

Effects on mammals of ADM.01851.H.1.A were not evaluated as part of the EU assessment of ethofumesate or clopyralid. However, the provision of further data on the formulation is not considered essential, because the active substance data available in the EU reviews are considered adequate to predict the toxicity and related risk assessment to mammals.

An assessment of combined toxicity is required as there are two active substances in the formulated product ADM.01851.H.1.A.

Acceptable acute risk is presented with all TERs for dietary exposure of mammals towards the active substances and the product exceeding the trigger based on screening and Tier 1 evaluations. Likewise, an acceptable reproductive risk is presented for dietary exposure based on screening and Tier 1 evaluations.

Detailed drinking water assessments are not triggered. Assessments of the potential risks to earthworm-eating mammals and fish-eating mammals from indirect exposure due to secondary poisoning are not triggered as the log Pow of ethofumesate amounts to 2.7 and the log P_{ow} of clopyralid amounts to -2.63, thus do not exceed the trigger value of 3.

3.8.2 Effects on aquatic species

Based on the performed calculations in Core Dossier, Section B9 for aquatic organism following conclusions may be derived for scenarios relevant for Poland (D3, D4 and R1):

Sugar beet :

- Clopyralid: acceptable risk with no need for risk mitigation measures
- Ethofumeate: D3, D4 and R1 scenarios: risk acceptable with no need for risk mitigation measures

The combined risk assessment indicated no synergism or antagonism. Acceptable risks were indicated for all scenarios relevant for Poland at FOCUS Step 3.

3.8.3 Effects on bees

Acute oral and acute contact tests chronic toxicity to adults and larvae toxicity tests were carried out on honey bees with the formulated product ADM.01851.H.1.A.

The acute risk assessments according to SANCO/10329/2002 rev.2 for the active substances as well as for formulated product with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses of ADM.01851.H.1.A.

The chronic studies for adult bees and larva bees according to Reg. 284/2009 have been provided and evaluated by zRMS.

3.8.4 Effects on other arthropod species other than bees

Acceptable in-field and off-field risks are indicated for the standard test species *Typhlodromus pyri* and *Aphidius rhopalosiphii* at Tier 1 with no need risk mitigation measures to aquatic organism.

3.8.5 Effects on soil organisms

Meso- and macrofauna

Studies were carried out on *Eisenia fetida*, *Folsomia candida* and *Hypoaspis aculeifer* with the formulated product ADM.01851.H.1.A. Studies to determine the effects of ethofumesate metabolites NC8493 and NC20645, and clopyralid on all indicator species were assessed during the relevant active substance renewal submissions.

Acceptable risks are indicated for soil meso- fauna based on TERs for the active substances, relevant soil degradation products and the formulated product ADM.01851.H.1.A exceeding the trigger values.

Microbial activity

A new study was carried out to determine the effects on soil micro-organisms of the formulated product ADM.01851.H.1.A.

An acceptable risk for soil microbial functions is indicated by predicted environmental concentrations lower than the No Observed Adverse Effect Concentrations (i.e. concentrations causing less than 25% effect on nitrogen transformation after 28 days).

3.8.6 Effects on non-target terrestrial plants

News studies were carried out to determine the effects on non-target terrestrial plants of the formulated product ADM.01851.H.1.A.

Based on deterministic risk assessment an acceptable off-field risk is indicated for the Polish GAP when 50 % DRN or 5 meter unsprayed buffer zone is applied to non-crop land. zRMS used higher Tier approach – probabilistic risk assessment as a refined option.

In case of probabilistic risk assessment the risk is considered acceptable with AF of 1.

Finally, no risk mitigation measures are required to NTTP for the Polish GAP.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

No metabolites are predicted above 0.1 µg/L in the groundwater.

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

The active substances ethofumesate and clopyralid are not approved as candidates for substitution therefore a comparative assessment is not foreseen.

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

Efficacy Section:

In order to introduce 2 additional controlled weed species to the label, **one and two trials are needed** for SOLNI and POLPE respectively.

A minimum of 2 selectivity trials in fodder beet are required to allow for extrapolation of the use from the sugar beet. Without them, the use in the fodder crop can be authorised only following Article 51 of the Regulation 1107/2009.

The issue of impact on succeeding crops has remained unresolved. The proper data, produced and processed according to directions of the EPPO guideline PP 1/207 Effects on succeeding crops, are necessary to reconsider the options and to support the necessary label statement concerning succeeding and replacement crops. Without such data, i.e. according to the present shape of the dossier, the only conclusion possible is that there is a risk. This risk is, however, non-quantified in terms of time intervals needed to mitigate it, and as such it cannot make any robust basis for label directions as detailed as initially proposed.

Analytical methods:

Noticed data gaps are:

- A method for clopyralid in body fluids with an LOQ of 0.01 mg/L;
- Verification of the efficiency of the extraction procedures used in monitoring methods for clopyralid for animal products (EFSA, 2018);
- Analytical method for clopyralid used in the developmental toxicity study in rats (EFSA, 2018).

The above methods for clopyralid are considered a data gap and should be addressed at the active substance and product renewal.

Metabolism and residues:

- In accordance with national harmonization arrangements, for products containing clopyralid, after completing the procedure under Article 12 of Regulation No 396/2005, it will be necessary to verify the assessment performed in terms of the established residues definition for the accepted uses.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem~~ i jasno-szaryą czcionką (fragmenty usunięte).

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2-letnie badania są rozpoczęte. Można uznać 2-letni okres przechowywania warunkowo na postawie 14-dniowych badań przyspieszonego starzenia w temperaturze 54°C środka przechowywanego w opakowaniach wykonanych z HDPE/PA. Na podstawie zapisów wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 05/09/2023 dla środków ochrony roślin w postaci roztworu wodnego (formulacja SC) możliwa jest ekstrapolacja pomiędzy każdym typem opakowań z tworzyw sztucznych.
W związku z powyższym wszystkie opakowania wymienione w punkcie 4.1 Sekcji 1,2,4 oraz w punkcie 2.1 dokumentu A można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do nazw grup chemicznych, do których przyporządkowano substancje czynne. Skorygowano zawartości substancji czynnych. (zgodnie z punktem 2.6.1 Sekcji 1,2,4 gęstość $d=1.155 \text{ g/cm}^3$).
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Z tabeli zwalczanych chwastów usunięto 2 gatunki: psiankę czarną i rdest plamisty, w porównaniu do części B3 raportu. Postępowanie to wynika z krajowych ustaleń harmonizacyjnych w zakresie minimalnej liczby badań dla poszczególnych chwastów: obydwa gatunki uznano za krytycznie ważne w uprawie buraka cukrowego, zatem liczba wymaganych dla nich badań wynosi 4, podczas gdy dla wymienionych chwastów liczby te wynoszą odpowiednio 3 i 2. Zagadnienie wpisano także do pkt. 5 tego (Part A) dokumentu.
2. Z uwagi na brak badań selektywności nie zostało zaakceptowane zastosowanie środka w uprawie buraka pastewnego w trybie art. 33. Burak pastewny jest gatunkiem małoobszarowym w Polsce i możliwa jest jego rejestracja w trybie art. 51.
3. W rozdziale NASTĘPSTWO ROŚLIN usunięto dotychczasowe brzmienie zaleceń, a zamiast nich wprowadzono zapis zaproponowany przez wnioskodawcę, uwzględniający brak danych w zakresie wpływu na rośliny następce w przedłożonej obecnie treści rozdziału 3.4.6 *Impact on succeeding crops* w części B3. Ustalenie następstwa roślin i stosownych zaleceń do etykiety dotyczących tego zagadnienia wymaga uzupełnienia wniosku przez aplikanta o właściwe badania przeprowadzone prawidłowo zgodnie z wytyczną EPPO PP 1/207 Effects on succeeding crops. Stanowisko oceniającego uzasadniono w komentarzu do tego rozdziału w części B3. Zagadnienie wprowadzono także do pkt. 5 tego (Part A) dokumentu.
4. Brak uwag do rozdziału „Strategia zarządzania odpornością”. Rozdział prawidłowo i wyczerpująco przenosi do etykiety zagadnienia podjęte przez wnioskodawcę w części B3 i niezbędne dla racjonalnego stosowania środka.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis został zmodyfikowany zgodnie z zaproponowaną klasyfikacją CLP śor. H15 i H318 (ustalenia harmonizacyjne Min Rol Toksykologia, wer. 11/12/2024)

Sekcja pozostałości:

1. Zapisy dotyczące upraw następnych zostały odpowiednio skorygowane zgodnie z prośbą Wnioskodawcy i zostały zaakceptowane przez sekcję pozostałości.

Sekcja los i zachowanie w środowisku:

1. Ze względu na ochronę wód podziemnych dodano zwrot wskazujący możliwość stosowania środka ADM.01851.H.1.A oraz innych środków zawierających etofumesat czy chlopyralid na buraku cukrowym jeden raz co dwa lata (zwrot SPe 1).
2. Poprawiono zwrot wskazujący możliwość stosowania środka ADM.01851.H.1.A oraz wszystkich innych środków zawierających etofumesat nie częściej niż co dwa lata, tak by maksymalna skumulowana dawka etofumesatu ze wszystkich stosowanych środków z tą substancją nie przekroczyła łącznie 1 kg na hektar raz na 2 lata.
3. Dopisano zwrot wskazujący możliwość stosowania środka ADM.01851.H.1.A oraz wszystkich innych środków zawierających chlopyralid nie częściej niż co dwa lata, tak by maksymalna skumulowana dawka chlopyralidu ze wszystkich stosowanych środków z tą substancją nie przekroczyła łącznie 150 g na hektar raz na 2 lata.

Sekcja ekotoksykologia:

1. Usunięto 10 metrową strefę buforową od zbiorników i cieków wodnych. Strefa ochronna od zbiorników i cieków wodnych nie jest wymagana dla scenariuszy właściwych dla Polski.
2. Dodano zwrot P501 do etykiety instrukcji stosowania.

Posiadacz zezwolenia:

ADAMA Polska Sp. z o.o., ul. Sienna 39, 00-121 Warszawa, tel.: +48 22 395 66 60, infolinia: +48 22 395 66 66, e-mail: biuro@adama.com, www.adama.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie:

.....

TAXATUM

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

etofumesat – związek z grupy pochodnych benzofuranu - 500 g/l (~~44,6%~~) (43,3%)

chlopyralid – związek z grupy pochodnych kwasów pirydynokarboksylowych - 75 g/L (6,49%)

Zezwolenie MRiRW nr z dnia



UWAGA

H315 – Działa drażniąco na skórę

H318 – Powoduje poważne uszkodzenie oczu

H410 – Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

EUH208 - Zawiera 1,2-Benzotiazol-3(2H)-on. Może powodować wystąpienie reakcji alergicznej.

P280 – Stosować rękawice ochronne i ochronę oczu

P302 + P352 – W przypadku kontaktu ze skórą umyć dużą ilością wody z mydłem

P305 + P351 + P338 – W przypadku dostania się do oczu: ostrożnie płukać kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

P391 – Zebrać wyciek.

P 501 – Zawartość/pojemnik usuwać do odpowiedniego miejsca utylizacji zgodnie z lokalnymi i krajowymi przepisami.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany dolistnie w formie stężonej zawiesiny do rozcieńczania wodą (SC).

Zgodnie z klasyfikacją HRAC substancja czynna etofumesat zaliczana jest do grupy 15 (dawnej grupy N), natomiast substancja czynna chlopyralid zaliczana jest do grupy 4 (dawnej grupy O).

DZIAŁANIE NA CHWASTY

Środek zawiera dwie substancje czynne o odmiennym mechanizmie działania.

Substancja czynna etofumesat blokuje biosyntezę kwasów tłuszczowych o długich łańcuchach wykorzystywanych do produkcji wosków lub innych związków wchodzących w skład wosków w najmłodszych tkankach już w czasie kiełkowania nasion. Kiełki lub młode siewki pozbawione ochronnego działania kwasów tłuszczowych o długich łańcuchach nie są odporne na działania warunków zewnętrznych w konsekwencji szybko więdną, spowalniają lub nie inicjują procesów biochemicznych i szybko zamierają.

Chlopyralid 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.

Środek pobierany jest przez korzenie chwastów i liście. Najskuteczniej zwalcza chwasty w okresie ich kiełkowania.

Wrażliwe gatunki zwykle nie kiełkują lub kiełkują bardzo wolno, mają poskręcane liście często o ciemnozielonym zabarwieniu, zatrzymują wzrost w fazie siewek i szybko zamierają.

Odpowiednia wilgotność gleby sprzyja lepszemu pobieraniu środka z gleby co potęguje efekt chwastobójczy.

Ze względu na długie utrzymywanie się środka w górnej warstwie gleby zabezpiecza on plantację przed zachwaszczeniem wtórnym.

Chwasty wrażliwe	gwiazdnica pospolita, przytulia czepna, maruna bezwonna
Chwasty średnio wrażliwe	komosa polna, ~~psianka czarna~~ , tobołki polne, jasnota purpurowa
Chwasty odporne	rdest ptasi, rdestówka powojowata, ~~rdest plamisty~~

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego

Burak cukrowy, ~~burak pastewny~~

1) Termin stosowania

Środek stosować od momentu widocznego pierwszego liścia do fazy 9 liści (BBCH 10-19)

Środek stosować w dawce dzielonej według podanego poniżej schematu:

Pierwszy zabieg: stosować od pierwszej pary liści właściwych do drugiej pary liści właściwych, na wschodzące chwasty.

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,66 l/ha.

Drugi zabieg: stosować co najmniej 5 dni po pierwszym zabiegu.

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,66 l/ha.

Trzeci zabieg: stosować co najmniej 5 dni po drugim zabiegu.

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,66 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

lub

2) aplikacja pasmowa na 50% powierzchni wzdłuż rzędów roślin.

Termin stosowania: stosować od momentu widocznego pierwszego liścia do fazy 9 liści (BBCH 10-19)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,33 L/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

Maksymalna liczba zabiegów w sezonie wegetacyjnym:

Odstęp między zabiegami: co najmniej 5 dni.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: średniokropliste

ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA

Na tym samym polu, na którym został użyty środek Taxatum nie stosować tego środka ani żadnego innego produktu zawierającego etofumesat w okresie dwóch ~~trzech~~ kolejnych lat w dawkach przekraczających łącznie 1,0 kg etofumesatu substancji czynnej na 1 ha.

Na tym samym polu, na którym został użyty środek Taxatum nie stosować tego środka ani żadnego innego produktu zawierającego chlopypirid w okresie dwóch kolejnych lat w dawkach przekraczających łącznie 150 g chlopypiridu na 1 ha.

Środek nie jest przeznaczony do ochrony plantacji nasiennych w żadnej fazie produkcji (ani jesienią, ani wiosną).

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy, zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin
- stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszanek herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym takiego zmianowania upraw które umożliwi rotację mechanizmów działania herbicydów stosowanych w kolejnych sezonach wegetacyjnych itp.,
- nie upraszczać zespołów uprawek mechanicznych gleby; następujące przy tym mechaniczne zwalczanie chwastów jest niezbędnym uzupełnieniem zwalczania chemicznego,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:

- na rośliny mokre lub chore, uszkodzone przez szkodniki czy wykazujące niedobór składników pokarmowych, w warunkach suszy,
- po długotrwałej suszy

3. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

OKRESY KARENCJI

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

NASTĘPSTWO ROŚLIN

Po upływie 5 miesięcy od zastosowania środka, na polu na którym zastosowano środek (po wykonaniu głębokiej orki na głębokość, co najmniej 15 cm) można uprawiać wszystkie rośliny.

W przypadku wcześniejszego zaorania plantacji buraka z powodu uszkodzenia roślin np. przez choroby, szkodniki lub przymrozki, można uprawiać jedynie burak cukrowy, burak pastewny, burak éwikłowy, groch, szpinak, len, kukurydzę i lucernę pod warunkiem, że w tym samym sezonie nie zastosuje się żadnego środka z etofumesatem i nie przekroczy się dawki 1 kg s.cz./ha w ciągu 3 lat.

W przypadku wcześniejszego zaorania plantacji buraka z powodu uszkodzenia roślin np. przez choroby lub szkodniki można uprawiać jedynie burak cukrowy, pod warunkiem, że w tym samym sezonie nie zastosuje się żadnego środka z etofumesatem czy chlopyralidem oraz nie przekroczy się dawki 1 kg s.cz./ha etofumesatu oraz 150 g s.cz./ha chlopyralidu w ciągu 2 lat. Ostatni warunek - niestosowania środka z etofumesatem czy chlopyralidem na buraku cukrowym nie częściej niż co 2 lata - podyktowany jest ochroną wód podziemnych.

W przypadku ponownej uprawy buraków nie stosować środka ponownie.

Stosując środek w mieszaniu z innymi herbicydami należy przestrzegać zaleceń następstwa roślin dla środków wchodzących w skład mieszanin.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszało hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, 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.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne i odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

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.

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.

Unikać niezgodnego z przeznaczeniem uwolnienia do środowiska.

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 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.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C-30°C.

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

W przypadku kontaktu ze skórą umyć dużą ilością wody z mydłem

W przypadku dostania się do oczu: ostrożnie płukać kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

This is business confidential information. If needed, the Letters of Access are provided separate to this submission.

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	Vertebrate study Y/N	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.2.1/01	Michnik, I.	2024	Hazard Properties Testing on a Sample of ADM.01851.H.1.A Report No. GLP3016013507R1/2023, Sponsor report no. 000116227 DEKRA UK Ltd., United Kingdom GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.2.2/01	Michnik, I.	2024	Hazard Properties Testing on a Sample of ADM.01851.H.1.A Report No. GLP3016013507R1/2023, Sponsor report no. 000116227 DEKRA UK Ltd., United Kingdom GLP Unpublished Filed under KCP 2.2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.3.1	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.3.3/01	Michnik, I.	2024	Hazard Properties Testing on a Sample of ADM.01851.H.1.A Report No. GLP3016013507R1/2023, Sponsor report no. 000116227 DEKRA UK Ltd., United Kingdom GLP Unpublished Filed under KCP 2.2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA

KCP 2.4.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.4.1/02	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.5.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.5.2/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.6.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA

			Filed under KCP 2.1/01				
KCP 2.7.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.7.4/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.7.5/01	Massardi, E.	2024b	STUDY PLAN - ADM.01851.H.1.A: Shelf life at 20 ± 2 °C for 2 years Report No. CPU-007-24, Sponsor report No. 000118841 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.8.2/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.8.3.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA

KCP 2.8.3.2/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.8.5.1.1/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.8.5.1.2/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 2.8.7.2/01	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished Filed under KCP 2.1/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 4.3/01	Anonymous	2024	Safety Data Sheet – ADM.01851.H.1.A ADAMA Agan Ltd., Ashdod., Israel Report no.: not available No GLP Unpublished	N	N	-	ADAMA
KCP 4.4/01	Anonymous	2007	HDPE - 1 L packaging information (Amraz) Amraz Ltd., Israel Report no.: not available	N	N	-	Amraz

			No GLP Unpublished				
KCP 4.4/02	Anonymous	2013	HDPE (Reyde) 1 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	N	-	Reyde
KCP 4.4/03	Anonymous	2020	HDPE (Reyde) 1 L rectangular bottle - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	N	-	Reyde
KCP 4.4/04	Anonymous	2005	HDPE - 4x5 L packaging information Amraz Ltd., Israel Report no.: not available No GLP Unpublished	N	N	-	Amraz
KCP 4.4/05	Anonymous	2019	HDPE (Reyde) 5 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	N	-	Reyde
KCP 4.4/06	Anonymous	2018	HDPE (Mobilak) 5 L - Packaging information Mobilak Report no.: not available No GLP Unpublished	N	N	-	Mobilak
KCP 4.4/07	Anonymous	2017	HDPE (Pachmas) 5 L - Packaging information Pachmas Packaging Ltd Report no.: not available No GLP Unpublished	N	N	-	Pachmas
KCP 4.4/08	Anonymous	2020	HDPE (Mobilak) 10 L - Packaging information Mobilak Report no.: not available No GLP Unpublished	N	N	-	Mobilak
KCP 4.4/09	Anonymous	2019	HDPE (Reyde) 10 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	N	-	Reyde
KCP 4.4/10	Anonymous	2020	HDPE (Pachmas) - 10 L packaging information PACHMAS Packaging Ltd., Israel	N	N	-	Pachmas

			Report no.: not available No GLP Unpublished				
KCP 5.1.1/01	Massardi E.	2024	ADM.01851.H.1.A: Validation of analytical method for active ingredients and content determination Research Center BioSphereS by Biotechnologie BT, Italy Report No. CPU-024-23, ADAMA reference no. 000116317 GLP, Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/01	Watson, G.	2022	Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years Report No. RES-00278 Study ID 000106576 GLP, Unpublished Filed under KCA 6.1/02	N	Y	Data protection started with authorisation of the product <i>Ethosat 500 SC</i> (authorisation no R-132/2022 dated on 15/11/2022) Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/02		2024	Acute toxicity of ADM.01851.H.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour static test Report no. 23 48 AFA 0006, ADAMA Reference No. 000116374 GLP, Unpublished Filed under KCP 10.2/01	Y	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/03	Renner P.	2024a	Acute toxicity of ADM.01851.H.1.A to <i>Daphnia magna</i> in a 48-hour static test Report no. 23 48 ADL 0020, ADAMA Reference No. 000116373 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.2/03	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/04	Renner P.	2024b	Effects of ADM.01851.H.1.A on <i>Raphidocelis subcapitata</i> in an algal growth inhibition test Report no. 23 48 AAL 0014, ADAMA Reference No. 000116375 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.2/03	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/05	Warning D.	2022	Effects of ADM.01851.H.1.A on <i>Myriophyllum spicatum</i> in a static water-sediment system 22 48 AMS 0001 BioChem agrar, Machern OT Gerichshain, Germany	N	Y	Data/study report never submitted before to support a product authorisation	ADAMA

			GLP, Unpublished Filed under KCP 10.2/04			in Poland	
KCP 5.1.2/06	Ruhland S.	2023	Chronic toxicity of ADM.01851.H.1.A to the honey bee <i>Apis mellifera</i> L. under laboratory conditions ~~18 48 BAC 0007~~ 22 48 BAC 0024 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.3.1.2/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/07	Kleebaum K.	2022	ADM.01851.H.1.A – Repeated Exposure of Honey Bee (<i>Apis mellifera</i> L.) Larvae under Laboratory Conditions 22 48 BLC 0025 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.3.1.3/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/08	Friedemann A.	2024	Effects of ADM.01851.H.1.A on seedling emergence and seedling growth of ten non-target terrestrial plant species under greenhouse conditions 23 46 PSE 0012 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.6.2/01	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/09	Friedemann A.	2024a	Effects of ADM.01851.H.1.A on vegetative vigour of ten non-target terrestrial plant species under greenhouse conditions 23 46 PVV 0011 BioChem agrar, Machern OT Gerichshain, Germany GLP, Unpublished Filed under KCP 10.6.2/02	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 5.1.2/10	Teasdale, R.	1996	Frozen Storage Stability of Clopyralid Residues in Strawberries Corteva Report No. GHE-P-4832 Study No. CEMS-235 CEM Analytical Services Ltd. GLP Unpublished Filed under KCA 6.1/02 of clopyralid	N	N	-	Corteva Agriscience LoA is available
KCP 5.1.2/11	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 Filed under KCA 6.1/01 of clopyralid	N	N	-	Corteva Agriscience LoA is available

KCP 6.1-01	Dagmar von Hörsten	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, in Gemrnay Trial ID: DE23HEBEAVA123C Company Report No FRS016/23 GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.1.02	PD Dr. agr. habil. Peter Wolf	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Germany in 2023 Trial ID: DE23HEBEAVA123D GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-01	Udo Zickart	2023	Selectivity of ADM.01851.H.1.A on sugar beet, in Germany in 2023 Trial ID: DE23HSBEAVA125A GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-02	Karl-Wilhelm Maßmann	2023	Selectivity of ADM.01851.H.1.A on sugar beet, in Germany in 2023 Trial ID: DE23HSBEAVA125B GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.1-03	dr inż. Justyna Trajdos, PhD	2022	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2022 Trial ID: PL22HEBEAVA008B Report nr: 22ADA01065-2 GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.1-04	Mgr Krzysztof Rusek	2022	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2022 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2022 Report number: 48_01_F22_103 Trial ID: PL22HEBEAVA008C GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-03	Mgr Krzysztof Rusek	2022	Selektywność preparatu ADM.01851.H.1.A stosowanego w zwalczaniu chwastów w uprawie buraka cukrowego.Polska 2022 Selectivity of ADM.01851.H.1.A in weed control in sugar beet,	N	Y	Data/study report never submitted before to support a	ADAMA

			Poland 2022 Report number: 49_02_F22_105 Trial ID: PL22HSBEAVA010A GEP Unpublished			product authorisation in Poland	
KCP 6.2-04	Mateusz Pszczółkowski	2022	Selectivity of ADM.01851.H.1.A on sugar beet, in Poland in 2022 Trial ID: PL22HSBEAVA010B Report nr: MP2-22-101837-01-PL01 GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCP 6.1-05	dr inż. Justyna Trajdos, PhD	2023	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego ,Polska 2023 Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, Poland 2023 Trial ID: PLHEBEAVA001A Report nr: 23ADA01249-1 GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCP 6.1-06	dr inż. Justyna Trajdos, PhD	2023	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego ,Polska 2023 Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, Poland 2023 Trial ID: PLHEBEAVA001B Report nr: 23ADA01249-2 GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCP 6.1-07	Adam Szemen- dera	2023	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2023 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2023 Report nr: 09_01_F23_012 Trial ID: PLHEBEAVA001C GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCP 6.1-08	Adam Szemen- dera	2023	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2023 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2023 Report nr: 09_02_F23_013 Trial ID: PLHEBEAVA001D GEP	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA

			Unpublished				
KCP 6.1-09	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023 Report nr: MP2-23-105198-01-PL02 Trial ID: PL23HEBEAVA001F GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.1-10	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023. Report nr: MP2-23-105198-01-PL03 Trial ID: PL23HEBEAVA001G GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.1-11	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023. Report nr: MP2-23-105198-01-PL04 Trial ID: PL23HEBEAVA001H GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-05	dr inż. Justyna Trajdos, PhD	2023	Ocena selektywności preparatu ADM.01851.H.1.A w uprawie buraka cukrowego Trial ID: PLHEBEAVA003A Report nr: 23ADA1251-1 GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-06	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003B Report number: 11_01_F23_016 GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-07	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003C Report number: 11_01_F23_017 GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 6.2-08	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland,	N	Y	Data/study report never submitted before to support a	ADAMA

			in 2023. Trial ID: PLHEBEAVA003D Report number: 11_01_F23_018 GEP Unpublished			product authorisation in Poland	
KCP 6.2-09	Adam Szemen- dera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003E Report number: 11_01_F23_019 GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCP 6.2-10	Mateusz Pszczółkowski	2023	Selectivity of ADM,01851,H,1,A on sugar beet, in Poland, in 2023 Trial ID: PL23HSBEAVA003F GEP Unpublished	N	Y	Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCA 6.1/01 for ethofumesat	Schulte, G.	2015	Storage Stability of open-ring-2-keto ethofumesate (AE C520645) in Plant Matrices for 24 Months Bayer CropScience AG, 40789 Monheim, Germany Report No. MR-12/058 Study ID P642120507 GLP Unpublished	N	Y	Data protection started with authori- sation of the product Ethosat 500 SC, dated on 15/11/2022 (au- thorisation no R- 132/2022)	TFE*
KCA 6.1/02 for ethofumesat	Watson, G.	2022	Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years Report No. RES-00278 Study ID 000106576 GLP Unpublished	N	Y	Data protection started with authori- sation of the product Ethosat 500 SC (au- thorisation no R- 132/2022 dated on 15/11/2022) Data/study report never submitted be- fore to support a product authorisation in Poland	ADAMA
KCA 6.1/01 for clopyralid	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	N	N	-	Corteva Agriscience LoA is avail- able

			Unpublished				
KCA 6.1/02 for clopyralid	Teasdale, R.	1996	Frozen Storage Stability of Clopyralid Residues in Strawberries Corteva Report No. GHE-P-4832 Study No. CEMS-235 CEM Analytical Services Ltd. GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.2.1/01 for clopyralid	Morton Lloyd, G.	2020	The Metabolism of [14C]-Clopyralid in Wheat Corteva Study No. 191200 Study No. 229882 Charles River Laboratories GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.2.1/02 for clopyralid	MacKenzie, A.	2021	The Metabolism of [14C]-Clopyralid in Spring Oilseed Rape Corteva Study No. 200928 Study No. 231101 Charles River Laboratories GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.2.1/03 for clopyralid	Tuffnail, W.	2022	[14C]-Clopyralid: A Nature of Residue in Sugar Beet (2020); Corteva Study No. 210071 Lab Study No. DWA/10 Pharmaron-UK Ltd, Rushden, Northamptonshire, United Kingdom GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.5.3/01 for clopyralid	Phillips, A.M.	1994	Determination of residues of clopyralid in sugar beet processed frac- tions CORTEVA Report No. GH-C 3305 North American Environmental Chemistry Laboratory GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.5.3/02 for clopyralid	Devine, C.	2020	Residues of Clopyralid in Sugar Beet and Process Fractions Follow- ing Multiple Applications of GF-1966 – Northern Europe – 2019 CORTEVA Report No. 181493 Study No. CEMS-8908 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	N	-	Corteva Agriscience LoA is avail- able
KCA 6.6.2/01 for clopyralid	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)	N	N	-	Corteva Agriscience LoA is avail- able

			GLP Unpublished				
KCP 9.2.4	Hicks J.	2024a	PECgroundwater Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No: ETF/EFA/12 000119037 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	N	-	ADAMA
KCP 9.2.4	Hicks J.	2024b	PECgroundwater Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No: CLO/EFA/01 000119036 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	N	-	ADAMA
KCP 9.2.5	Hicks J.	2024c	PECsurfacewater and PECsediment Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No. ETF/EFA/13 000119039 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	N	-	ADAMA
KCP 9.2.5	Hicks J.	2024d	PECsurfacewater and PECsediment Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No. CLO/EFA/02 000119038 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	N	-	ADAMA
KCP 10.2/01		2024a	Acute toxicity of ADM.01851.H.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour static test 23 48 AFA 0006 GLP Unpublished	Y	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.2/02	Renner P.	2024b	Acute toxicity of ADM.01851.H.1.A to <i>Daphnia magna</i> in a 48-hour static test 23 48 ADL 0020 BioChem agrar, Machern OT Gerichshain, Germany	N	Y	Data/study report never submitted before to support a product authorisation	ADAMA

			GLP Unpublished			in Poland	
KCP 10.2/03	Renner P.	2024c	Effects of ADM.01851.H.1.A on <i>Raphidocelis subcapitata</i> in an algal growth inhibition test 23 48 AAL 0014 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.2/04	Warning D.	2022	Effects of ADM.01851.H.1.A on <i>Myriophyllum spicatum</i> in a static water-sediment system 22 48 AMS 0001 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.3.1.1/01	Poráčzki K.	2022	Acute toxicity of ADM.01851.H.1.A to the honeybee <i>Apis mellifera</i> L. under laboratory conditions 22 48 BAA 0079 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.3.1.2/01	Ruhland S.	2023	Chronic toxicity of ADM.01851.H.1.A to the honey bee <i>Apis mellifera</i> L. under laboratory conditions 22 48 BAC 0024 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.3.1.3/01	Kleebaum K.	2022	ADM.01851.H.1.A – Repeated Exposure of Honey Bee (<i>Apis mellifera</i> L.) Larvae under Laboratory Conditions 22 48 BLC 0025 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.3.2.1/01	Röhlig U.	2024a	Effects of ADM.01851.H.1.A on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test 23 48 NTL 0010 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.3.2.1/02	Röhlig U.	2024b	Effects of ADM.01851.H.1.A on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEPHANI-PEREZ) in a laboratory test 23 48 NAL 0010 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA

KCP 10.4.1.1/01	Friedrich S.	2018	Effects of ADM.01851.H.1.A on the reproduction of the earthworm <i>Eisenia fetida</i> in artificial soil 22 48 TEC 0019 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.4.2.1/01	Schulz L.	2024a	Effects of ADM.01851.H.1.A on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> , 23 48 THC 0023 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.4.2.1/02	Ruhland S.	2024g	Effects of ADM.01851.H.1.A on the mortality and reproduction of the collembolan <i>Folsomia candida</i> 23 48 TCC 0020 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.5/01	Schulz L.	2024b	Effects of ADM.01851.H.1.A on the activity of soil microflora (Nitrogen Transformation Test) 23 48 SMN 0023 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.6.2/01	Friedemann A.	2024a	Effects of ADM.01851.H.1.A on seedling emergence and seedling growth of ten non-target terrestrial plant species under greenhouse conditions 23 46 PSE 0012 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 10.6.2/02	Friedemann A.	2024b	Effects of ADM.01851.H.1.A on vegetative vigour of ten non-target terrestrial plant species under greenhouse conditions 23 46 PVV 0011 BioChem agrar, Machern OT Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA

*TFE (TaskForce Ethofumesate), ADAMA Agricultural Solutions and all its affiliates has also access as ADAMA is member of the TFE.

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

Ethofumesate: For studies owned by Bayer the applicant has a Letter of Co-ownership. For studies owned by the TFE (TaskForce Ethofumesate), ADAMA Agricultural Solutions and all its affiliates has also access as ADAMA is member of the TFE. For studies owned by UPL or ACM the TFE has either equivalent studies or a Letter of Access.

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance Ethofumesate.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 5.1.2	Whiteoak R. J., Crofts M., Harris, R.J.	1973	ANALYTICAL METHOD FOR RESIDUE IN SUGAR BEET TREATED WITH NORTRON Fisons plc, United Kingdom Bayer CropScience, Report No.: A83491/ M-155727-01, Non GLP, unpublished	N	Bayer Crop-Science
CP 5.1.2	Whiteoak, R. J.; Crofts, M.; Harris, R. J.	1976	ANALYTICAL METHOD FOR RESIDUES IN SUGAR BEET TREATED WITH NORTRON Fisons plc, United Kingdom Bayer CropScience, EPA MRID No.: 00084997 Report number: A83492/ M-155728-01 Non GLP, unpublished	N	Bayer Crop-Science
CP 5.1.2	Manley, J. D., Snowdon, P.J.,	1984	ANALYTICAL METHOD FOR RESIDUES OF ETHOFUMESATE AND MAJOR METABOLITES IN SUGAR BEET (IMPROVED METHOD) FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report number: A83493/M-155729-01-1 Non GLP, unpublished	N	Bayer Crop-Science
CP 5.1.2	Wrede, A.;	2000	Validation of the method AL 081/96-0 in peas and sugar beet roots by GC-MSD - ethofumesate - Code: AE B049913 Report No: C009934, Document no: M-199547-01-1 Aventis CropScience GmbH, Germany GLP, unpublished	N	Bayer Crop Science
CP 5.1.2	Perny A.	2002	Validation of the Method of Analysis of the residues of Ethofumesate and its metabolite 2-keto ethofumesate (free and conjugated form) in Sugar Beet Report number: A0019 GLP	N	UPL
CP 5.1.2	Konrad S.	2012	Analytical method 00955/M002 for the determination of ethofumesate and its metabolite AE C509607 in three different plant groups (sugar beet, leaf and body and orange) Currenta GmbH & Co. OHG, Leverkusen, Germany Bayer CropScience, Report No.: 00955/M002 / M-438402-01-1 GLP, unpublished	N	Task Force Ethofumesate

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 5.1.2	Schulte G.	2013	Formation of 2-keto-ethofumesate (AE C509607) by acidic extraction of plant matrices containing open-ring-2-keto-ethofumesate (AE C520645) - (sugar beet (leaf), sugar beet (body), orange (fruit), wheat (grain)) Bayer CropScience, Report No.: MR-13/061/ M-459805-01 GLP, unpublished	N	Task Force Ethofumesate
CP 5.1.2	Schulte G.	2013	STORAGE STABILITY OF OPEN-RING-2-KETO ETHOFUMESATE (AE C520645) IN PLANT MATRICES FOR 24 MONTHS - PHASE REPORT AFTER 6 MONTHS Bayer CropScience Report No: MR-13/086, M-459806-01 GLP, unpublished	N	Task Force Ethofumesate
CP 5.1.2	Thom M.	2005	Validation of an analytical method for the determination of residues of ethofumesate and ethofumesate-2-keto in various plant commodities Report No.: OFC00004832, M-351876-01-1 GAB Analytik GmbH, Germany GLP, unpublished	N	ADAMA
CP 5.1.2	Ross, D. B.; Roberts, N. L	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 1 Huntingdon Research Centre Ltd., Huntingdon, United Kingdom Bayer CropScience, Report number: A83024, M-155301-01-1 Non GLP, unpublished	N	Bayer Crop- Science
CP 5.1.2	Whiteoak, R. J	1990	GAS LIQUID CHROMATOGRAPHIC DETERMINATION OF RESIDUES OF ETHOFUMESATE AND ITS METABOLITES IN MILK AND CATTLE TISSUES Schering AG, Berlin, Germany Bayer CropScience Report no: A83109, M-155384-01-1 GLP, unpublished	N	Bayer Crop- Science
CP 5.1.2	Harris, R. J.	1975	INVESTIGATION OF TISSUE AND EGG RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS Fisons plc, United Kingdom Bayer CropScience, Report no: A83011, M-155288-01-1 Non GLP, unpublished	N	Bayer Crop- Science
CP 5.1.2	Peatman, M. H.	1999	Review of analytical methodology for residues in edible animal products (dairy, tissues, fat and offal) Ethofumesate AE B049913 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer CropScience, Report no: C003328, M-185949-01-1	N	Bayer Crop- Science

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Non GLP, unpublished		
CP 5.1.2	Castro, L. E.	1994	Ethofumesate-derived residues in the meat and milk of dairy cows: resulting from oral ingestion of ethofumesate AgrEvo USA Company, Residue Chemistry, Pikeville, NC, USA Bayer CropScience, Report No: B002201/M-237976-01 Non GLP, unpublished	N	Bayer Crop-Science
CP 5.1.2	Cole M.G.	2000	Validation of an analytical method for the residues of NC 20645 in sugar beet roots and whole milk, USA, 1998 Code: AE C639175 00 1B97 0001 Aventis CropScience USA LP, Residue Chemistry, Pikeville, NC, USA Bayer CropScience Report No: C004116/M-187353-01 Non GLP	N	Bayer Crop-Science
CP 5.1.2	Author(s)	2010	Ethofumesate - Magnitude of the residue in dairy cow Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience Report No.: RAADP014/M-388797-01-1 GLP, unpublished	N	Bayer Crop-Science
CP 5.1.2	Perez R., Schmitt J.L., Patel D.	2014	FREEZER STORAGE STABILITY OF ETHOFUMESATE IN ANIMAL MATRIX SAMPLES - INTERIM REPORT Bayer Crop Science Report No.: M-467206-01, RAADP031 GLP, unpublished	N	Task Force Ethofumesate
CP 5.2	Schulte G., Diehl P.	2014	Validation of the analytical method 01392 for the determination of the relevant ethofumesate metabolites in plant matrices by HPLC-MS/MS Bayer CropScience, Report. number: MR-13/101, M-479926-01 GLP, unpublished	N	Task Force Ethofumesate
CP 5.2	Ingham R.	2014	Letter of access - Regulation (EC) No. 1107/2009 - Active substance - Ethofumesate post Annex I inclusion - Letter of access from UPL to protected data United Phosphorus Limited, Cheshire, United Kingdom TF- Ethofumesate, Report No.: M-475932-01-1, GLP: n.a., unpublished	N	Task Force Ethofumesate
CP 5.2	Spiegel K.	2014	Ethofumesate - Discussion on the usability of plant enforcement method 01392 for metabolite AE C520645 in matrices with high oil content Report No.: M-497717-01 Non GLP, unpublished	N	Task Force Ethofumesate

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CP 5.2	Jooß S.	2012	Ethofumesate - Validation of an Analytical Method for the Determination of the Ethofumesate and its two Metabolites NC 9607 and NC 20645 in Foodstuffs of Animal Origin Report No.: P 2371 G PTRL Europe, Ulm, Germany GPL, unpublished	N	Task Force Ethofumesate
CP 5.2	Schlewitz P.	2013b	Independent laboratory validation of an analytical method for the analysis of Ethofumesate and its two metabolites NC 9607 and NC 20645 in foodstuffs of animal origin Report No.: R B1218 Anadiag S.A. Haguenau, France GLP, unpublished	N	Task Force Ethofumesate
CP 5.2	Brumhard B.	2003	Method 00806 for the determination of residues of Ethofumesate in soil by HPLC-MS/MS Report No.: 00806, M-122176-01-1 Bayer CropScience GLP, unpublished	N	Bayer Crop- Science
CP 5.2	Schneider E.	2000	PR00/003 - Confirmation method for the determination of residues of ethofumesate in soil Report No. OFC00004917, M-351953-01-1 Dr Krebs Analytik, Koeln, Germany GLP, unpublished	N	ADAMA
CP 5.2	Krebber R., Braune M.	2013	Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Report No.: MR-13/085, M-466732-01-1 Bayer CropScience GLP, unpublished	N	Task Force Ethofumesate
CP 5.2	Class T. Stanislowski T.	2013	Independent laboratory validation of BCS analytical methods 01333 and 01387 for determination of various pesticides in surface water by Di-HPLC-MS/MS Report No.: P3117 G PTRL Europe, Ulm, Germany GPL, unpublished	N	Task Force Ethofumesate
CP 5.2	Schneider E.	2000	PR00/02 – Validation of an analytical method for the determination of residues of ethofumesate in air – Monitoring method Report No.: OFC00004919 UCL GmbH, Koeln, Germany GLP, unpublished	N	ADAMA
CP 5.2	██████	1994	Ethofumesate: Oral (Capsule/Gavage) maximum tolerated dose (MTD) and 28 day repeat dose range finding study in dog ██████ Report No.: A87557 Bayer CropScience	Y	Task Force Ethofumesate

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			GLP, unpublished		
KCA 6.1	Whiteoak, R. J.	1975	STABILITY OF RESIDUES DURING STORAGE OF CROP AND SOIL SAMPLES FROM TRIALS WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83296, Edition Number: M-155565-01-1 Date: 1975-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.1	Bright, J. H. M.	1991	STABILITY OF ETHOFUMESATE AND NC 9607 RESIDUES IN SUGARBEET ROOTS AND TOPS DURING DEEP FREEZE STORAGE Schering AG, Berlin, Germany Bayer CropScience, Report No.: A83111, Report includes Trial Nos.: 041/02/001 Edition Number: M-155386-01-1 Date: 1991-03-08 GLP Unpublished	N	Bayer CropScience
KCA 6.1	Schulte, G.	2013	Storage stability of open-ring-2-keto ethofumesate (AE C520645) in plant matrices for 24 months - Phase report after 6 months Bayer CropScience, Report No.: MR-13/086, Edition Number: M-459806-01-1 Date: 2013-07-11 GLP Unpublished	N	Task Force Ethofumesate
KCA 6.1	Hamberger, R.	2013	Determination of the storage stability of Ethofumesate and its metabolite NC20645 in sugar beet matrices during storage at < or = to - 18°C for a period of 12 months AgriChem B.V., 12A04042-01-SSSB CIP Chemisches Institut Pforzheim GmbH GLP Unpublished	N	ACM*
KCA 6.1	Schlewitz, P.	2014	Frozen storage stability of residues of ethofumesate metabolite NC 20645 in sugar beet (roots and tops with leaves) United Phosphorus Ltd., R B1312 ANADIAG GLP Unpublished	N	UPL

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KCA 6.1	Perez, R.; Schmitt, J. L.; Patel, D.	2014	Freezer storage stability of ethofumesate in animal matrix samples - interim report ADPEN Laboratories, Inc., Jacksonville, FL, USA Bayer CropScience, Report No.: RAADP031, Edition Number: M-467206-02-1 Date: 2013-09-26 GLP Unpublished	N	Task Force Ethofumesate
KCA 6.2 /01	Miller, C.	1999	Summary of the metabolism of ethofumesate in plants Ethofumesate AE B049913 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer CropScience, Report No.: C003349, Edition Number: M-185979-01-1 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /01	Adcock, J. W.; Warner, P. A., Challis, I. R.	1976	The metabolism of ¹⁴ C- ethofumesate in the onion Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82959, Edition Number: M-155236-01-1 Date: 1976-10-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /02	Warner, P. A.; Adcock, J. W.	1977	Metabolism of ethofumesate in tobacco Fisons plc, united kingdom Bayer Crop Science, Report no.: A82963, Edition number: m-155240-01-1 date: 1977-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /03	Lines, D. S.; Adcock, J. W.	1978	The metabolism of ethofumesate by sugar beet under greenhouse conditions Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82964, Edition Number: M-155241-01-1 Date: 1978-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /04	Lines, D. S.; Adcock, J. W.	1979	The metabolism of ethofumesate (98% pure ¹⁴ C - ethofumesate) by sugar beet under field conditions Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82965, Edition Number: M-155242-01-1 Date: 1979-01-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1	Chapleo, S.	1992	The metabolism of [¹⁴ C]- ethofumesate in sugar beet - a glasshouse study	N	Bayer

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/05			Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A82970, Report includes Trial Nos.: 381174 ENVIR 84B Edition Number: M-155247-01-1 Date: 1992-09-22 GLP Unpublished		CropScience
KCA 6.2.1 /06	Caley, C. Y.; Chapleo, S.; Haswell, A.	1994	The metabolism of ¹⁴ C- ethofumesate in sugar beet Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A87553, Report includes Trial Nos.: 382445 Edition Number: M-161455-01-1 Date: 1994-06-01 GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /07	Chapleo, S.	1992	The metabolism of [¹⁴ C]- ethofumesate in annual ryegrass - a glasshouse study Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A82971, Report includes Trial Nos.: 381169 ENVIR 85B Edition Number: M-155248-01-1 Date: 1992-09-17 GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /08	Mellet, M.	1993	Determination of the residues of ethofumesate, ethofumesate-2- keto and the conjugates in sugar beets after application of Ethosat 500 SC in France, 1992 ANADIAG S.A., Haguenau, France Feinchemie Schwebda, Report No.: M-468491-01-1, Report includes Trial Nos.: 92HBEBI01, 92HBEBI06 Edition Number: M-468491-01-1 Date: 1993-06-07 GLP Unpublished	N	Adama (former Feinchemie Schwebda)
KCA 6.2.1/01 (KCA 6.2.1/09)	Hennecke, D.	2003	Metabolism of Ethofumesate in sugar beets United Phosphorus Ltd., GAB-002/7-08 Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany GLP Unpublished	N	UPL
KCA 6.2.2 /01		1992	THE METABOLISM OF ¹⁴ C ETHOFUMESATE IN LAYING HENS Bayer CropScience, Report No.: A82969	Y	Bayer CropScience

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			Report includes Trial Nos.: SMS 297/920431 TOX 90542 Edition Number: M-155246-01-1 Date: 1992-06-09 GLP Unpublished		
KCA 6.2.2 /02		1999	Poultry - Metabolism, Distribution and nature of the residues in eggs and edible tissues Code AE B049913 Bayer CropScience, Report No.: C002998, Report includes Trial Nos.: Tox97227 Edition Number: M-185380-01-1 Date: 1999-06-01 GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /01		1976	THE METABOLISM OF ¹⁴ CETHOFUMESATE IN THE SHEEP Bayer CropScience, Report No.: A82958, Edition Number: M-155235-01-1 Date: 1976-09-01 No GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /02		1992	THE METABOLISM OF ¹⁴ C-ETHOFUMESATE IN THE COW Bayer CropScience, Report No.: A82968, Report includes Trial Nos.: SMS 296/920441 TOX 90541 Edition Number: M-155245-01-1 Date: 1992-06-04 GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /03		1999	Metabolism, distribution and nature of the residues in milk and edible tissues Ethofumesate ruminant Code: AE B049913 Bayer CropScience, Report No.: C003362,	Y	Bayer CropScience

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			Report includes Trial Nos.: TOX97226 Edition Number: M-185993-01-1 Date: 1999-04-07 No GLP Unpublished		
KCA 6.3.5 /01	Crofts, M.	1975	RESIDUES IN FODDER BEET AND RED BEET FROM 1974 APPLICATIONS OF NORTRON IN THE UK Fisons plc, United Kingdom Bayer CropScience, Report No.: A83007, Edition Number: M-155284-01-1 EPA MRID No.: 41214220 Date: 1975-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /02	Crofts, M.; Whiteoak, R. J.	1976	RESIDUES IN MANGOLDS, FODDER BEET AND RED BEET FROM 1975 AND 1976 APPLICATIONS OF NORTRON IN THE UK (AND 1 RED BEET TRIAL IN SWEDEN) Fisons plc, United Kingdom Bayer CropScience, Report No.: A83020, Edition Number: M-155297-01-1 EPA MRID No.: 41214219 Date: 1976-09-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /03	Crofts, M.; Whiteoak, R. J.	1977	RESIDUES IN RED BEET ROOTS FROM 1976 TRIALS WITH NORTRON IN AUSTRALIA Fisons plc, United Kingdom Bayer CropScience, Report No.: A83022, Edition Number: M-155299-01-1 EPA MRID No.: 41214220 Date: 1977-02-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /04	Crofts, M.	1978	HARVEST RESIDUES IN RED BEET FROM NORTRON TRIALS IN THE USA (NEW YORK, TEXAS AND WISCONSIN) IN 1976/77 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83036, Edition Number: M-155313-01-1 EPA MRID No.: 41214219 Date: 1978-01-31 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /05	Crofts, M.	1978	HARVEST RESIDUES IN RED BEET FROM A NORTRON TRIAL IN CANADA IN 1977 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83039, Edition Number: M-155316-01-1 EPA MRID No.: 41214233 Date: 1978-11-02 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /06	Wrede, A.	1995	Residues in red beet after application of Betanal progress in France 1993 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A83118, Report includes Trial Nos.: PF-R 93 098 Edition Number: M-155393-01-1 Date: 1995-04-04 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /07	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN THE UK Fisons plc, United Kingdom Bayer CropScience, Report No.: A82975, Edition Number: M-155252-01-1 EPA MRID No.: acc.36374 Date: 1973-07-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /08	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM FRENCH TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82976, Edition Number: M-155253-01-1 EPA MRID No.: 41214219 Date: 1973-07-01 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /09	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM DANISH TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82977, Edition Number: M-155254-01-1 EPA MRID No.: 41214219 Date: 1973-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /10	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM AUSTRIAN TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82978, Edition Number: M-155255-01-1 Date: 1973-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /11	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN YUGOSLAVIA Fisons plc, United Kingdom Bayer CropScience, Report No.: A82979, Edition Number: M-155256-01-1 EPA MRID No.: 41414219 Date: 1973-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /12	Whiteoak, R. J.; Crofts, M.; Harris, R. J.	1973	RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN W. GERMANY (UPDATED) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82980, Edition Number: M-155257-01-1 EPA MRID No.: 41214220 Date: 1973-10-01 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /13	Whiteoak, R. J.	1973	RESIDUE DECLINE STUDIES IN COLORADO (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82982, Edition Number: M-155259-01-1 EPA MRID No.: acc.36365 Date: 1973-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /14	Whiteoak, R. J.; Crofts, M.	1974	RESIDUE DECLINE STUDIES IN MICHIGAN (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82983, Edition Number: M-155260-01-1 EPA MRID No.: acc.37839 Date: 1974-02-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /15	Crofts, M.; Whiteoak, R. J.	1974	NORTRON RESIDUE IN HARVEST SUGAR BEET FROM NINE REGIONS OF THE USA IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82986, Edition Number: M-155263-01-1 EPA MRID No.: acc.36366 Date: 1974-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /16	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 PRE-EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN ITALY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82990, Edition Number: M-155267-01-1 Date: 1974-06-01 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /17	Crofts, M.; Whiteoak, R. J.	1974	RESIDUE DECLINE STUDY IN THE UK (1973) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82992, Edition Number: M-155269-01-1 Date: 1974-07-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /18	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN FODDER BEET FROM 1973 PRE-EMERGENCE APPLICATION OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82993, Edition Number: M-155270-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /19	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN FODDER BEET FROM 1972 AND 1973 POST- EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82996, Edition Number: M-155273-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /20	Crofts, M.; Whiteoak, R. J.	1974	RESIDUE DECLINE STUDY IN THE UK (1973) WITH SUGAR BEET TREATED POST-EMERGENCE WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82997, Edition Number: M-155274-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /21	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 PRE-EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82998, Edition Number: M-155275-01-1 Date: 1974-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /22	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET AND SOIL FROM 1973 POST- EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN ITALY Fisons plc, United Kingdom	N	Bayer CropScience

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			Bayer Crop Science, Report No.: A83290, Edition Number: M-155559-01-1 Date: 1974-12-01 No GLP Unpublished...also filed: KCA 7.1.2.2.1 /10		
KCA 6.3.5 /23	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 POST-EMERGENCE APPLICATIONS OF NORTRON IN THE UK Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82999, Edition Number: M-155276-01-1 Date: 1974-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /24	Crofts, M.	1975	HARVEST RESIDUES IN SUGAR BEET FROM 1974 PRE-EMERGENCE APPLICATIONS OF NORTRON IN CANADA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83004, Edition Number: M-155281-01-1 EPA MRID No.: 41214220 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /25	Crofts, M.	1975	DECLINE IN RESIDUES IN SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON (TRAMAT) IN ITALY (1974) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83005, Edition Number: M-155282-01-1 Date: 1975-04-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /26	Crofts, M.	1975	DECLINE OF RESIDUES IN SUGAR BEET TREATED POST-EMERGENCE WITH NORTRON (TRAMAT) IN ITALY (1974) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83006, Edition Number: M-155283-01-1 Date: 1975-04-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /27	Crofts, M.; Whiteoak, R. J.	1976	NORTRON RESIDUES IN MATURE SUGAR BEET FOLLOWING POST- EMERGENCE APPLICATIONS AS A TANK MIX WITH DESMEDIPHAM IN THE USA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83012, Edition Number: M-155289-01-1 Date: 1976-02-01	N	Bayer CropScience

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			No GLP Unpublished		
KCA 6.3.5 /28	Crofts, M.; Harris, R. J.; Wilkie, P. M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED PRE- EMERGENCE WITH NORTRON 20 EC OR TCA OR A TANK MIX OF BOTH COMPONENTS IN THE USA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83013, Edition Number: M-155290-01-1 Date: 1976-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /29	Crofts, M.; Harris, R. J.; Wilkie, P. M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED PRE- EMERGENCE WITH NORTRON OR PYRAMIN OR A TANK MIX OR BOTH COMPONENTS IN THE USA IN 1975 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83016, Edition Number: M-155293-01-1 Date: 1976-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /30	Crofts, M.	1976	NORTRON AND RO-NEET RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE-EMERGENCE APPLICATION AND TANK MIX IN THE USA IN 1974 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83017, Edition Number: M-155294-01-1 Date: 1976-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /31	Crofts, M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED WITH AN SC OR AN EC FORMULATION OF NORTRON IN UK, 1975 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83019, Edition Number: M-155296-01-1 Date: 1976-06-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /32	Crofts, M.	1978	HARVEST RESIDUES IN SUGAR BEET FROM PRE- EMERGENCE APPLICATIONS OF TRAMAT (NORTRON) SC FORMULATION IN W. GERMANY IN 1976. Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83034, Edition Number: M-155311-01-1 Date: 1978-01-23 No GLP	N	Bayer CropScience

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			Unpublished		
KCA 6.3.5 /33	Crofts, M.	1978	HARVEST RESIDUES IN SUGAR BEET FROM 1977 TRIALS WITH TRAMAT (NORTON) SC AND EC FORMULATIONS IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83035, Edition Number: M-155312-01-1 Date: 1978-01-23 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /34	Harris, R. J.; Reary, J. B.	1979	RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE-EMERGENCE APPLICATIONS OF SEPARATE OR TANK-MIX FORMULATIONS OF ETHOFUMESATE AND CHLORIDAZON IN MICHIGAN AND OHIO 1978 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83045, Edition Number: M-155322-01-1 Date: 1979-09-13 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /35	Browne, P. M.; Reary, J. B.	1979	ETHOFUMESATE RESIDUES IN MATURE SUGAR BEET TREATED POST EMERGENCE IN MIXTURES WITH PHENMEDIPHAM AND/OR DESMEDIPHAM IN USA 1977 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83046, Edition Number: M-155323-01-1 EPA MRID No.: 41214220 Date: 1979-08-30 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /36	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET TREATED POST-EMERGENCE WITH MIXTURES OF ETHOFUMESATE AND/OR PHENMEDIPHAM AND DESMEDIPHAM (COMMERCIAL EC FORMULATIONS) IN USA 1979 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83049, Edition Number: M-155326-01-1 EPA MRID No.: 41214219 Date: 1980-05-23 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /37	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE AND POST- EMERGENCE APPLICATION OF ETHOFUMESATE (20 EC) IN CALIFORNIA 1977 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83050,	N	Bayer CropScience

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			Edition Number: M-155327-01-1 EPA MRID No.: 41214220 Date: 1980-06-20 No GLP Unpublished		
KCA 6.3.5 /38	Browne, P. M.; Reary, J. B.	1980	RESIDUES IN SUGAR BEET TREATED PRE- EMERGENCE WITH A SUSPENSION CONCENTRATE FORMULATION (50 SC) OF ETHOFUMESATE IN WEST GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83053, Edition Number: M-155330-01-1 Date: 1980-09-12 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /39	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET TREATED PRE-EMERGENCE WITH MIXTURES OF ETHOFUMESATE AND/OR PEBULATE OR CYCLOATE (COMMERCIAL EC FORMULATIONS) IN CALIFORNIA 1979 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83051, Edition Number: M-155328-01-1 EPA MRID No.: 41214220 Date: 1980-08-14 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /40	Housden, M. C.; Reary, J. B.	1981	Residues of Ethofumestae and metabolites in sugar beet treated pre--emergence with a one-pack mixture of Ethofumestae and Lenacil in West Germany 1980 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83057, Edition Number: M-155334-01-1 Date: 1981-01-14 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /41	Reary, J. B.	1981	Residues of Ethofumesate and metabolites in sugar beet treated pre-emergence with a one-pack mixture of Ethofumesate and Chloridazon in West Germany 1980 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83058, Edition Number: M-155335-01-1 Date: 1981-01-15 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /42	Reary, J. B.	1981	Residues in sugar beet treated post- emergence with a suspension concentrate formulation (50 SC) of Ethofumesate in West Germany 1980 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83059,	N	Bayer CropScience

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			Edition Number: M-155336-01-1 Date: 1981-01-15 No GLP Unpublished		
KCA 6.3.5 /43	Haldeman, J. K.; Ford, J. J.	1982	ANTOR AND NORTON HERBICIDE RESIDUES IN SUGAR BEETS FROM TREATED PLOTS FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A89134, Edition Number: M-164269-01-1 Date: 1982-02-22 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /44	Cron, J. H.	1982	Residues of Ethofumesate and metabolites in sugar beet treated pre-emergence with a one-pack mixture of Ethofumesate and Chloridazon in West Germany 1981 FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83064, Edition Number: M-155341-01-1 Date: 1982-02-11 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /45	Haldeman, J. K.	1982	NORTON HERBICIDE RESIDUES IN SUGAR BEETS TREATED PRE- AND POST-PLANTING Hercules Inc.; Bayer Crop Science, Report No.: A83066, Edition Number: M-155343-01-1 Date: 1982-04-29 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /46	Cron, J. H.	1982	Residues of Ethofumesate and metaboiltres in sugar/fodder beet treated post-emergence with Ethofumesate (50 SC) in West Germany 1981 FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83065, Edition Number: M-155342-01-1 Date: 1982-04-02 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /47	Haldeman, J. K.	1982	ETHOFUMESATE RESIDUES IN SUGAR BEETS FROM TWO CALIFORNIA LOCATIONS FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83067, Edition Number: M-155344-01-1 Date: 1982-05-07 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /48	Ford, J. J.	1983	DIETHATYL ETHYL (ANTOR HERBICIDE) AND ETHOFUMESATE (NORTON HERBICIDE) RESIDUES IN 6-MONTH SUGAR BEETS FROM CALIFORNIA FBC Limited, Chesterford Park, United Kingdom	N	Bayer CropScience

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			Bayer CropScience, Report No.: A89135, Report includes Trial Nos.: H41/3/81 H79/3/3 Edition Number: M-164271-01-1 EPA MRID No.: 41214220 Date: 1983-07-13 No GLP Unpublished		
KCA 6.3.5 /49	Lee, G. E.; Weishedel, B. C.	1984	ETHOFUMESATE (NORTRON HERBICIDE) RESIDUES IN SUGAR BEETS FROM QUEBEC AND MANITOBA FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83069, Edition Number: M-155346-01-1 Date: 1984-04-16 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /50	Manley, J. D.; Snowdon, P. J.	1984	Residues of Ethofumesate and major metabolites in sugarbeet treated in West Germany 1982 and 1983, with a Co- formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83072, Report includes Trial Nos.: 041/03/080 Edition Number: M-155349-01-1 Date: 1984-09-20 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /51	Snowdon, P. J.	1985	Residues of Ethofumesate and major metabolites in sugarbeet treated in France 1984 with Ethofumesate and Phenmedipham as either a Co- formulation of a Tank-mix FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83071, Report includes Trial Nos.: 041/03/082 Edition Number: M-155348-01-1 Date: 1985-04-18 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /52	Manley, J. D.; Snowdon, P. J.	1986	Residues of Ethofumesate and major metabolites in sugar beet treated in the ederal Republic of Germany, 1983 with a Co-formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83077, Report includes Trial Nos.: 041/03/080 Edition Number: M-155353-01-1 Date: 1986-08-04 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /53	Manley, J. D.; Snowdon, P. J.	1986	Residues of Ethofumesate and major metabolites in sugarbeet treated in the Federal Republic of Germany 1985 with a Co-formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83078, Report includes Trial Nos.: 041/03/085 Edition Number: M-155354-01-1 EPA MRID No.: 41214220 Date: 1986-09-16 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /54	Banwell, M.; Bright, J. H. M.	1990	Residues of Ethofumesate and its major metabolites in sugar beet following multiple post-emergence application of an EC Co-formulation with Penmedipham and Desmedipham in Denmark 1989 (2nd Edition) Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83095, Report includes Trial Nos.: 041/03/116 Edition Number: M-155764-02-1 Date: 1990-07-11 ...Amended: 1990-11-01 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /55	Straszewski, A.	1993	Ethofumesate: SC (CQ 1273/01): Residues of Ethofumesate and its major metabolite in sugar beets France 1992 Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83115, Edition Number: M-155390-01-1 Date: 1993-09-23 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /56	Wrede, A.	1995	Residues in sugar beet after application of Betanal progress of in France 1993 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Crop Science, Report No.: A62042, Edition Number: M-145562-01-1 Date: 1995-04-04 GLP Unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.5 /57	Helgers, A.	1997	Ethofumesate and lenacil suspension concentrate 300 + 120 g/l AE B049913 02 SC 37 A101 and AE B049913 02 WP42 A101 Ethofumesate and lenacil SC compared with a WP formulation in sugar beet; determination of residues in sugar beet roots and Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A89772, Edition Number: M-165366-02-1 Date: 1997-01-27 ...Amended: 1997-02-27 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /58	Schulte, G.	2013	Amendment no. 1 to report no: 10- 2109 - Determination of the residues of ethofumesate in/on sugar beet after spray application of ethofumesate SC 500 in the field in Spain, Italy and Greece Bayer CropScience, Report No.: 10-2109, Report includes Trial Nos.: 10-2109-01 10-2109-02 10-2109-03 10-2109-04 Edition Number: M-444836-02-1 Date: 2013-01-15 ...Amended: 2013-07-09 GLP Unpublished	N	Bayer CropScience
KCA 6.3.1/01	Tandy, R.	2012a	Determination of residues of Ethofumesate, Phenmedipham and Desmedipham after one application of Ethofol 500SC or three applications of Betasana Trio SC in sugar beet (outdoor) at 4 sites in Northern Europe 2009 United Phosphorus Ltd., S09-01656 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.3.1/02	Perny, A.	2002	Residue study in sugar beets following treatments with a formulated product containing Ethofumesate 128 g/l, Phenmedipham 62 g/l and Desmedipham 16 g/l on sugar beet fields under field conditions in France and in the Netherlands in 2000 AgriChem B.V., R A0015 Anadiag S.A., Haguenau, France GLP Unpublished	N	ACM*
KCA 6.3.1/03	Perny, A.	2003	Residue study in sugar beets following treatments with a formulated product containing Ethofumesate 128 g/l, Phenmedipham 62 g/l and Desmedipham 16 g/l on sugar beet fields under field conditions in France and in The Netherlands in 2001 AgriChem B.V., R A1114 Anadiag S.A., Haguenau, France GLP Unpublished	N	ACM*
KCA 6.3.1/04	Huauilmé, J.-M.	2013a	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar	N	ACM*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Northern Europe (The Netherlands, Belgium) - 2012 AgriChem B.V., BPL12/436/GC BIOTEK Agriculture GLP Unpublished		
KCA 6.3.1/05	Chevallier, E.	2012	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Northern Europe (The Netherlands, Belgium) - 2011 AgriChem B.V., BPL11/380/GC BIOTEK Agriculture GLP Unpublished	N	ACM*
KCA 6.3.1/06	Waalkens, W.M., Hamberger, R.	2005a	Determination of the decline of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l EC, Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2003 AgriChem B.V., R03-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/07	Waalkens, W.M., Hamberger, R.	2005b	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto-Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l EC, Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2003 AgriChem B.V., R03-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/08	Waalkens, W.M., Hamberger, R.	2005c	Determination of the decline of the residues of Phenmedipham, MHCP, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2004 AgriChem B.V., R04-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/09	Waalkens, W.M., Hamberger, R.	2005d	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto-Ethofumesate in / on sugar beet plants and roots after foliar applications of	N	ACM*

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			Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2004 AgriChem B.V., R04-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished		
KCA 6.3.1/10	Anspach, T.	2001	Magnitude of the residue of Phenmedipham, Desmedipham, Ethofumesate and its metabolite 2- oxo-Ethofumesate in sugar beets (roots and leaves/tops) after the application of Betasana Trio under filed conditions in Germany, 2000 United Phosphorus Ltd., ADN-0004 Dr. Specht Partner, Chemische Laboratorien GmbH, Germany GLP Unpublished	N	UPL
KCA 6.3.1/11	Tandy, R.	2013	Determination of residues of ETHOFUMSATE and ETHOFUMESATE-2-KETO, after one or three applications of ETHOFOL 500SC, or three application of BETASANA TRIO SC in sugar beet (outdoor) at 5 sites in Northern europe and 5 stes in Southern Europe 2010 United Phosphorus Ltd., S10-00258 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.3.1/12	Waalkens, W.M. Hamberger, R.,	2005e	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, aniline, Ethofumesate, 2-Keto-Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in northern Spain, 2003 AgriChem B.V., R03-16-SP-06 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/13	Waalkens, W.M., Hamberger, R.	2005f	Determination of the decline of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on fodder beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to fodder beets in southern France, 2003 AgriChem B.V., R03-16-FR-07 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/14	Huauhmé, J.-M.	2013b	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Southern Europe (Italy, Spain)-2012	N	ACM*

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			AgriChem B.V., BPL12/435/GC BIOTEK Agriculture GLP Unpublished		
KCA 6.3.1/15	Tandy, R.	2012b	Validation of the analytical method A0019 to confirm the conversion of NC 20645 to NC 9607 in sugar beet roots and tops and wheat grain and straw United Phosphorus Ltd., S11-03715 Eurofins Agroscience Service GmbH No GLP Unpublished	N	UPL
KCA 6.3.1/16	Weir, A.	2014	METHOD MODIFICATION AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE AND ITS METABOLITES NC 20645 AND NC 9607 IN SUGARBEET ROOTS AND TOPS United Phosphorus Ltd., S13-03837 Eurofins Agroscience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.4.1/01	████	1975	INVESTIGATION OF TISSUE AND EGG - RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS Bayer CropScience, Report No.: A83011, Edition Number: M-155288-01-1 Date: 1975-09-01 No GLP Unpublished ...also filed: KCA 4.1.2 /27	Y	Bayer CropScience
KCA 6.4.1/02	████	1999	Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913 ████ Bayer CropScience, Report No.: C003329, Edition Number: M-185950-01-1 No GLP Unpublished ...also filed: KCA 6.4.2 /04	Y	Bayer CropScience

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KCA 6.4.2/01	████	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 1 ████ Bayer CropScience, Report No.: A83024, Edition Number: M-155301-01-1 EPA MRID No.: 41214208 Date: 1977-06-01 No GLP Unpublished ...also filed: KCA 4.1.2 /25	Y	Bayer CropScience
KCA 6.4.2/02	████	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 2 ████ Bayer CropScience, Report No.: A89223, Edition Number: M-164398-01-1 Date: 1977-06-01 No GLP Unpublished	Y	Bayer CropScience
KCA 6.4.2/03	████	1994	Ethofumesate-derived residues in the meat and milk of dairy cows: resulting from oral ingestion of ethofumesate ████ Bayer Crop Science, Report No.: B002201, Report includes Trial Nos.: B93R04/05 Edition Number: M-237976-01-1 EPA MRID No.: 43458701 Date: 1994-10-12 No GLP Unpublished ...also filed: KCA 4.1.2 /29	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.2 /04		1999	Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913 Bayer Crop Science, Report No.: C003329, Edition Number: M-185950-01-1 No GLP Unpublished ...also filed: KCA 6.4.1 /02	Y	Bayer CropScience
KCA 6.5.1 /01	Miebach, D.; Bongartz, R.	2010	Nature of the residues of ethofumesate in processed commodities - High temperature hydrolysis Bayer CropScience, Report No.: MEF-10/803, Edition Number: M-397800-01-1 Date: 2010-12-09 GLP Unpublished	N	Bayer CropScience
KCA 6.5.3 /01	Whiteoak, R. J.; Crofts, M.	1973	CONJUGATED RESIDUES IN FRACTIONS PROCESSED FROM SUGAR BEET TREATED WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82973, Edition Number: M-155250-01-1 EPA MRID No.: acc.36368 Date: 1973-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.5.3 /02	Crofts, M.; Whiteoak, R. J.	1974	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82985, Edition Number: M-155262-01-1 EPA MRID No.: acc.36369 Date: 1974-03-01 No GLP Unpublished ...also filed: KCA 4.1.2 /10	N	Bayer CropScience

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KCA 6.5.3 /03	Crofts, M.; Whiteoak, R. J.	1975	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN THE UNITED KINGDOM Fisons plc, United Kingdom Bayer CropScience, Report No.: A83002, Edition Number: M-155279-01-1 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.5.3 /04	Crofts, M.; Whiteoak, R. J.	1975	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUE IN BEET GROWN AND PROCESSED IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83003, Edition Number: M-155280-01-1 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.1 /01	Carlton, R.; Cordell, P.	1993	THE UPTAKE AND METABOLISM OF ETHOFUMESATE AND ITS SOIL METABOLITES IN A CONFINED ROTATIONAL CROP STUDY Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83396, Report includes Trial Nos.: 90B Edition Number: M-155664-01-1 Date: 1993-06-18 GLP Unpublished	N	Bayer CropScience
KCA 6.6.1 /02	Schneider, E.	1994	PR94/025 - Ethofumesate - Determination of ethofumesate residues in soil of a long time field study after the application of Ethosat (FSG031894) to sugar beet plants Dr. G. Krebs Analytik, Köln, Germany Feinchemie Schwebda, Report No.: M-468487-01-1, Edition Number: M-468487-01-1 Date: 1994-08-12 GLP Unpublished	N	Adama (former Feinchemie Schwebda)
KCA 6.6.1/01	Chapleo, S.	2003	The uptake of [¹⁴ C]-Ethofumesate residues in soil by rotational crops under confined conditions AgriChem B.V., Inveresk Research International, Tranent, Scotland Report No.: 22558 GLP Unpublished	N	ACM*
KCA 6.6.2 /01	Castro, L. E.	1994	ETHOFUMESATE EMULSIFIABLE CONCENTRATE 200 g/l CR 13768: AT-HARVEST RESIDUES OF ETHOFUMESATE AND METABOLITES IN ROTATIONAL CROPS AND SOIL FOLLOWING	N	Bayer CropScience

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			APPLICATIONS OF NORTRON EC TO SUGARBEETS, USA, 1990 Nor-Am Chemical Company, Pikeville, NC, USA Bayer CropScience, Report No.: A83117, Edition Number: M-155392-01-1 EPA MRID No.: 43298104 Date: 1994-05-05 GLP/GEP: yes, unpublished		
KCA 6.6.2 /02	Crofts, M.; Whiteoak, R. J.	1974a	RESIDUE ANALYSIS OF WHEAT GROWN IN THE UK AS A FOLLOWING CROP AFTER SUGAR BEET TREATED WITH NORTRON (1973) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82995, Edition Number: M-155272-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /03	Crofts, M.; Whiteoak, R. J.	1974b	RESIDUE ANALYSIS OF WHEAT AND CORN (MAIZE) GROWN AS FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTRON (1973) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82994, Edition Number: M-155271-01-1 Date: 1974-09-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /04	Peatman, M. H.; Snowdon, P. J.	1991	RESIDUES OF SOIL AND EMERGENCY CROPS FOLLOWING APPLICATION OF ETHOFUMESATE AS A 50 SC FORMULATION IN THE UK 1990/91 Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83376, Report includes Trial Nos.: 041/04/057 Edition Number: M-155644-01-1 Date: 1991-12-20 GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /05	Schulte, G.; Diehl, P.	2013	Amendment No. 1 to Report No: 10- 2501 - Determination of the residues of ethofumesate in/on the field rotational crop barley, carrot, lettuce and wheat after spray application of ethofumesate SC 500 on sugar beet and soil in the field, in the Netherlands, Italy, Spain and Germany Bayer CropScience, Report No.: 10-2501, Report includes Trial Nos.: 10-2501-02 10-2501-03 10-2501-04 10-2501-05 Edition Number: M-463906-02-1 Date: 2013-08-22 ...Amended: 2013-09-13	N	Task Force Ethofumesate

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.6.2/01	Spence, C.	2014	Evaluation of Ethofumesate Herbicide Residues Crop Rotation Study, Cereal, Root and Leafy Vegetable Crops Following Sugar Beet - One Application to Two Trials Initiated in 2012 - NEU (the United Kingdom) and SEU (Italy) AgriChem B.V., 697614, 34890 Charles River Laboratories , Edinburgh, UK GLP Unpublished	N	ACM*
KCA 6.10 /01	Wang, P.; Wang, Q.; Jiang, S.; Qiu, J.; Wang, P.; Zhou, Z.	2005	Stereoselective degradation of ethofumesate in turfgrass and soil. Journal:Pestic. Biochem. Physiol., Volume:82, Issue:3, Pages:197-204, Year:2005, Report No.: M-458577-01-1, Edition Number: M-458577-01-1 Date: 2005-12-31 No GLP Published ...also filed: KCA 7.1.2.1.1 /14	N	published
KCA 6.10.1/01	Lückmann, J.	2013	Ethofumesate - exposure of honeybees to residues in nectar, pollen and guttation fluid in sugar and fodder beets United Phosphorus Ltd., P13096 RIFCon GmbH, Hirschberg, Germany No GLP Unpublished	N	UPL

Clopyralid: For studies owned by Corteva (previously Dow AgroSciences S.A.S.) and submitted for the renewal of clopyralid the applicant has a Letter of Access. Studies from the initial clopyralid approval (DAR, 2005) are not data protected.

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval or renewal of the active substance Clopyralid.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
IIA 4.1.2/01	Hastings M.J.	2002a	Determination of residues of clopyralid on agricultural crops by gas chromatography with negative-ion chemical ionization mass spectrometry. Dow AgroSciences LLC, Indianapolis, Indiana, USA Report No.: GH-C 5439, Date:19.04.2002, GLP, Non Published DAS No. O97	N	DAS
IIA 4.1.2/02	Rawle, N.	2002	Independent laboratory validation of a method for the determination of clopyralid residues in crops. CEM Analytical Services Ltd. North Ascot, UK Report No.: CEMS-1671, Date: 12.03.2002, GLP, Non Published DAS No. O95	N	DAS
IIA 4.1.2/03	Wood, S.J	1994	Determination of residues of clopyralid in grass. Dow Elanco Europe, Letcombe Laboratory, Wantage, Oxon, UK Report No.: RV94.08, Date: 30.08.1994 GLP, Non Published DAS No. O47	N	DAS
IIA 4.1.2/04	Kubitschek, C.E. and Kyle, J.A.	1994	Determination of clopyralid in sugar beets and sugar beet processed products by capillary gas chromatography/mass spectrometry. North American Environmental Chemistry Laboratory, Dow Elanco, Indianapolis, Indiana, USA Report No.: GRM 94.04 Date: 16.06.1996 Non GLP, Non Published DAS No. O102	N	DAS
IIA 4.1.2/05	Anon	1989	Analytical method: Determination of clopyralid residues in refined sugar.	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Dow Elanco Europe, Letcombe Laboratory, Wantage, Oxon, UK Report No.: ERC 88.2, Date: 25.10.1989 Non GLP, Non Published DAS No. O34		
IIA 4.1.2/06	Anon	1988	Analytical method: Determination of clopyralid residues in sugar beet molasses. Dow Elanco Europe, Letcombe Laboratory, Wantage, Oxon, UK Report No.: ERC 88.1, Date: 25.10.1988 Non GLP, Non Published DAS No. O31	N	DAS
CA 4.2 (a)/1	Vogl E.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Agricultural Commodities by LC-MS/MS ABC Laboratories, Inc., Columbia, Missouri, USA DAS Report No. 120610 21.9.2012 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (a)/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” Battelle UK Ltd, Ongar, Essex, United Kingdom DAS Report No. 120614 12.10.2012 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (a)/3	████	2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection DAS Report No. 120483 17.9.2012 GLP/GEP (Y/N): Yes Published (Y/N): No	Y	DAS
CA 4.2 (a)/4	████	2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices	Y	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DAS Report No. 120484 11.9.2012 GLP/GEP (Y/N): Yes Published (Y/N): No		
CA 4.2 (a)/5	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 7.10.2013 DAS Report No. 130729 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (a)/6	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 DAS Report No. 130728 25.2.2014 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (b)/1	Vincent, T. P.	2013	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Soil by LC-MS/MS ABC Laboratories, Inc., Columbia, Missouri, USA DAS Report No. 120612 20.2.2013 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (b)/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 Battelle UK Ltd, Chelmsford, Essex, United Kingdom DAS Report No. 140079 19.5.2014 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (b)/3	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 ABC Laboratories, Inc., Columbia, Missouri, USA DAS Report No. 120611 4.12.2012	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/GEP (Y/N): Yes Published (Y/N): No		
CA 4.2 (b)/4	Austin, R., Turner, R.	2014	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” Battelle UK Ltd, Ongar, Essex, United Kingdom DAS Report No. 120613 5.4.2013 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (c)/1	Bacher R.	2012	The Development and Validation of a Method for the Analysis of Clopyralid in Air PTRL Europe GmbH, D-89081 Ulm, Germany DAS Report No. 120601 4.10.2012 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
CA 4.2 (d)/1	Senciuc, M.	2014	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluid(s) DAS Report No. 130727 9.7.2014 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1	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 Report No. GH-C 3779, File No. N136 DowElanco, Indianapolis, Indiana, US GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.1	Clements, B., Bolton, A.	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Report No. GHE-P-5350, File No. N138 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.1	Anon.	2015	Frozen Storage Stability of Clopyralid in Bovine Fat DAS Study No. 120602 GLP	N	Corteva (new study submitted for

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		renewal)
KCA 6.1	Anon.	2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg DAS Study No. 020120.01 GLP Unpublished	N	Corteva (new study submitted for renewal)
KCA 6.2.1	Chapleo, S. ; Caley, C. Y.	2002	The Metabolism of [14C]-Clopyralid in Sugar Beet DAS Report No. GHE-P-9939, File No. L10 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.2.1	Guo, C.	1996	Metabolism of 14C -Clopyralid in Cabbage DAS Report No. GH-C-4289, File No. L06 ABC Laboratories Inc, Columbia, Missouri, USA GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.2.1	Chapleo, S., Caley, C. Y., White, D. E.	2002	The Metabolism of (14C)-Clopyralid in Oilseed Rape DAS Report No. GHE-P 9938, File No. L09 Inveresk Research International, Tranent, East Lothian, UK GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.2.2	████	2014	A Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid DAS Study No. 130906 ████ GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.2.3	████	2015	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid DAS Study No. 130202 GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.3	Freeman J.M.H., Walker, S.M.	1980	Determination of residues of 3,6-dichloropicolinic acid (DOWCO* 290) in sugar beet, roots and tops, treated with FORMAT** - UK 1980 Dow Chemical Company DAS Report No. GHE-P-803, File No. N76	N	Corteva (Study from DAR, 2005)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			No GLP Unpublished		
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at intervals under open field conditions following multiple applications of Lontrel 100 (EF-1136), Northern France and UK – 2000 DAS Report No. GHE-P-9356, File No. N195 GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at harvest under open field conditions following multiple applications of Lontrel 100 (EF-1136), Northern France and UK – 2000 DAS Report No. GHE-P-9357, File No. N198 GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at intervals and at harvest following multiple applications of Lontrel (EF-1136), EU Northern Zone – 2001 DAS Report No. GHE-P-9381, File No. N199 GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.4.1	████	1974	Dowco 290 and 2,4-D Chicken Feeding Study DAS Study No. TA-517 No GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.4.1	████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Chickens Fed the Herbicide DAS Study No. GH-C 819 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.1	████	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens DAS Study No. 150031 ████ GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.4.2	████	1974	Milk Residue Study with Dairy Cows Fed Lontrel Herbicide, Nellite Nematocide and 2,4-D Herbicide: Animal Care, Sampling and Production Records	Y	Corteva (Study from

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DAS Study No. GH-A 579 No GLP Unpublished		DAR, 2005)
KCA 6.4.2	████	1974	Residues of Dowco 290 (3,6-dichloropicoloni acid) in Milk and Cream from Cows Fed the Herbicide DAS Study No. GH-C 745 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.2	████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Bovine Tissues from Calves Fed the Herbicide DAS Study No. GH-C 811 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.2	████	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle DAS Study No. 150030 ████ GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.4.3	████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Swine Fed the Herbicide DAS Study No. GH-C 874 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.5.1	Adusumilli, H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP Unpublished	N	Corteva (new study submitted for renewal)
KCA 6.5.3	Almond, R.H.	1985	Determination of residues of clopyralid in sugar beet molasses Dow Chemical Company DAS Report No. GHE-P-1334, File No. N79 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Day, S.R.,	1988a	Clopyralid residues in sugar N beet molasses produced by British S N ugar beet factories in the UK – 1986/87 sugar	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Osborne, K.A.		processing campaign Dow Chemical Company DAS Report No. GHE-P-1802, File No. N80 No GLP Unpublished		(Study from DAR, 2005)
KCA 6.5.3	Day, S.R., Osborne, K.A.	1988b	Clopyralid residues in sugarbeet molasses produced by two factories in the UK – 1986/7 sugarbeet processing campaign Dow Chemical Company DAS Report No. GHE-P-1803, File No. N81 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Osborne, K.A.	1988	Clopyralid in refined white sugar produced by British sugar factories in the UK – 1986/7 sugar beet processing campaign Dow Chemical Company DAS Report No. GHE-P-1804, File No. N82 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Osborne, K.A., Walker, S.M.	1989	Clopyralid residues in sugarbeet molasses and massecuite prepared from sugarbeet treated with DOW SHIELD – UK 1988 Dow Chemical Company DAS Report No. GHE-P-1954, File No. N84 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.6.1	Yackovich, P. R. ; Lardie, T. S. ; Brink, D. L.	1993	A 10-1/2 Month Rotational Crops Study With 14C -Labeled Clopyralid - MET90080 DAS Study No. GH-C 2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.6.1	Yackovich, P.R.; Lardie T.S.; Miller J.H.	1989	A 125-Day Rotational Crops Study with 14C Labelled Clopyralid DAS Study No. GH-C 2277 DowElanco, Midland, Michigan, USA Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.6.1	Hall, L. R.	2015	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733	N	Corteva (new study)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP Unpublished		submitted for renewal)

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-