

REGISTRATION REPORT

Part A

Risk Management

Product code: HBZ10

Product name: Wizard/ Beetup Pro/ Betasana Max

Chemical active substance:

Phenmedipham, 125 g/L

Ethofumesate, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT POLAND

(Authorisation - Art. 33 application)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: October 2021

MS Finalisation date: December 2022 (initial National Assessment)

October 2023 (final National Assessment),

updated March 2024, April 2024

Version history

When	What
October 2021	Part A - Core Assessment - Central Zone, version 1
December 2022	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 the product label are highlighted in grey, while not agreed use pattern is struck through and shaded.
October 2023	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 . Information no longer relevant is struck through and shaded.
March 2024, April 2024	Updated the GAP table, the product label and the point 2.1. All changes are highlighted in turquoise .

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PART A

RISK MANAGEMENT

1 Details of the application

This document has been prepared in the context of the first approval in Poland for the plant protection product Wizard / Beetup Pro / Betasana Max (HBZ10) containing Phenmedipham and Ethofumesate. The use of Wizard / Beetup Pro / Betasana Max (HBZ10) is intended on beet crops (sugar beet, red beet, yellow beet, fodder beet and chards) for the control of broadleaved weeds in Poland for application at growth stages BBCH 10 through to BBCH 39. Different application rates are sought in the framework of this application, from 5.4 L/ha per year to a maximum of 7.2 L/ha per year. Further to this, it is proposed that the minimum in use water volume is of 80 litres per hectare.

Ethofumesate was renewed as an active substance under Regulation 1107/2009 with Regulation 2016/1426 and Part B of Regulation 540/2011 has been amended with Regulation 2016/1426.

Phenmedipham is approved as an active substance under Commission Directive 2004/58/EC and its approval period has been extended according to Commission Implementing Regulation (EU) 2021/745 amending Implementing Regulation (EU) No 540/2011.

Wizard / Beetup Pro / Betasana Max (HBZ10) is an emulsifiable concentrate (EC) formulation. This application is based on data previously submitted in support of the Annex I inclusion of Ethofumesate and Phenmedipham, with new data on the formulation provided where appropriate. The product is an herbicide, and the proposed use relates to the control of broadleaved weeds on beet crops. An evaluation of the risks to humans and the environment is presented.

The risk assessment conclusions are based on the information, data and assessments in Registration Report, Part B 0 – 10 and Part C. The information, data and assessments provided in Registration Report, Parts B include assessment of further data or information as required at national level for this first approval. It also includes assessment of data and information relating to Wizard / Beetup Pro / Betasana Max (HBZ10) where that data has not been considered in the EU review. Otherwise, assessments for the safe use of Wizard / Beetup Pro / Betasana Max (HBZ10) have been made using endpoints agreed following the EU renewal of Ethofumesate and EU approval of Phenmedipham.

This document describes the specific conditions of use and labelling required in Poland for the first approval of the authorisation of Wizard / Beetup Pro / Betasana Max (HBZ10).

Appendix 1 of this document provides a copy of the final product authorisation in Poland.

Appendix 2 of this document is a copy of the approved product label for Poland.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation if relevant.

1.1 Application background

This dossier is being submitted for the first authorisation under article 33 of Reg. No. 1107/2009 for the plant protection product “Wizard / Beetup Pro / Betasana Max” (product code HBZ10) in Poland. In the framework of this application, Poland is acting as zRMS, and concerned Member States are Austria, Belgium, Czech Republic, and The Netherlands. The only use applicable is as an herbicide for use on beet crops, where the target is broadleaf weeds. The product is intended to be applied from BBCH stage 10 to 39, by using a minimal water volume of 80 litres per hectare. Details on the intended uses and to which country they are intended are provided in section B0 of the core dossier.

1.2 Letters of Access

The applicant UPL Europe Ltd (for which UPL Holdings Coöperatief U.A. is part of) was one of the notifiers of the renewal procedure of Ethofumesate. A full data package on the active substance was therefore already submitted to the rapporteur Member State Austria and found sufficient except for a few studies as listed in the final addendum to the Renewal Assessment Report (December 2015), Volume 1, Level 3, Point 3.1.4. These studies are covered by a letter of access from the other notifier of the renewal procedure (the Task Force Ethofumesate). The letter of access is attached to **Appendix 3** of this document.

The applicant UPL Limited (formerly United Phosphorus Ltd. and for which UPL Holdings Coöperatief U.A. is part of) was one of the notifiers for the re-evaluation of Phenmedipham for its inclusion in Annex I of the directive 91/414/EC. A full data package of the active substance was therefore already submitted to the Rapporteur Member State Finland and found sufficient. Moreover, all the data relied on this dossier are drawn from the DAR and are nowadays out of data protection. The only exception is the study provided in regard to KCP point 10.1.2.2, which is co-owned by UPL Europe Ltd. and Bayer CropScience in the context of the renewal of the active substance under the Task Force on Phenmedipham. Therefore, no letter of access is considered as necessary regarding the use of this study, but a letter of ownership can be provided upon request.

The product Wizard / Beetup Pro / Betasana Max was not one of the representative products of the EU Review procedure for renewal of approval of Ethofumesate or Phenmedipham. All data submitted with this dossier are owned by UPL Europe Ltd. Therefore, no letters of access are required for the relevant data package on the formulated product Wizard (HBZ10).

1.3 Justification for submission of tests and studies

New studies provided in this dossier have been submitted to support the first authorisation of Wizard / Beetup Pro / Betasana Max (HBZ10). These new studies are relevant and necessary to support the first product authorisation. A full list of new studies with justifications for submission is given in **Appendix 4**.

1.4 Data protection claims

Plant protection product studies for which data protection is claimed in accordance with Articles 59 of Regulation (EC) No. 1107/2009 are indicated in the Reference List provided in **Appendix 4**.

2 Details of the authorization decision

2.1 Product identity

Product code	HBZ10
Product name in MS	Wizard Beetup Pro Betasana Max
Authorization number	Not relevant - First registration
Function	Herbicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance(s) (incl. content)	Ethofumesate; 125 g/L Phenmedipham; 125 g/L
Formulation type	Emulsifiable Concentrate [Code: EC]
Packaging	1litre bottle – Coex HDPE/EVOH- professional user
	5 litres jerry can – Coex HDPE/PA – professional user
	10 litres jerry can – Coex HDPE/PA – professional user
	5 litres jerry can – HDPE Fluorinated – professional user
	10 litres jerry can – HDPE Fluorinated – professional user
	20 litres pail – HDPE Fluorinated – professional user
Co-formulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for Wizard/ Beetup Pro/ Betasana Max (product code HBZ10) resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

No national monitoring data available.

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 classes, categories:	Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category 1 Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation Hazardous to the aquatic environment - Aquatic acute , Cat 1, Chronic Hazard, Category 1
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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, GHS07, GHS09
Signal word:	Danger
Hazard statement(s):	H315, H318, H335, H400, H410
Precautionary statement(s):	<p>P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.</p> <p>P264 - Wash hands, forearms and face thoroughly after handling.</p> <p>P271 - Use only outdoors or in a well-ventilated area.</p> <p>P273 - Avoid release to the environment.</p> <p>P280 - Wear protective gloves/eye protection/face protection.</p> <p>P302+P352 - IF ON SKIN: Wash with plenty of water.</p> <p>P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310 - Immediately call a POISON CENTER or doctor.</p> <p>P312 - Call a POISON CENTRE or doctor if you feel unwell.</p> <p>P321 - Specific treatment (see supplemental first aid instruction on this label).</p> <p>P332+P313 - If skin irritation occurs: Get medical advice/attention.</p> <p>P362+P364 - Take off contaminated clothing and wash it before reuse.</p> <p>P391 - Collect spillage.</p> <p>P403+P233 - Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405 - Store locked up.</p> <p>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

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

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).
SPe 1	To protect groundwater do not apply this or any other product containing ethofumesate more than every second year
SPe 3	All uses: To protect aquatic organisms, respect vegetative buffer zone of 10 m to surface water bodies for all uses.

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

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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:
N/A
Worker protection:
N/A
Integrated pest management (IPM)/sustainable use:
N/A
Environmental protection
N/A
Other specific restrictions
None.

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

Integrated pest management (IPM)/sustainable use:
N/A

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 0 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
SPe 3	To protect aquatic organisms, respect vegetative buffer zone of 10 m to surface water bodies.	All uses.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. rev. 2, date: 2022-12-30

PPP (product name/code): Wizard / HBZ10

Formulation type: EC (a, b)

Active substance 1: Ethofumesate

Conc. of a.s. 1: 125 g/L (c)

Active substance 2: Phenmedipham

Conc. of a.s. 2: 125 g/L (c)

Safener: -

Conc. of safener: - (c)

Synergist: -

Conc. of synergist: - (c)

Applicant: UPL Holdings Coöperatief U.A.

Professional use: ☒

Zone(s): Central (d)

Non professional use: ☐

Verified by MS: Yes

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destinatio n / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha (f)	Overall conclusions							
					Method / Kind	Timing / Growt h stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Sugar beet	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 5 b) 5	7	a) 1.2 b) 6.0	a) ETO: 150 PMP: 150 b) ETO: 750 PMP: 750	80 200-400	-	Max. 6.0 L/ha per year dose range: 0.9-1.2 L/ha	A	A	A	A	A	R aquatic	A	A
																			A	Remained organism	
2	PL	Sugar beet	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 3 b) 3	6	a) 1.8 b) 5.4	a) ETO: 225 PMP: 225 b) ETO: 675 PMP: 675	80 200- 400	-	Max. 5.4 L/ha per year	A	A	A	A	A	R aquatic	A	A
																			A	Remained organism	

3	PL	Sugar beet	F	Broadleaf weeds	Overall spray	Spring - summer BBC H 10-39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) ETO: 300 PMP: 300 b) ETO: 900 PMP: 900	80-200-400	-	Max. 7.2 L/ha per year	A	A	A	A	R Biennial application (Château dun, FOCUS PEARL 4.4.4)	R aquatic A Remained organism	A	A
Minor uses according to Article 51 (zonal uses)																					
4	PL	Red beet	F	Broadleaf weeds	Overall spray	Spring - summer BBC H 10-39	a) 5 a) 5	7	a) 1.2 a) 6.0	a) ETO: 150 PMP: 150 b) ETO: 750 PMP: 750	80-400	-	Max. 6.0 L/ha per year	A	A	A	A	A	R aquatic A Remained organism	A	n.r.
5	PL	Red beet	F	Broadleaf weeds	Overall spray	Spring - summer BBC H 10-39	a) 3 a) 3	6	a) 1.8 a) 5.4	a) ETO: 225 PMP: 225 b) ETO: 675 PMP: 675	80-400	-	Max. 5.4 L/ha per year	A	A	A	A	A	R aquatic A Remained organism	A	n.r.
6	PL	Red beet	F	Broadleaf weeds	Overall spray	Spring - summer BBC H 10-39	a) 3 a) 3	9	a) 2.4 a) 7.2	a) ETO: 300 PMP: 300 b) ETO: 900 PMP: 900	80-400	-	Max. 7.2 L/ha per year	A	A	A	A	R Biennial application (Châteaudun, FOCUS PEARL 4.4.4)	R aquatic A Remained organism	A	n.r.
7	PL	Fodder beet	F	Broadleaf weeds	Overall spray	Spring - summer BBC H 10-39	a) 5 b) 5	7	a) 1.2 b) 6.0	a) ETO: 150 PMP: 150 b) ETO: 750 PMP: 750	80-400	-	Max. 6.0 L/ha per year	A	A	A	A	A	R aquatic A Remained organism	A	n.r.
8	PL	Fodder	F	Broadleaf	Overall	Spring	a) 3	6	a) 1.8	a) ETO: 225	80-400	-	Max. 5.4	A	A	A	A	A	R aquatic	A	n.r.

		beet		weeds	spray	- summ er BBC H 10- 39	b) 3		b) 5.4	b) PMP: 225 ETO: 675 PMP: 675			L/ha per year						A Remained organism		
9	PL	Fodder beet	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) ETO: 300 PMP: 300 b) ETO: 900 PMP: 900	80-400	-	Max. 7.2 L/ha per year	A	A	A	A	R Biennial applicatio n (Châteaudu n, FOCUS PEARL 4.4.4)	R aquatic A Remained organism	A	n.r.
10	PL	Chard	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 5 b) 5	7	a) 1.2 b) 6.0	a) ETO: 150 PMP: 150 b) ETO: 750 PMP: 750	80-400	-	Max. 6.0 L/ha per year	A	A	A	N	A aquatic A Remained organism	R aquatic A Remained organism	A	n.r.
11	PL	Chard	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 3 b) 3	6	a) 1.8 b) 5.4	a) ETO: 225 PMP: 225 b) ETO: 675 PMP: 675	80-400	-	Max. 5.4 L/ha per year	A	A	A	N	A aquatic A Remained organism	R aquatic A Remained organism	A	n.r.
12	PL	Chard	F	Broadleaf weeds	Overall spray	Spring - summ er BBC H 10- 39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) ETO: 300 PMP: 300 b) ETO: 900 PMP: 900	80-400	-	Max. 7.2 L/ha per year	A	A	A	N	R Biennial applicatio n (Châteaudu n, FOCUS PEARL 4.4.4)	R aquatic A Remained organism	A	n.r.

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	Numeration necessary to allow references
	2	Use official codes/nomenclatures of EU Member States
	3	For, the crops EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8	The maximum number of application possible under practical conditions of use must be provided.
9	Minimum interval (in days) between applications of the same product
10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13	PHI - minimum pre-harvest interval
14	Remarks may include: Extent of use/economic importance/restrictions
15	Overall conclusions - explanation for the column 15 is below *

*** Explanation for column 15 “Overall conclusions”**

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use
n.r.	Not relevant for section 3

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 a uniform brown liquid, with an organic solvent type odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 128°C. It has a self-ignition temperature above 400°C. In aqueous solution, it has a pH value around 4.0 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C ± 2°C and 14 days at 54 °C ± 2°C, neither the active ingredient content nor the technical properties were changed. A 2-years shelf-life study at ambient temperature when stored in HDPE/EVOH, HDPE/PA and HDPE-F commercial packaging is on-going and study plan is provided until final report will be available. Its technical characteristics are acceptable for a Emulsifiable Concentrate formulation.

The intended concentration of use is 0.3% to 3.0%.

3.2 Efficacy (Part B, Section 3)

A good level of control has been demonstrated against a wide range of major broadleaved weeds in sugar beet. Application rate will depend on the number of applications used in the program, from 1.2 L product/ha by considering 5/6 applications, to 2.4 L product/ha by considering 3 applications. The resistance risk of HBZ10 is considered as low. Nevertheless, to reduce the development of further resistance, further recommendations are raised like a maximum of six applications per season, a maximum total dose of 1000 g/ha of Ethofumesate every three years, and to apply the product when weeds are small and at an active stage of weed growth for optimal control. Biological processing effects and propagation effects are not considered relevant for this crop. No significant adverse effects were observed on the sugar beets, and due to the long, problem-free history of use of similar products in Europe, the risk of effects on succeeding crops and adjacent crops is considered to be low.

3.3 Efficacy data

Preliminary tests

A total programme of 15 replicated trials was conducted in France and Germany in 2019 and in Germany, UK, Netherlands and Poland in 2020, in order to address preliminary questions, including the ratio of active substances in the product and the composition of the final formulation. Of these, six trials were for ratio confirmation, with a further nine trials bridging between two candidate formulations at the selected ratio.

There is no clear difference in performance between HBZ08 and HBZ10, on any weed species or at either of the two rates tested. Overall means for key weeds such as CHEAL were 90.9% for HBZ08 at 2.4L/ha x3, compared to 89.6% for HBZ10 at the same rate. When used at 1.2L/ha x5, the overall mean for the same weed was 94.1% for HBZ08 and 95.5% for HBZ10. Similarly, for POLCO the mean at the low rate was 97.2% for HBZ08 at the 2.4L/ha x3 rate and 93.0% for HBZ10 at the same rate; at the 1.2L/ha x 5 use rate HBZ08 achieved 97.4% control while HBZ10 achieved 98.1%.

There was no clear difference in performance which could be related to the location of the trials in the Maritime or North-East zones. Mean levels of control achieved on CHEAL at the HBZ08 2.4L/ha x 3 rate were 92.3% in the Maritime zone, compared to 87.9% in the North-East zone. The same rate of HBZ10 achieved 91.88% control in the Maritime zone and 85.0% in the North-East zone.

Minimum effective dose tests

A total programme of 15 replicated trials was conducted in France, Poland, the Netherlands, the United Kingdom and Germany in 2019.

The dose of 1.8 L/ha or 2.4L/ha of HBZ10 provided the optimum overall control and should be considered as effective against a wide range of annual broadleaved weeds, when used as part of a three-spray programme.

The dose of 0.9 L/ha or 1.2L/ha of HBZ10 provided the optimum overall control and should be considered as effective against a wide range of annual broadleaved weeds, when used as part of a 5/6 spray programme.

As weed populations often occur as complexes of several species throughout a season, weed control programmes should be tailored to the species observed and the opportunities for application.

Efficacy tests

A total programme of 15 replicated trials was conducted in France, Poland, the Netherlands, the United Kingdom and Germany in 2019 and 2020. For control programmes including three applications, use rates tested were 1.8 and 2.4L/ha. Different weed species are controlled by different rates.

All efficacy trials were conducted in areas of commercial sugar beet, rather than specially planted areas of crops. These trials are therefore truly representative of the performance of HBZ10 in the conditions for which it is intended.

General trends indicate that HBZ10 when used at the recommended rate is often superior to the performance of the Ethofumesate + Phenmedipham reference products, while being equivalent to the more complex reference products and programmes. Products with Desmedipham are no longer available to growers, which further demonstrates the value of the formulation optimization work which resulted in HBZ10.

Control of the majority of weed species is high, with almost every species tested being Susceptible or Very Susceptible to HBZ10, when used in either the 3-spray programme or in the 5/6 spray programme.

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

HBZ10 is an emulsifiable concentrate (EC) formulation containing Ethofumesate (125 g/L) and Phenmedipham (125 g/L) for use as a post-emergence herbicide for the control of broadleaved weed species in sugar beet and other beet crops. The possibility of development of resistance or cross-resistance to the active substances contained in is discussed hereafter based on the requirements detailed in the EPPO standard PP1/213(4) “*Resistance risk analysis*”.

Ethofumesate is a benzofurane herbicide in HRAC Group 15 (Legacy group K3) and is a known inhibitor of several plant processes, including: 1) biosynthesis of fatty acids and lipids, which may account for reported reductions in cuticular wax deposition; 2) biosynthesis of proteins, isoprenoids (including gibberellins) and flavonoids (including anthocyanins); and 3) gibberellin synthesis inhibition, which may result from the inhibition of kaurene synthesis. Photosynthesis may also be inhibited. A currently viable hypothesis that may link all these effects involves the conjugation of acetyl coenzyme A and other sulfhydryl-containing biomolecules by thiocarbamate sulfoxides. The sulfoxide forms may be the active herbicides.

Ethofumesate is a selective systemic herbicide absorbed by the emerging shoots (grasses) and roots (broad-leaved weeds) with translocation to the foliage. It has good residual activity in the soil.

Most reported cases of resistance occur outside of Europe and/or in cereals, maize and soybean crops. Despite the long history of use over a wide range of geographies, only one instance of resistance has ever been reported to Ethofumesate; this was outside of Europe and in grass seed. Whilst the ‘theoretical risk’ cannot be completely excluded, it does seem reasonable to conclude that up to this point, the ‘practical risk’ of resistance development, especially in Europe, is low.

Phenmedipham is a phenyl-carbamate herbicide in HRAC Group 5 (legacy group C1). It acts by inhibition of photosynthesis (photosystem II), and is both a selective and systemic active substance, used as post-emergence herbicides. It is absorbed through the leaves and then translocated, and is efficient against broadleaved weeds, especially at cotyledon stages. It has been used for many years,

Phenmedipham was first reported in 1967. It is recognised as vital pest management tool for the efficient control of broad-leaved weeds in beet crops.

According to the cases of resistance reported globally and in Europe, the majority of cases of resistance to Group 5 herbicides occur to triazines, and in particular atrazine. Most reported cases of resistance occur outside of Europe and/or in maize crops. Despite the long history of use over a wide range of geographies, only one instance of resistance has ever been reported Phenmedipham; this was in a sugar beet crop in Belgium.

Since both Phenmedipham and Ethofumesate have a single-site mode of action, it must be considered they present a moderate to high ‘theoretical risk’ of resistance development if used intensively and without restriction, and therefore have a higher potential for developing ‘practical resistance’ in the field. However, the evidence from reported cases of resistance suggests that whilst resistance has developed, the majority is outside of Europe, and the number of cases of resistance to Phenmedipham or Ethofumesate is limited.

Overall, the risk of cross resistance from use of HBZ10 against broad-leaved weed in beet crops can be considered low. There are currently only two cases of cross-resistance between Group 15 herbicides and other herbicides in Europe, and these are grassweeds in cereals. For both Phenmedipham and Ethofumesate there are no reported cases of cross-resistance. Globally, there are only three reported cases of resistance to both Group 5 and Group 15 herbicides. Only one of these was in Europe and relates to *Alopecurus myosuroides* in wheat (Germany, 2007).

The majority of cases of cross-resistance between Group 5 and other herbicides occur outside Europe, most often on grassweeds in cereals.

The risk of resistance arising through the use of HBZ10 is mitigated by label recommendations, including a maximum of six applications per season, a maximum total dose of 1000 g/ha of Ethofumesate every three years, and to be applied when weeds are small and at an active stage of weed growth for optimal control.

As the risk of resistance development from Group 15 herbicides (including Ethofumesate) and Group 5 (including Phenmedipham) is low to medium, there are no specific HRAC Working Groups dedicated to resistance management of these herbicide groups, and which publishes specific guidance. In the absence of specific guidance, zRMS proposes to use the below recommendations:

1. Follow label use instructions, such as application rates, timing and equipment recommendations.
2. Use mixtures or sequential treatments of herbicides having different sites of action.
3. Avoid continued use of the same herbicides, or herbicides with the same site of action in the same field, unless integrated with other weed control practices.
4. Limit the number of applications of a single herbicide or herbicides with the same site of action in a single growing season.
5. Monitor herbicide results

3.3.2 Adverse effects on treated crops

A total programme of twelve replicated selectivity trials was conducted in France, Poland, the Netherlands, the United Kingdom and Germany in 2019 and 2020.

All products were applied at N and 2N dose rates. HBZ08/10 was tested at 2.4 and 4.8L/ha applied three times, as this represents the worst case for the crop, and is also equivalent in the total dose to the Low Dose System programme (1.2L/ha applied at 5-6 applications).

According to EPPO PP 1/257 HCET 68 (1) the indicator crop for selectivity in beet crops is red beet (BEAVD), with extrapolation to any Beta species (BEASS). However, given the well-known selectivity of Ethofumesate and Phenmedipham, when used as recommended, it is reasonable to extrapolate that selectivity data generated on sugar beet is representative of selectivity on other beet crops.

Phytotoxicity effects observed included necrosis of the leaf tip, crop thinning, leaf deformation, crop stunting and chlorosis. Not all symptoms were observed in all trials. In all trials, with the exception of one trial in which the GAP was not respected, phytotoxicity from both formulations was transient and not observed at the time of the final assessment. In all efficacy trials in which the GAP was respected the crop safety of HBZ10 was clear, with transient effects reducing to acceptable levels over the course of the trial.

When used as recommended HBZ10 is safe to sugar beet crops. Extrapolation to other beet crops is also proposed.

Yield was assessed in seven bridging trials conducted in France (3), the United Kingdom (2) and Poland (2). All trials included 2.4L/ha and 4.8L/ha of HBZ08 and HBZ10, applied three times. Yield was also assessed in twelve weed-free trials conducted in Germany (3), France (3), the Netherlands, (2), the United Kingdom (2) and Poland (2). All trials included 2.4L/ha (1N) and 4.8L/ha (2N) of HBZ10, applied three times.

In no trial was there a statistically significant difference in total yield between the untreated plots and the plots treated with HBZ10, regardless of use rate. Similarly, there was no statistically significant difference between HBZ10 and any of the reference products. This indicates that the crop safety of HBZ10 is comparable to that of all the reference products.

Crop quality was assessed in seven bridging trials conducted in France (3), the United Kingdom (2) and Poland (2). All trials included 2.4L/ha (1N) and 4.8L/ha (2N) of HBZ08 and HBZ10, applied three times. This was also assessed in twelve weed-free trials conducted in Germany (3), France (3), the Netherlands, (2), the United Kingdom (2) and Poland (2). All trials included 2.4L/ha and 4.8L/ha of HBZ10, applied three times. All weed-free trials were harvested by hand at the normal commercial harvest timing. Samples of beet were then analysed for quality parameters.

In no trial was there a statistically significant difference in any of the quality parameters tested, between the plots treated with HBZ08 or HBZ10, regardless of use rate, indicating that HBZ10 is safe to the sugar beet crop when applied as directed.

HBZ10 has been evaluated on a number of cultivars over a number of seasons, in a variety of climatic conditions and with a range of application timings and rates (N and 2N in weed-free trials). When used as directed the product has shown no permanent phytotoxicity at any evaluation. This strongly supports the conclusion that this product is safe to sugar beet. Extrapolation to other beet crops is also proposed.

3.3.3 Observations on other undesirable or unintended side-effects

Based on the combined risk of both molecules, the following statements are considered supported:

- Safe use for sowing of Onion, Radish, Sunflower, Tomato and Soybean immediately with no cultivation requirement.
- Safe use for sowing Oilseed rape and Lettuce after 2 months with no cultivation requirement, or immediately if ploughing to 15cm is performed.
- Safe use for sowing of flax after 3 months, with not cultivation requirement; or immediately if ploughing to 15cm is performed.
- Safe use for sowing of Oats and Wheat after 5 months or 11 months (respectively), with no cultivation requirement; or immediately for Oats and 3 months for Wheat if ploughing to 15cm is performed.

Based upon the above statements and the label recommendations of other co-formulated and solo Phenmedipham and Ethofumesate products, extrapolation to planting of all crops is proposed based upon a planting interval of 3 months and ploughing to a depth of 15cm.

No adverse effects on other plants including adjacent crops away from the site of application have been observed in efficacy trials following the application of HBZ10, even when applied at double dose rate.

Therefore, it is reasonable to conclude that HBZ10 when used according to other label recommendations has no adverse effects on other plants, including adjacent crops.

It is important to reduce the drift of the product onto neighbouring crops.

Triple water rinsing the sprayer tank allows to remove the residues of active substances to a level that is safe for the next crops

In all the trials, observations were conducted concerning any adverse impact on beneficial or non-target organisms. No negative effects were reported.

3.4 Methods of analysis (Part B, Section 5)

Please refer to the Registration Report of HBZ10, Part B, Section 5 for the central zone.

3.4.1 Analytical method for the formulation

The analytical method submitted is acceptable for the determination of the active substances Phenmedipham and Ethofumesate in the plant protection product HBZ10 and has been validated according to SANCO 3030/99 rev. 5. A method for determination of impurities:

- Impurity 1 (3-Methylaniline (3MA))
- Impurity 2 (Toluene)
- Impurity 3 (3-Aminophenol)

in HBZ10 was successfully validated. ~~and is provided in Part C, no further consideration is required.~~

Analytical methods for the relevant impurities EMS and iBMS in the formulation should be provided, as this is required according to Reg. (EU) 284/2013.

Since the data could not be prepared and supplemented during the commenting period, a data gap was identified.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. A full robust data package is submitted to cover both pre-registration and enforcement methods for all the relevant crop groups as well as animal and environmental matrices. Most of the methods were assessed during the EU evaluation for the renewal of Ethofumesate (EFSA Journal 2016;14(1):4374), during the EU review of Phenmedipham (SANCO/4060/2001) and during Phenmedipham renewal (evaluated by RMS Finland in RAR version May 2022). No further data is necessary.

3.5 Mammalian toxicology (Part B, Section 6)

No new toxicity data is provided in support of this application. Toxicological classification of Wizard / Beetup Pro / Betasana Max (HBZ10) is based on the extrapolation from the composition of the formulation. Based on the toxicological data of the co-formulants, Wizard / Beetup Pro / Betasana Max (HBZ10) is considered to cause skin irritation and serious eye damage, as well as respiratory irritation. No toxicological concern is expected after administration by the oral or dermal route and the formulation is not considered as a skin sensitiser.

3.5.1 Acute toxicity

Acute toxicity endpoints

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	> 2000 mg/kg bw	None	Extrapolation from the composition of the formulation according to Reg. No (EC) 1272/2008
LD ₅₀ dermal, rat	> 2000 mg/kg bw	None	
LC ₅₀ inhalation, rat	> 5 mg/L	None	

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Skin irritation	Causes skin irritation	H315	– please refer to Part C
Eye irritation	Causes serious eye damage	H318	
Skin sensitisation	Non-sensitising to skin	None	
Specific Target Organ Toxicity (STOT) – single exposure	May cause respiratory irritation	H335	
Supplementary studies for combinations of plant protection products	No data – not required		

3.5.2 Operator exposure

Wizard / Beetup Pro / Betasana Max (HBZ10) containing 125 g/L Ethofumesate and 125 g/L Phenmedipham is intended to be used as an herbicide for the control of broadleaf weeds in beet crops (sugar beet, red beet, fodder beet, and chards). Exposure estimate has been calculated using the EFSA model and considering the worst-case exposure scenario to cover all the intended uses (highest application rate per application as well as the highest application rate per year with the shorter interval between each application). The results of the calculation show an acceptable risk for the critical use, leading to 13.25% of the combined systemic AOEL, without using Personal Protective Equipment.

According to the model calculations, it can be concluded that the risk for the operator using Wizard / Beetup Pro / Betasana Max (HBZ10) on beet crops is acceptable, without the use of Personal Protective Equipment.

NDE assessment indicates safe use (exposure E below limit AOEL) but due to the irritating effect on skin and serious eye damage effects, it is recommended the use of protective gloves and eye/face protection as prevention during handling and applying of the product.

3.5.3 Worker exposure

According to the EFSA model calculations, it can be concluded that the risk for the worker carrying out crop inspection tasks following the application of According to the model calculations, it can be concluded that the risk for the operator using Wizard / Beetup Pro / Betasana Max (HBZ10) on beet crops is acceptable, without the use of Personal Protective Equipment. (HBZ10) on beet crops is acceptable, without the use of personal protective equipment. The predicted exposure for a worker carrying out crop inspection tasks has been calculated to be 12.43 % of the combined systemic AOEL when wearing long sleeved shirt and long trousers (“permeable”) but no gloves. According to results given in NDE assessment, the worker exposure estimations indicate that the acceptable operator exposure level (AOEL) will not be exceeded for specific task consisting of manual removal of bolting beets when considering worker is wearing T-shirt, long trousers and gloves, or long clothes (workwear) and gloves.

3.5.4 Bystander and resident exposure

According to the model calculations, it can be concluded that the risk for bystanders and residents during the application of According to the model calculations, it can be concluded that the risk for the operator using Wizard / Beetup Pro / Betasana Max (HBZ10) on beet crops is acceptable, without the use of Personal Protective Equipment. (HBZ10) on beet crops is acceptable. Resident exposure after the application of According to the model calculations, it can be concluded that the risk for the operator using Wizard / Beetup Pro / Betasana Max (HBZ10) on beet crops is acceptable, without the use of Personal Protective Equipment. (HBZ10) is estimated to be 20.42% of the combined systemic AOEL for children. Adults are estimated to be exposed at levels not exceeding 8.56% of the combined systemic AOEL. Therefore, there is no undue risk for residents towards Ethofumesate when Wizard (HBZ10) is applied as recommended by the Good Agricultural Practices.

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

3.6.1 Residues

Phenmedipham

Information on the residue behaviour of the active substance Phenmedipham was already evaluated during Annex I inclusion. It was concluded that Phenmedipham and metabolite MHPC (methyl 3-hydroxyphenylcarbanate) were the main components of the residue. Both are also conjugated to glucose or glucose-2 sulphate. Furthermore, metabolite 3-aminophenol was found. Metabolism in rotational crops and in livestock was considered identical as for primary crops. No further data is required. Storage stability of residues has been demonstrated in high water and high starch commodities for at least 24 months.

The residue definition for monitoring and for risk assessment is currently established as parent Phenmedipham only for plants and commodities of animal origin.

Four new supervised residue trials for N-EU were presented in the framework of this application, performed with the intended formulation HBZ10. The trials confirmed that no residues above the LOQ of 0.01 mg/kg are expected in sugar beet roots. The number of trials presented is therefore considered sufficient. According to guideline SANTE/2019/12752, extrapolation from sugar beets is possible to fodder beet, red beet, and yellow beet.

The residues arising from the proposed uses will not exceed the MRLs established for phenmedipham for root of sugar beet of 0.05 mg/kg, beetroots of 0.15 mg/kg in Reg. (EC) No 2015/2075.

The proposed uses on roots of sugar beet, red beet, yellow beet, fodder beet are considered acceptable.

Beet leaves and chard belong to the group of leafy vegetables and the metabolism of phenmedipham has not been investigated on this crop group. No general residue definition has been proposed for primary crops (root and fruit crops only). Additionally, according to the SANTE/2019/12752, extrapolation from sugar beet tops to tops of red beet, yellow beet and chard is not possible.

Considering the above, in our opinion, **the proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on beet leaves and chard are not acceptable.**

Due to the low expected livestock dietary intake, livestock feeding studies are not required.

Since no residues above 0.01 mg/kg are expected in raw commodities to be processed and since the contribution of residues in beets amounts to less than 10% of the ADI to the theoretical maximum exposure, data on the nature of the residue is not required. Therefore, also data on the magnitude of the residue in processed commodities is not required.

No significant residues of Phenmedipham are expected in rotational crops.

No other special studies are deemed necessary.

Ethofumesate

Information on the residue behaviour of the active substance Ethofumesate was already evaluated during Annex I inclusion and during the AIR 3 renewal process. Metabolism of Ethofumesate leads to the formation of NC 9607, NC 8493 and NC 20645 free or conjugated. NC 20645 is the open ring form of NC 9607 and both are interconvertible depending on the pH, where in acidic conditions, the main form is NC 9607. Metabolism in rotational crops and in livestock was considered identical as for primary crops. No further data is required.

The residue definition for monitoring and for risk assessment is established as the sum of Ethofumesate, NC 9607, NC 20645 and its conjugate, expressed as Ethofumesate. The residue definition for animal commodities is the sum of Ethofumesate, NC 9607, and NC 20645, expressed as Ethofumesate.

Storage stability of Ethofumesate residues has been demonstrated in high water and high starch commodities for at least 18 and 24 months, respectively. Storage stability of metabolites residues (NC 9607, NC 20645 and conjugated NC 20645) has been demonstrated for at least 24 months in high water and high starch commodities, and at least for 6 months in high oil, high protein and high acid matrices.

Storage stability in animal commodities is considered acceptable for up to 6 months for Ethofumesate and its metabolites NC 9607, NC8493 and NC 20645.

A sufficient number of supervised residue trials were conducted in accordance with the representative uses of Ethofumesate 500 SC: a total of 40 trials in Northern Europe and 11 trials in Southern Europe conducted in sugar beet. Most of these trials were already evaluated and accepted during the renewal of Ethofumesate, only 4 new trials for N-EU were submitted with this dossier confirming that residue levels resulting from the use of Wizard (HBZ10) are consistent with those obtained in trials with other formulations. According to the document SANTE/2019/12752, extrapolation from sugar beets is possible to fodder beet, red beet, yellow beet.

The residues arising from the proposed uses will not exceed the MRLs established for ethofumesate (as sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate) for root of sugar beet, red beet, yellow beet of 0.2 mg/kg in Reg. (EC) No 2017/1016. The proposed uses on roots of sugar beet, red beet, yellow beet, fodder beet are considered acceptable.

According to the SANTE/2019/12752, extrapolation from sugar beet tops to tops of red beet, yellow beet and chard is not possible.

Considering the above, in our opinion, **the proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on beet leaves and chard are not acceptable.**

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

Data on the effect of processing on the nature and level of the residue were presented in the EU Review of Ethofumesate. It was concluded that parent compound Ethofumesate is stable after conditions simulating industrial and household common processes. Residue levels in the intended commodities are expected to be < 0.1 mg/kg and the contribution of each of these commodities to the theoretical maximum daily intake (TMDI) is < 10% of the ADI. Processing studies previously evaluated permit to derive robust processing factors and are considered sufficient. No further studies are deemed necessary, considering that the trigger for requiring new studies is not met by the intended uses.

No significant residues of Ethofumesate are expected in rotational crops, whereas the only residue detected above the LOQ of 0.01 mg/kg was parent Ethofumesate. Residues in rotational crop trials were already evaluated during the renewal of the active substance and considered as acceptable.

Remark:

In EFSA Journal 2016;14(1):4374 it is highlighted that the maximum amount of active substance must not exceed 1.0 kg/ha every 3 years.

No other special studies are deemed necessary.

3.6.2 Consumer exposure

Consumer risk assessments were performed for Phenmedipham and Ethofumesate using the EFSA PRIMO model rev. 3.1. For each active substance, TMDI calculations were performed taking into account MRLs currently set in EU regulations. The chronic exposure for Phenmedipham was maximum 14% of the ADI based on NL toddler. The chronic exposure for Ethofumesate was maximum 0.5% of the ADI based on NL toddler. As no acute reference doses have been set for Phenmedipham and Ethofumesate, there is no need to evaluate the acute risk for these active substances.

It is concluded that the intended use of HBZ10 according to the GAP does not lead to residues which might have harmful effects on human health by demonstrating an acceptable chronic risk for the consumer.

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

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

Soil exposure for ethofumesate, phenmedipham and their relevant metabolites was calculated using approach described in respective FOCUS guidance for the intended uses of HBZ10. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. Obtained PEC_{soil} values were used in the risk assessment for soil organisms.

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

The PEC in groundwater of ethofumesate, phenmedipham and their major metabolites NC 8493, NC 20645 and MHPC were calculated with standard FOCUS scenarios using the modelling software FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 with the respective FOCUS groundwater scenarios for sugar beet.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L for phenmedipham and its metabolite in all relevant Polish scenarios, demonstrating that no unacceptable leaching of these compounds is expected when HBZ10 is used according to recommendations.

Groundwater modelling performed for ethofumesate resulted with PEC_{GW} above the threshold concentration of 0.1 µg/L in Châteaudun scenario (relevant in Poland) following application to sugar beet at the rate of 2.4 L product/ha by considering 3 applications with 9 days interval. PEC_{GW} were all <0.1 µg/L when application frequency was restricted to one every second year.

Overall, in order to protect groundwater uses of HBZ10 must be restricted to biennial application to sugar beet at the rate of 2.4 L product/ha by considering 3 applications with 9 days interval.

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

The surface water exposure was estimated using the respective FOCUS models for scenarios defined for sugar beet. Scenarios relevant for Poland (D3, D4 and R1) were considered in these calculations. EU agreed endpoints and intended use pattern of HBZ10 were considered.

FOCUS step 2 calculations of predicted environmental concentrations in surface water led to safe uses for Ethofumesate metabolite NC 8493 for all critical uses.

FOCUS step 3 calculations of predicted environmental concentrations in surface water led to safe uses for ethofumesate metabolite NC 20645 and phenmedipham metabolite MHPC for all critical uses.

FOCUS step 4 with the implementation of a no spray buffer zone and vegetated strip of 10 m was sufficient to demonstrate a safe use of active substances ethofumesate and phenmedipham for all critical uses.

Considering all assessed uses the PEC_{sw} values led to levels acceptable for aquatic risk assessment. The obtained PEC_{sw} results were used in the risk assessment for aquatic organisms.

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

Based on the available data contamination of the atmosphere with ethofumesate and phenmedipham from the intended uses of HBZ10 is considered to be negligible.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The risk assessment for effects on birds and wild mammals is carried out according to the Guidance of EFSA on Risk Assessment for Birds and Mammals (EFSA/2009/1438).

Birds

Acute risk assessment

No acute LD₅₀ values are available for HBZ10. Thus, the acute risk for birds was assessed with the lowest endpoint of the active substances as well as the surrogate LD₅₀ for the formulated product.

The TER_A values at the screening step exceed the Annex VI trigger value of 10 what indicates that HBZ10 applied according to the intended use pattern does not pose an acute risk to birds.

Long-term risk assessment

The EU agreed endpoint of the active substances has been used in the assessment of chronic risk.

The TER_{LT} values at the screening step exceed the Annex VI trigger value of 5 what indicates that HBZ10 applied according to the intended use does not pose a reproductive risk to birds. The long-term combined risk assessment achieved relevant trigger value of 5.

Secondary poisoning

The TER values for secondary poisoning of earthworm-eating birds (dry soil and pore water approach) and fish-eating birds are above the trigger value of 5. There is no risk expected for birds exposed to the active substance through consumption of contaminated water from puddles on soil.

Mammals

Acute risk assessment

No acute LD₅₀ values are available for HBZ10. Thus, the acute risk for mammals was assessed with the EU agreed endpoint of the active substances as well as the predicted mixture LD₅₀ for the formulated product.

The TER_A values at the screening step exceed the Annex VI trigger value of 10 what indicates that HBZ10 applied according to the intended use does not pose an acute risk to wild mammals.

Long-term risk assessment

The EU agreed endpoint of the active substances have been used in the assessment of chronic risk. The first tier TER_{LT} values for the active substances Ethofumesate and Phenmedipham are above the respective trigger value of 5 indicating an acceptable risk for mammals following application of HBZ10 in beet crops, except for the active substance Phenmedipham for the generic focal species small insectivorous mammal, large herbivorous mammal, and small omnivorous mammal (growth stage BBCH 10-39).

The refined TER_{LT} values for the active substance Phenmedipham are above the respective trigger value for the focal species small insectivorous mammal “shrew”, large herbivorous mammal “lagomorph”, and small omnivorous mammal “mouse”, indicating an acceptable risk for mammals following application of HBZ10 in beet crops. In case of combined long-term risk assessment, the TERcombi did not achieve the triggers of 5 for wood mouse for application 3 x 2.4 L/ha with 9 d interval in June. Based on the fact that toxicity of the mixture is driven mainly by Phenmedipham (89%) for which the trigger of 5 is achieved for long-term risk, the risk from mixture can be based on this a.s. In addition, it should be noted that for ethofumesate the long-term risk is considered acceptable. No additional calculation are required to conclude acceptable long-term risk for mammals.

Secondary poisoning

The TER values for the active substance Ethofumesate for secondary poisoning of earthworm-eating mammals (dry soil and pore water approach) are above the trigger value of 5, indicating an acceptable risk for earthworm-eating mammals after application of HBZ10 in beet crops.

The TER values for the active substance Phenmedipham for secondary poisoning of earthworm-eating mammals (dry soil and pore water approach) are above below the trigger value of 5, indicating no a possible risk for earthworm-eating mammals after application of HBZ10 in beet crops.

The TER values for the active substances Ethofumesate and Phenmedipham for secondary poisoning of fish-eating mammals are above the trigger value of 5, indicating an acceptable risk for fish-eating mammals after application of HBZ10 in beet crops.

There is no risk expected for wild mammals exposed to the active substance through consumption of contaminated water from puddles on soil.

3.8.2 Effects on aquatic species

Based on the results of the risk assessment following national requirements, a low risk to aquatic organisms can be expected from the use of HBZ10 in beet crops. Based on the results of the risk assessment for the respective active substances and for the mixture itself (please refer to the core assessment, Part B, Section 9 for the Central zone), a low risk to aquatic organisms can be expected from the use of HBZ10 when applying the following risk mitigation measures:

- For all the intended uses in beet crops, to protect aquatic organisms, the implementation of a vegetated filter strip of 10m including a no-spray buffer zone of 10m is required.

3.8.3 Effects on bees

There is no acute oral and contact risk to adult honeybees and bumblebees following application of HBZ10 in beet crops. The chronic study for adult bees and larvae bees have been conducted according to the UE Regulation 284/2009 and they have considered valid.

3.8.4 Effects on other arthropod species other than bees

Effects of HBZ10 on non-target arthropods were not evaluated as part of the EU review of the active substances Ethofumesate and Phenmedipham. Two laboratory studies on glass plates were conducted with *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Additional extended laboratory tests with *A. rhopalosiphi*, *T. pyri* and *Chrysoperla carnea* were performed.

For the representative species *A. rhopalosiphi* and *T. pyri*, the HQ_{in-field} values at Tier 1 are above the trigger value of 2 indicating a possible risk after exposure to HBZ10 according to the proposed use pattern in beet crops.

For the representative species *A. rhopalosiphi* as well as for the additional species *C. carnea*, the in-field PER is below the Tier-2 endpoint indicating low in-field risk for all intended uses. For the representative species *T. pyri*, the in-field PER is above the Tier-2 endpoint indicating a possible in-field risk for all intended uses. The comparison of the course of the actual PER over time and acceptable predicted exposure rate indicate a potential for recovery of affected insect populations within 10 to 16 days for in-field exposure for all intended uses of HBZ10 in beet crops.

The off-field HQs are below the trigger value of 2, indicating no risk to non-target arthropods is expected in off-field areas following the application of the product HBZ10 according to the proposed use pattern in beet crops.

3.8.5 Effects on soil organisms

The evaluation of the risk for non-target soil meso- and macrofauna and soil microbial activity was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Effects of HBZ10 on non-target soil meso- and macrofauna and soil microbial activity were not evaluated as part of the EU review of the active substances Ethofumesate and Phenmedipham. Three laboratory studies assessing the effects of HBZ10 on *Eisenia fetida*, *Folsomia candida* and *Hypoaspis aculeifer* were conducted and are also considered in the risk assessment. A study on soil microbial activity has been carried out with the product HBZ10.

The TER values for the active substances Ethofumesate and Phenmedipham are above the trigger of 5, indicating a low long-term risk to soil meso- and macrofauna after application of HBZ10 for all intended uses in beet crops.

The TER values for the formulated product HBZ10 are above the trigger of 5, indicating a low long-term risk to soil meso- and macrofauna after application of HBZ10 for all intended uses in beet crops.

The risk to soil micro-organisms following the application of HBZ10 was evaluated by comparing the PEC value in soil after application to beet crops with the concentrations for the active substances Ethofumesate and Phenmedipham and their relevant metabolites, as well as for the formulated product HBZ10 at which the adverse effects on the soil microbial activity were below 25%. The results of the comparison expressed as Margin of Safety (MoS) for active substances Ethofumesate and Phenmedipham and their relevant metabolites, as well as for the formulated product HBZ10 indicate an acceptable risk following the application of HBZ10 in beet crops.

3.8.6 Effects on non-target terrestrial plants

The risk assessment is based on the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev.2 final, 2002).

After refinement of the risk assessment using a probabilistic approach, the TER value is above the trigger of 1 at the drift rate following the application HBZ10 according to the proposed use pattern. Thus, the risk to non-target plants after the application of HBZ10 is considered acceptable.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

The spectrum of the biological activity of HBZ10 is well represented by the results and the risk assessments in this section. Therefore, further data from biological primary screening or other preliminary tests are not considered relevant, as they would not change the ecotoxicological assessment.

3.9 Relevance of metabolites (Part B, Section 10)

According to the PEC_{gw} calculations performed to assess the intended uses of According to the model calculations, it can be concluded that the risk for the operator using Wizard / Beetup Pro / Betasana Max (HBZ10) on beet crops is acceptable, without the use of Personal Protective Equipment. (HBZ10), no metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L (see section 8 of the dRR, Chapter 8.8). No consideration of the relevance of metabolites in groundwater is therefore required and no further information is provided.

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

Wizard (HBZ10) contains Ethofumesate and Phenmedipham, which are not approved as candidates for substitution.

In this context, no national comparative assessment is considered as necessary and no further information is required.

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

- Analytical methods for the relevant impurities EMS and iBMS in the formulation should be provided, as this is required according to Reg. (EU) 284/2013.

- Ambient temperature study is currently ongoing, and should be provided upon completion.

None.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem.

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 letnie badania stabilności są w toku. Możliwe jest wydanie zgody warunkowo, na podstawie zaakceptowanych wyników 14-dniowego badania przyspieszonego starzenia w temperaturze 54°C środka przechowywanego w opakowaniach wykonanych z HDPE/PA, HDPE/EVOH i HDPE/F. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania.
4. Brak uwag do zapisu nazw grup chemicznych, do których przyporządkowano substancje czynne (zawartości substancji czynnych wyrażone w procentach obliczono w oparciu o gęstość środka ochrony roślin 0,978 g/ml zgodnie z danymi zawartymi w punkcie 1.2.1 dokumentu C).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Na podstawie danych przedłożonych przez wnioskodawcę możliwa jest rejestracja środka Wizard i środków tożsamyh (Beetup Pro oraz Betasana Max) do zwalczania chwastów jednorocznych dwuliściennych w buraku cukrowym w zakresie sekcji skuteczność.
2. Zgodnie z klasyfikacją HRAC, grupy MoA są obecnie określane w formie liczbowej, a nie literowej. Naniesiono stosowne poprawki.
3. W dRR B3 w tabeli 3.2-2 przedstawiono wnioskowane zakresy dawek dla środka HBZ10 (Wizard). W przypadku schematu 3 zabiegów jest to 1,8 i 2,4 l/ha, natomiast w przypadku 5 zabiegów to 0,9 i 1,2 l/ha. Tabela GAP uwzględnia tylko dawkę maksymalną środka, a w miejscu „uwag (remarks)” brak jest informacji dotyczących dopuszczanego zakresu dawek. Wnioski przedstawione przez wnioskodawcę w rozdziale 3.2.3 w dRR B3 także uwzględniają zakres dawek 0,9 i 1,2 l/ha w przypadku 5/6 zabiegów. Na podstawie przeprowadzonej oceny można zaakceptować ten zakres dla celów rejestracji środka w Polsce. HBZ10 w dawce 0,9 l/ha skutecznie zwalcza rdestówkę powojową, rdest psia oraz gwiazdnicę pospolitą.
4. Zgodnie z tabelą GAP środek można stosować w maksymalnie 3 lub 5 zabiegach w pełnych dawkach 1,8 i 2,4 l/ha lub 0,9-1,2 l/ha. Wniosek nie uwzględnia zastosowania w postaci dawek dzielonych (split application). W dRR B3 brak jest wniosków dotyczących takiego schematu. Z etykiety wykreślono tę informację.
5. Z zakresu zwalczanych chwastów wykreślono następujące gatunki:
 - chwasty wrażliwe w dawce 2,4 l/ha: maruna bezwonna, szarłat szorstki, łoboda rozłożysta, przetaczniki i rdest plamisty (przedłożono tylko 1 badanie skuteczności), pokrzywa żegawka wystąpiła tylko w badaniu w UK, dymnica pospolita i szczyr roczny wystąpiły tylko w badaniu we Francji, rzodkiew świrzepa nie wystąpiła w przedłożonych badaniach,
 - chwasty wrażliwe w dawce 1,8 l/ha: mak polny, mlecz kolczasty (przedłożono tylko 1 badanie), psianka czarna wystąpiła tylko w badaniach prowadzonych we Francji i Holandii,
 - chwasty wrażliwe w dawce 1,2 l/ha: szarłat szorstki, tasznik pospolity, bodziszek drobny, maruna bezwonna, mak polny, rdest plamisty, mlecz kolczasty, łoboda rozłożysta, przetaczniki (przedłożono tylko 1 badanie), psianka czarna wystąpiła tylko w badaniach prowadzonych we Francji i Holandii,
 - chwasty średnio wrażliwe w dawce 2,4 l/ha: bodziszek drobny i gorczyca polna (przedłożono tylko 1 badanie skuteczności),
 - chwasty średnio wrażliwe w dawce 1,2 l/ha: gorczyca polna (przedłożono tylko 1 badanie skuteczności).
6. Rumianek pospolity zakwalifikowano jako średnio wrażliwy, zarówno w dawce 2,4 l/ha jak i 1,2 l/ha. Średnia skuteczność osiągnięta w 2 badaniach prowadzonych w Niemczech wskazuje na to, że gatunek ten jest średnio odporny. Niemniej jednak, wzięto pod uwagę niekorzystne warunki panujące podczas jednego z badań, które wpłynęły na uzyskaną zaniżoną skuteczność, nie tylko środka wnioskowanego ale i referencyjnego.
7. Dodano zapis o możliwym wystąpieniu przemijających objawów fitotoksyczności na buraku cukrowym po zastosowaniu środka.

8. W części NASTĘPSTWO ROŚLIN wprowadzono zalecenia dotyczące zaakceptowanych gatunków w przypadku normalnego następstwa po uprawie buraków cukrowych. Zalecenia te wynikają z przeprowadzonej oceny w zakresie sekcji skuteczność. Ostateczny zapis w tej części uzależniony będzie jednak także od oceny w zakresie sekcji pozostałości.
9. Zmieniono zalecaną ilość wody z 80-400 l/ha na 200-400 l/ha, zgodnie z danymi przedstawionymi w badaniach. Dawka 80 l/ha nie wystąpiła w żadnym z nich.
10. Zalecenia dla dawek 1,8 l/ha i 2,4 l/ha zostały rozdzielone. Z uwagi na różnice w interwale między kolejnymi zabiegami, nie można ich rozważać jako zakresu dopuszczonych dawek w programie 3 aplikacji.
11. Biorąc pod uwagę wysoką wrażliwość chwastów w dawkach 0,9 l/ha dla 5 aplikacji i 1,8 l/ha dla 3 aplikacji, uwzględniono te same chwasty w zakresie stosowania dawek wyższych 1,2 l/ha (rdestówka powojowata, rdest ptasi, gwiazdnica pospolita) oraz 2,4 l/ha (gwiazdnica pospolita), odpowiednio do stosowanego programu zabiegowego. Wszystkie dawki testowane były w tych samych badaniach, zatem nie zachodzi ryzyko różnic w fazie wzrostu chwastów w momencie ich oceny.

Sekcja metody analityczne:

1. Należy przedstawić metodę analityczną oznaczania zanieczyszczeń o znaczeniu toksykologicznym, zidentyfikowanych w substancji czynnej etofumesat (zgodnie z zapisami Rozporządzenia Wykonawczego Komisji 540/2011: EMS; metanosulfonian etylu: maksymalnie 0,1 mg/ kg; iBMS; metanosulfonian izobutyli: maksymalnie 0,1 mg/kg) – wymaganie zgodnie z Rozporządzenie Komisji (UE) nr 284/2013.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń zaproponowano zmianę zwrotu wskazującego środki ostrożności Zapobieganie P280 zgodnie z wynikami szacowania zagrożeń (ATEmix) oraz zasadami CLP.
2. W części dotyczącej środków ostrożności dla osób stosujących środek ochrony roślin odpowiedni zapis dostosowano do wyników szacowania NDE oraz klasyfikacji zagrożeń zgodnie z wymaganiami harmonizacyjnymi (dokument Min. Rol. Toksykologia; data aktualizacji 26.10.2021).

Sekcja pozostałości

1. Na podstawie przewodnika SANTE/2019/12752 nie ma możliwości ekstrapolacji z liści buraka cukrowego na buraka ćwikłowego uprawianego na liście oraz na boćwinę. Zastosowania te zostały wykreślone z etykiety.

Sekcja los i zachowanie w środowisku:

1. Ze względu na ochronę wód podziemnych dodano zwrot wskazujący możliwość stosowania środka HBZ10 oraz innych środków zawierających etofumesat na tym samym polu jeden raz co dwa lata (zwrot SPe 1).
2. Skorygowano punkt 2 w akapicie dotyczącym środków ostrożności, okresów karencji i szczególnych warunków stosowania.

Sekcja ekotoksykologia:

1. Przekreślono klasyfikację środka: H411. Dodano klasyfikację środka: H410.
2. Wprowadzono 10 metrową strefę zadarnioną od zbiorników i cieków wodnych.

Załącznik do zezwolenia MRiRW nr R - xx/2022 z dnia xx.xx.2022 r.

Posiadacz zezwolenia:

UPL Holdings Coöperatief U.A., Claudius Prinsenlaan 144a, Block A, 4818CP Breda, Królestwo Niderlandów, tel.: +31 85 071 23 00, e-mail: uplholdingscoop@upl-ltd.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

(...)

WIZARD

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:


etofumesat (związek z grupy pochodnych benzofuranu) - 125 g/l (12,8%)

fenmedifam (związek z grupy pochodnych fenylokarbaminianów) - 125 g/l (12,8%)

Zawiera masę reakcyjną N,N-dimetylodekano-1-amidu (CAS: 1118-92-9) i N,N-dimetylooktanamid (CAS: 14433-76-2).

~~Środki ochrony roślin zawierające substancję czynną etofumesat, należy stosować na tej samej powierzchni uprawnej nie częściej niż co trzy lata, w dawkach nie przekraczających łącznie 1,0 kg substancji czynnej na 1 ha.~~

Zezwolenie MRiRW nr R - xx/2022 z dnia xx.xx.2022 r.

	
Niebezpieczeństwo	
H315	Działa drażniąco na skórę.
H318	Powoduje poważne uszkodzenie oczu.
H335	Może powodować podrażnienie dróg oddechowych.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
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.
P261	Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.
P280	Stosować rękawice ochronne/ odzież ochronną /ochronę oczu/ochronę twarzy.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P304+P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310	Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P391	Zebrać wyciek.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym w formie koncentratu do sporządzania emulsji wodnej (EC), przeznaczony do zwalczania rocznych chwastów dwuliściennych.

Zgodnie z klasyfikacją HRAC substancja czynna fenmedifam zaliczana jest do grupy **5** ~~CH~~, a substancja czynna etofumesat do grupy **15** ~~N~~.

DZIAŁANIE NA CHWASTY

Środek zawiera dwie substancje czynne o odmiennym mechanizmie działania. Fenmedifam zaliczany jest do grupy inhibitorów fotosyntezy na poziomie fotosystemu II. Pierwsze objawy jego działania to występujące po kilku dniach od zastosowania żółknięcie, widoczne w przestrzeniach międzynerwowych, a także na brzegach i wierzchołkach najstarszych liści. Następnie widoczne jest silne zahamowanie wzrostu i zasychanie rośliny. Etofumesat jest substancją blokującą 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. Środek pobierany jest poprzez liście i korzenie chwastów. Poprzez głębokie działanie etofumesatu środek ogranicza zachwaszczenie wtórne. Środek najskuteczniej działa na chwasty znajdujące się we wczesnych fazach rozwojowych. Niszczy też chwasty w późniejszych fazach rozwojowych.

Chwasty wrażliwe w dawce 2,4 l/ha. (w programie 3 zabiegów)	<i>Komosa biała, rdestówka powojowata, maruna bezwonna, szarłat szorstki, przytulia czepna, fiołek polny, łoboda rozłożysta, rdest ptasi, pokrzywa żegawka, przetaczniki, dymnica pospolita, szczyr roczny, rzodkiew świrzepa, rdest plmisty, gwiazdnica pospolita</i>
Chwasty wrażliwe w dawce 1,8 l/ha. (w programie 3 zabiegów)	<i>Mak polny, gwiazdnica pospolita, psianka czarna, mlecz kołczasty</i>
Chwasty wrażliwe w dawce 1,2 l/ha. (w programie 5 zabiegów)	<i>Komosa biała, przytulia czepna, rdestówka powojowata, gwiazdnica pospolita, szarłat szorstki, tasznik pospolity, dymnica pospolita, bodziszek drobny, maruna bezwonna, mak polny, rdest ptasi, rdest plamisty, rzodkiew świrzepa, psianka czarna, mlecz kołczasty, pokrzywa żegawka, fiołek polny, szczyr roczny, łoboda rozłożysta, przetaczniki</i>
Chwasty wrażliwe w dawce 0,9 l/ha (w programie 5 zabiegów)	<i>Rdestówka powojowata, rdest ptasi, gwiazdnica pospolita</i>
Chwasty średnio wrażliwe w dawce 2,4 l/ha. (w programie 3 zabiegów)	<i>Bodziszek drobny, rumianek pospolity, gorczyca polna</i>
Chwasty średnio wrażliwe w dawce 1,2 l/ha. (w programie 5 zabiegów)	<i>Rumianek pospolity, gorczyca polna</i>

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Burak cukrowy

Termin stosowania: środek stosować od fazy w pełni rozwiniętych liści roślina uprawnej do momentu całkowitego zakrycia międzyrzędzi (BBCH 10–39), gdy chwasty są w fazie liści. Kolejne zabiegi wykonywać na nowo wschodzące chwasty w fazie liści.

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 2,4 l/ha.

~~Zalecana dawka dla jednorazowego zastosowania: 1,8 – 2,4 l/ha~~

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3, **nie częściej niż co dwa lata.**

Odstęp między zabiegami: co najmniej 9 dni.

Zalecana ilość wody: ~~80~~ 200 - 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

lub

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,8 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.

Odstęp między zabiegami: co najmniej 6 dni.

lub

~~Środek można stosować również w dawkach dzielonych według jednego z poniższych zaleceń.~~

Maksymalna / ~~zalecana~~ dawka dla jednorazowego zastosowania: 1,2 l/ha.

~~Zalecana dawka dla jednorazowego zastosowania: 0,9 – 1,2 l/ha~~

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 5.

Odstęp między zabiegami: co najmniej 7 dni.

~~lub~~

~~Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,8 l/ha.~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.
Odstęp między zabiegami: co najmniej 6 dni.~~

Zalecana ilość wody: ~~80~~ 200 - 400 l/ha.
Zalecane opryskiwanie: średniokropliste.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.**

Burak ćwikłowy uprawiany na korzeń, ~~burak ćwikłowy uprawiany na liście, boćwina~~, burak pastewny

Termin stosowania: środek stosować od fazy w pełni rozwiniętych liści rośliny uprawnej do momentu całkowitego zakrycia międzyrzędzi (BBCH 10–39), gdy chwasty są w fazie liści. Kolejne zabiegi wykonywać na nowo wschodzące chwasty w fazie liści.

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 2,4 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3, **nie częściej niż co dwa lata.**

Odstęp między zabiegami: co najmniej 9 dni.

Zalecana ilość wody: 80 - 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

Środek można stosować również w dawkach dzielonych według jednego z poniższych zaleceń.

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,2 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 5.

Odstęp między zabiegami: co najmniej 7 dni.

lub

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,8 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.

Odstęp między zabiegami: co najmniej 6 dni.

Zalecana ilość wody: 80 - 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

1. W celu uzyskania najlepszych rezultatów środek stosować we wczesnych stadiach rozwoju chwastów.
2. Środek Wizard w dawkach 5x1,2 l/ha oraz 3x1,8 l/ha (co odpowiada łącznej dawce etofumesatu odpowiednio 750 i 675 g/ha/rok) może być stosowany co roku. Natomiast po zastosowaniu środka Wizard w dawce 3x2,4 l/ha (co odpowiada dawce etofumesatu 900 g/ha/rok), w celu ochrony wód podziemnych środki zawierające etofumesat można zastosować na tym samym polu najwcześniej za 2 lata, niezależnie od dawki, przestrzegając restrykcji wskazanych w etykietach tych środków.

~~W celu ochrony wód podziemnych nie stosować na tym samym polu tego ani żadnego innego produktu zawierającego etofumesat częściej niż co dwa lata w przypadku jednorazowego zastosowania: 2,4 l/ha, z maksymalną liczbą zabiegów w sezonie wegetacyjnym: 3, z odstępem między zabiegami: co najmniej 9 dni.~~

~~Środki ochrony roślin zawierające substancję czynną etofumesat, należy stosować na tej samej powierzchni uprawnej nie częściej niż co trzy lata, w dawkach nie przekraczających łącznie 1,0 kg~~

substancji czynnej na 1 ha.

3. Środek może powodować przemijające objawy fitotoksyczności (skarłowacenia, deformacje, chlorozy, przerzedzanie, martwica wierzchołków liścia lub przebarwienia) nie mające wpływu na plon.
4. 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 zalecany 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 mieszankę 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 zmianowania upraw itp.,
 - używać kwalifikowanego materiału siewnego,
 - czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
 - informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
5. Środka nie stosować:
 - na plantacjach roślin chorych lub osłabionych przez szkodniki,
 - na rośliny mokre,
 - w temperaturze powietrza (mierzonej przy gruncie) powyżej 25 °C , w okresie południowych upałów i silnego nasłonecznienia,
 - w okresie spodziewanych przymrozków,
 - po długotrwałej suszy.
6. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie nie stwarzając zagrożenia dla roślin uprawianych następczo.

W przypadku wcześniejszego zaorania plantacji buraków (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) na polu tym można uprawiać buraki.

~~Wszelkie inne rośliny można wysiewać po upływie 3 miesięcy od zastosowania środka, po uprzednim wykonaniu orki na głębokość minimum 15 cm.~~

W przypadku normalnego następstwa roślin, cebulę, rzodkiew, słonecznik, pomidory i soję można wysiewać bez konieczności wykonywania zabiegów uprawowych. Po upływie 3 miesięcy można wysiewać len. Po upływie 5 miesięcy można uprawiać owies, a po 11 miesiącach pszenicę. Powyższe gatunki (oprócz pszenicy) można wysiewać bez zachowania odstępu czasowego, jednak po uprzednim wykonaniu orki na głębokość minimum 15 cm. W przypadku pszenicy, pomimo wykonania zabiegów uprawowych, zaleca się zachować 3-miesięczny odstęp.

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 mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło 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 oraz przepłukać co najmniej trzykrotnie wodą.

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

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

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 uwalniania do środowiska.

W celu ochrony wód podziemnych nie stosować na tym samym polu tego ani żadnego innego produktu zawierającego etofumesat częściej niż **co dwa lata** w przypadku jednorazowego zastosowania: 2,4 l/ha., z maksymalną liczbą zabiegów w sezonie wegetacyjnym: 3, z odstępem między zabiegami: co najmniej 9 dni.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie **zadarnionej** 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, z dala od źródeł ciepła.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą: umyć dużą ilością wody.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.

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

Natychmiast skontaktować się z ośrodkiem zatruc/lekarzem.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

TASK FORCE ETHOFUMESATE

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To whom it may concern

16 January 2017

Dear Sir/Madam,

Re. Letter of Access - Regulation (EC) No. 1107/2009 - ACTIVE SUBSTANCE

The Task Force Ethofumesate comprising of the companies Bayer CropScience AG and ADAMA Deutschland GmbH is aware of the fact that UPL Europe Ltd. and its Affiliates (hereafter, 'the Data Access Purchaser') wishes to support, maintain, obtain, amend, or renew a new or existing authorization of certain plant protection product[s] or active substance, formulated with the active substance **ETHOFUMESATE**, CAS No. 26225-79-6, EC# 247 525-3, whether alone or in combination with other active substances, in the territory of the EU and the EAA (hereafter, 'the Product' or 'Products'):

This letter of access authorises the relevant competent national authority for granting PPP authorisations to refer to the studies listed below in table 1, which are the property of the Task Force Ethofumesate for the sole benefit of the Data Access Purchaser.

In particular, the studies may be referred to by relevant competent national authority for granting PPP authorisation for the sole and exclusive purpose of enabling the Data Access Purchaser to demonstrate to relevant competent national authority for granting PPP authorisation that it has access to a dossier for **ETHOFUMESATE** satisfying the requirements of Regulation (EC) No. 1107/2009 (the 'right of referral'). The Data Access Purchaser may further use its access rights to the studies in order to support, maintain, obtain, amend or renew

TASK FORCE ETHOFUMESATE

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existing or new plant protection product registrations and applications for registrations in the EU and EEA.

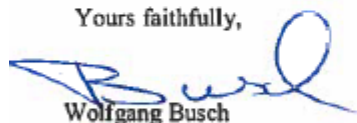
The Data Access Purchaser is not granted the right to inspect the studies or rely upon the studies for any purpose other than those described in this letter of access. The confidentiality of the studies included in this letter of access is not waived by the **Task Force Ethofumesate** and must be respected at all times. All property rights in the studies remain exclusively with the **Task Force Ethofumesate**.

For the avoidance of doubt, the studies are the Data Owner's confidential commercial or industrial information and intellectual property, the disclosure of which would adversely affect its legitimate economic interests. The Data Owner asserts that the studies do not relate to information on emissions into the environment (as defined under the Aarhus Convention and its implementing measures in EU and national law). It reserves its right to be consulted in the event that a request to receive copies of all or part of the studies or underlying material or supporting data is made by any third party including but not limited to the Data Access Purchaser.

Modification of this letter of access may only be affected in writing signed by the **Task Force Ethofumesate** (following agreement by the parties).

In the event of any questions regarding the scope and effect of this letter of access, the **Task Force Ethofumesate** will be available to provide a prompt clarificatory response, copying the Data Access Purchaser where matters of confidential commercial interest are not addressed.

Yours faithfully,



Wolfgang Busch
Secretary of the Task Force Ethofumesate

ADAMA Deutschland GmbH

TASK FORCE ETHOFUMESATE

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TABLE I	
ANNEX II DATA POINT	DATA FOR WHICH THIS LETTERS OF ACCESS APPLIES FOR THE BENEFIT OF THE DATA REFERRAL PURCHASER
4.1.2 Methods for risk assessment	Schulte, G. and P. Diehl (2014), Validation of the analytical method 01392 for the determination of the relevant ethofumesate metabolites in plant matrices by HPLC-MS/MS, Bayer CropScience AG, study report MR-13/101
4.1.2 Methods for risk assessment	Betson, S. (2014), Independent Laboratory Validation (ILV) of the analytical method 01392 for the determination of the relevant ethofumesate metabolites in plant matrices by HPLC-MS/MS, LGC Limited, study report RL/SN/2014-001
4.1.2 Methods for risk assessment	Spiegel, K. (2014), Ethofumesate - Discussion on the usability of plant enforcement method 01392 for metabolite AE C520645 in matrices with high oil content , Bayer CropScience AG, (M-497717-01)
5.4 Genotoxicity testing	Bomann, W. and Mallyon, B. (2013), Regulatory toxicology position paper, subject: Ethofumesate, waiver for conduct of a photomutagenicity study, Bayer CropScience AG, (M-463353)
7.1.1.3 Soil photolysis	Stupp, H.P. and M. Weuthen (2013), [Phenyl-UL-14C] Ethofumesate: Phototransformation on soil, Bayer CropScience AG, study report EnSa-12-0221, (M-455051-01-1)
7.1.2.1.2 Aerobic degradation of metabolite in soil	Traub, M (2012), Ethofumesate-carboxylic acid (as potassium salt: AE C639175): Aerobic degradation in four European soils, Eurofins-GAB GmbH, study report S11-03264, (M-432551-01-1)
7.1.3.1.2 Adsorption of metabolite	Moendel, M. and A. D'Ambrosio (2012), [phenyl-UL-14C] AE C639175: Adsorption/desorption in five different soils, RLP AgroScience GmbH, study report AS204, (M-446350-01-1).
8.2.2.2 Fish full life cycle	Teigeler, M. (2013), Zebra fish (Danio rerio), life cycle test, flow through conditions - Ethofumesate , Fraunhofer Institut, study report BAY-035/4-60/A
8.2.6.2 Effects on an additional algal species	Banman, C.S. Daly, R.A. and C.V. Lam (2009), Toxicity of ethofumesate technical to the blue green algae <i>Anabaena flos-aquae</i> , Bayer CropScience LP, study report EBADL008, (M-349150-01-1).

16 January 2017

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 protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 2.3.1 2.3.3 2.4.1 2.4.2 2.5.1 2.5.2 2.6.1 2.7.1 2.7.3 2.7.4 2.8.2 2.8.6.1 2.8.6.2 2.8.6.3 2.8.7.2	Norris, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Ethofumesate and Phenmedipham, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice Report No DNA6253 and its appendix David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 2.2.1 2.2.2	Buchholz, V.	2021	Physico-chemical tests on HBZ10 (Ethofumesate 125 + Phenmedipham 125 EC) Report No 21-921003-001 Defitraces GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.5	Norris, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Ethofumesate and Phenmedipham, stored at ambient temperature for 2 years, in Compliance with Good Laboratory Practice Report No DNA6254 (only study plan is available at submission time) David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 4.4/01	Anonymous	2017	Specification sheet for 1L Coex EVOH packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 4.4/02	Anonymous	2017	Specification sheet for 5L HDPE-F packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 4.4/03	Anonymous	2017	Specification sheet for 5L Coex PA packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 4.4/04	Anonymous	2017	Specification sheet for 10L Coex PA packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 4.4/05	Anonymous	2017	Specification sheet for 10L HDPE-F packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 4.4/06	Anonymous	2017	Specification sheet for 20L HDPE-F packaging UPL Not GLP Unpublished	N	N	Not relevant	UPL
KCP 5.1.1/01 KCP 5.1.1/02	Norris, D.	2021	Validation Of The Methods Of Determination Of Ethofumesate And Phenmedipham And Specified Impurities In An EC Formulation, In Compliance With Good Laboratory Practice DNA6255 and its appendices David Norris Analytical Laboratories Ltd, UK GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/03	Pomeroy, D.	2023	Certificate of analysis for method development for the analysis of EMS and iBMS in an EC formulation containing 125g/L Ethofumesate and Phenmedipham Report No. DNA7245 David Norris Analytical Laboratories Ltd, UK Non GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 5.1.2/01	Stouvenot, C.	2021	Validation of the Analytical Method for the Analysis of Phenmedipham (Free and Conjugated Forms), MHPC (Free and Conjugated Forms) and 3-Methylaniline in Sugar Beet (Leaves with Tops and Roots) Report No R C0327 and its deviation sheet ANADIAG S.A., Haguenau, France GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 6/01	Anonymous	2021	Detailed summary (Biological Assessment Dossier). Product Code HBZ10 UPL Not GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCA 6.3/01	Schneider, E.	2021	DETERMINATION OF ETHOFUMESATE AND PHENMEIDPHAM RESIDUES IN SUGAR BEETS FOLLOWING FOLIAR APPLICATION WITH HBZ10 (ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC) UNDER FIELD CONDITIONS IN NORTHERN EUROPE IN 2020 Report No. R C0252 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 7.3/01		2020	Ethofumesate 125 and Phenmedipham 125 EC (HBZ10): The In Vitro Percutaneous Absorption of Radiolabelled Phenmedipham in an Emulsion Concentrate (EC) Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 9.2.4/01	Lindim, C	2021a	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PECGW) FOR THE ACTIVE SUBSTANCES ETHOFUMESATE AND PHENMEDIPHAM AND THEIR MAJOR METABOLITES USING THE MODEL SOFTWARE FOCUS	N	Y N	New data for new formulation, not previously submitted nor	UPL

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
			PELMO 5.5.3, FOCUS PEARL 4.4.4 AND FOCUS MACRO 5.5.4 - PRODUCT: HBZ10 - Report No. 1182122-CP-090204-01-CEU GAB Consulting GmbH, Stade, Germany not GLP Unpublished			evaluated	
KCP 9.2.5/01	Lindim, C	2021b	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECSW) FOR THE ACTIVE SUBSTANCES ETHOFUMESATE AND PHENMEDIPHAM AND THEIR MAJOR METABOLITES USING FOCUS_SW MODELLING SOFTWARE AND SCENARIOS - PRODUCT: HBZ10 - Report No. 1182122-CP-090205-01-CEU GAB Consulting GmbH, Stade, Germany not GLP Unpublished	N	Y N	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.2.1/01	Scheerbaum, D.	2021a	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ACUTE IMMOBILIZATION TEST TO DAPHNIA MAGNA, SEMI-STATIC, 48 HOURS Report No. SO20127 / DAI18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.2.1/02	Scheerbaum, D.	2021b	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ALGA, GROWTH INHIBITION TEST WITH PSEUDOKIRCHNERIELLA SUBCAPITATA, 72 HOURS Report No. SO20126 / SPO18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.2.1/03	Scheerbaum, D.	2021c	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): AQUATIC PLANT TOXICITY TEST, LEMNA GIBBA, SEMI-STATIC, 7 DAYS Report No. SO20128 / SLG18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.2.1/04	Scheerbaum, D.	2021d	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): WATER- SEDIMENT MYRIOPHYLLUM SPICATUM TOXICITY TEST SEMI- STATIC, 14 D	N	Y	New data for new formulation, not previously	UPL

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
			Report No. SO20129 / SMS18743 Noack Laboratorien GmbH, Germany GLP Unpublished			submitted nor evaluated	
KCP 10.2.2/01	Scheerbaum, D.	2021e	MHPC: DAPHNIA MAGNA REPRODUCTION TEST, SEMI-STATIC, 21 DAYS Report No. SO20407 / DRE19098 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.1.1.1/01	Klix, V.	2021a	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ACUTE ORAL TOXICITY TO THE HONEYBEE APIS MELLIFERA (HYMENOPTERA, APIDAE) Report No. SO20043 / IBO18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.1.1.1/02	Klix, V.	2021b	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ACUTE ORAL TOXICITY TEST ON THE BUMBLEBEE BOMBUS TERRESTRIS Report No. SO20046 / IUO18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.1.1.2/01	Klix, V.	2021c	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ACUTE CONTACT TOXICITY TO THE HONEYBEE APIS MELLIFERA (HYMENOPTERA, APIDAE) Report No. SO20044 / IBT18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.1.1.2/02	Klix, V.	2021d	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): ACUTE CONTACT TOXICITY ON THE BUMBLEBEE BOMBUS TERRESTRIS Report No. SO20045 / IUT18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.1.2/01	Klix, V.	2021e	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): CHRONIC ORAL TOXICITY TEST ON THE HONEYBEE APIS MELLIFERA (HYMENOPTERA, APIDAE)	N	Y	New data for new formulation, not previously	UPL

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
			Report No. SO20047 / IBC18743 Noack Laboratorien GmbH, Germany GLP Unpublished			submitted nor evaluated	
KCP 10.3.1.3/01	Klix, V.	2021f	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): HONEYBEE (APIS MELLIFERA) LARVAL TOXICITY TEST, REPEATED EXPOSURE Report No. SO20048 / IBL18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.1/01	Klix, V.	2021g	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): EFFECTS ON THE PARASITIC WASP APHIDIUS RHOPALOSIPHI (HYMENOPTERA: BRACONIDAE) IN A GLASS PLATE LABORATORY TEST Report No. SO20131 / IWA18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.1/02	Klix, V.	2021h	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): A GLASS PLATE LABORATORY STUDY WITH THE PREDATORY MITE TYPHLODROMUS PYRI (ACARI: PHYTOSEIIDAE) Report No. SO20132 / IRL18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.2/01	Maspohl, A.-K.	2021a	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): EXTENDED LABORATORY TEST ON THE PARASITIC WASP APHIDIUS RHOPALOSIPHI, EXPOSED TO BARLEY PLANTS (HYMENOPTERA: BRACONIDAE) Report No. SO20512 / IWE18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.2/02	Maspohl, A.-K.	2021b	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): EXTENDED LABORATORY STUDY WITH THE PREDATORY MITE TYPHLODROMUS PYRI (ACARI: PHYTOSEIIDAE) Report No. SO20513 / IRE18743 Noack Laboratorien GmbH, Germany	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL

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
			GLP Unpublished				
KCP 10.3.2.2/03	Leopold, J.	2021	ETHOFUMESATE + PHENMEDIPHAM 125/125 G/L EC: EFFECTS ON THE LACEWING CHRYSOPERLA CARNEA (NEUROPTERA: CHRYSOPIDAE), EXTENDED LABORATORY STUDY - DOSE RESPONSE TEST - Report No. 159181047 IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.2/04	Knautz, T.	2021	HBZ10: EFFECTS ON THE REPRODUCTION OF ROVE BEETLES ALEOCHARA BILINEATA - EXTENDED LABORATORY STUDY - DOSE-RESPONSE TEST - Report No. 159181071 IBACON GmbH, Rossdorf, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.3.2.2/05	Wagenhoff, E.	2021	ETHOFUMESATE + PHENMEDIPHAM 125 + 125 G/L: TOXICITY TO THE PREDATORY MITE, TYPHLODROMUS PYRI SCHEUTEN (ACARI, PHYTOSEIIDAE) AFTER EXPOSURE TO FRESHLY APPLIED AND AGED SPRAY DEPOSITS ON APPLE LEAVES Report No. S21-05449 Eurofins Agrosience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.4.1/01	Winkelmann, G.	2021a	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): EARTHWORM (EISENIA FETIDA), EFFECTS ON REPRODUCTION Report No. SO20133 / RBN18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.4.2.1/01	Klix, V.	2021i	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): COLLEMBOLAN (FOLSOMIA CANDIDA) REPRODUCTION TEST IN SOIL Report No. SO20135 / ICR18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP	Klix, V.	2021j	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10):	N	Y	New data for new	UPL

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
10.4.2.1/02			PREDATORY MITE REPRODUCTION TEST IN SOIL (HYPOASPIIS ACULEIFER) Report No. SO20134 / IHL18743 Noack Laboratorien GmbH, Germany GLP Unpublished			formulation, not previously submitted nor evaluated	
KCP 10.5/01	Winkelmann, G.	2021b	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): SOIL MICRO-ORGANISMS: NITROGEN TRANSFORMATION TEST Report No. SO20136 / TBN18743 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.6.2/01	Winkelmann, G.	2021c	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): TERRESTRIAL PLANT TEST: SEEDLING EMERGENCE AND SEEDLING GROWTH TEST SO20031 / TNK18743 Report No. Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL
KCP 10.6.2/02	Winkelmann, G.	2021d	ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC (HBZ10): TERRESTRIAL PLANT TEST: VEGETATIVE VIGOUR TEST Report No. SO20032 / TNW18743 and its amendment Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	New data for new formulation, not previously submitted nor evaluated	UPL

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

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
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KCP 5.1	Wrede, A.	1999	DATA GENERATION METHOD WITH VALIDATION FOR SUGAR BEETS BY LC-MS/MS PHENMEDIPHAM (AE B038584), DESMEDIPHAM (AE B038107), AE B038210, AE F132319 Report No. C004350 not available GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Kossmann, K., Jenny, N.A.	1973	PHENMEDIPHAM Analytical methods for pesticides and plant growth regulators, 7, 1973, 611-623. Report No. A61343 not available Not GLP Unpublished	N	N	Not protected	AGE
KCP 5.1	Kossmann, K	1974	RESIDUE ANALYSIS OF PLANT PROTECTION PRODUCTS: PHENMEDIPHAM (RUECKSTANDSANALYTIK VON PFLANZENSCHUTZMETTELN: PHENMEDIPHAM). Report No. A61863 Rueckstandsanalytik von Pflanzenschutzmitteln. Verlag Chemie, Weinheim, deerfied beach (Florida, USA), Basel, 233-B-1 Not GLP Published	N	N	Not protected	-
KCP 5.1	Williamson, P.F.	1995	KEMIFAM: DETERMINATION OF PHENMEDIPHAM RESIDUES IN SUGAR BEET AT HARVEST AND TO PREPARE DECLINE CURVES Report No. A62782 not available Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Specht, W.	1988a	UEBERPRUEFUNG DER ANWENDBARKEIT DER DFGMULTIMETHODE S 19 ZUR QUANTITATIVEN BESTIIVEVIUNG VON RUECKSTAENDEN VON PHENMEDIPHAM IN BODEN, WASSER UND RUEBENKOERPERN Report No. A62003 Chemische Laboratorien GmbH Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Specht, W.	1988b	UEBERPRUEFUNG DER ANWENDBARKEIT EINER MODIFIZIERTEN DFG-MULTIMETHODE S 6-A ZUR QUANTITATIVEN BESTIMIVIUNG VON RUECKSTAENDEN VON PHENMEDIPHAM IN BODEN, SER UND RUEBENKOERPERN Report No. A62015 Chemische Laboratorien GmbH Not GLP Unpublished	N	N	Not protected	TFP

KCP 5.1	Wrede-Rucker, A.	1992	ANALYTICAL METHOD FOR. THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM IN TISSUE AND MILK BY GLC Report No. R166 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Wrede, A.	1998	ANALYTICAL METHOD AND VALIDATION FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM AND ITS METABOLITE MI-IPC IN TISSUE, MILK AND EGG BY HPLC CODE: AE B038584 Report No. A64037 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Moede, J.	1989	ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM AND A MAJOR METABOLITE IN SOIL BY HPLC Report No. A62523 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Offizorz, P.	1992a	METHOD VALIDATION: TOP PURE PHENMEDEPHAM AND METABOLITE METHYLHYDROXYPHENYLCARBAMATE (MHPC) IN/ON SOIL Report No. A62750, C547 Bayer Crop Science AG Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Scheuermann, H.J.	1986	ANALYTICAL METHOD FOR. THE DETERMINATION OF TOTAL RESIDUES OF PHENMEDIPHAM IN SOIL (38 584/8) Report No. A62471, W133 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Offizorz, P.	1992b	METHOD VALIDATION: TOP2 PURE PHENMEDIPHAM IN WATER Report No. A62751, C548 Bayer Crop Science AG Not GLP Unpublished	N	N	Not protected	TFP

KCP 5.1	Straszewski, A.	1990	ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM AND MAJOR METABOLITES IN WATER BY HPLC Report No. A62609, W210 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Moede, J.	1988	ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM IN WATER (38 584/3) Report No. A62486, W148 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Wrede-Rücker, A.	1993a	ANALYTICAL METHOD FOR THE DETERMINATION OF PHENMEDIPHAM IN AIR Report No. A62667, W265/2 SCC Scientific Consulting Company Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Chambers, J., Everitt, S.	1998	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF PHENMEDIPHAM IN AIR, 1998 PHENMEDIPHAM ACTIVE SUBSTANCE CODE: AE B038584 Report No. A64017 AgrEvo UK Ltd. Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	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 Report No. C004116 not available Not GLP Unpublished	N	N	Not protected	TFP
KCP 5.1	Tandy, R.	2012	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 Report No. S09-01656 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL

KCP 5.2	Straszewski, A., Wrede-Rücker, A.	1993	ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM AND A MAJOR METABOLITE IN SUGAR BEETS (LEAVES/ROOTS) BY HPLC Report No. A62037 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	not protected	TFP
KCP 5.2	Wrede-Rucker, A.	1992	ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM IN TISSUE AND MILK BY GLC Report No. R166 Schering AG, Berlin, Germany Not GLP Unpublished Submitted in: KCP 5.1/07	N	N	not protected	TFP
KCP 5.2	Chambers, J., Everitt, S.	1998	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF PHENMEDIPHAM IN AIR, 1998 PHENMEDIPHAM ACTIVE SUBSTANCE CODE: AE B038584 Report No. A64017 AgrEvo UK Ltd. Not GLP Unpublished Submitted in: KCP 5.1/16	N	N	not protected	TFP
KCP 5.2	Wrede, A.	2000	ENFORCEMENT METHOD AND VALIDATION OF SURFACE AND DRINKING WATER BY HPLC/UV PHENMEDIPHAM, AE B038210 CODE: AE B038584, AE B038210 Report No. C007532 Aventis Cropscience GmbH, Frankfurt am Main, Germany Not GLP Unpublished	N	N	not protected	TFP
KCP 5.2	Anspach, T.	2003	ENFORCEMENT METHOD (INCLUDING VALIDATION) FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM AND ITS METABOLITE MHPC IN DRINKING AND SURFACE WATER Report No. C029326 Chemische Laboratorien GmbH Not GLP Unpublished	N	N	not protected	TFP
KCP 5.2	Billian, P.	2003	SUPPLEMENT E001 OF THE ANALYTICAL METHOD 00802 FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM, DESMEDIPHAM AND THEIR METABOLITES MHPC AND EHPC IN/ON MILK, MEAT AND EGG BY HPLC-MS/MS Report No. C030876 not available Not GLP Unpublished	N	N	not protected	TFP

KCP 5.2	Brumhard, B.	2003a	INDEPENDENT LABORATORY VALIDATION OF ENFORCEMENT METHOD 00802/E001 FOR THE DETERMINATION OF RESIDUES OF PHENMEDIPHAM, DESMEDIPHAM AND THEIR METABOLITES MHPC AND EHPC IN/ON SAMPLE MATERIALS OF ANIMAL ORIGIN BY HPLC-MS/MS Report No. C031372 Bayer Crop Science AG Not GLP Unpublished	N	N	not protected	TFP
KCP 5.2	Stanislawski, 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 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFP
KCP 5.2	Brumhard, B.	2003b	METHOD 00806 FOR THE DETERMINATION OF RESIDUES OF ETHOFUMESATE IN SOIL BY HPLCMS/MS Report No. 00806 not available Not GLP Unpublished	N	N	Not protected	TFP
KCA 6.1	Scheuermann, H.-J.	1988	STABILITY OF TOTAL RESIDUES OF PHENMEDIPHAM IN BEET ROOTS AND LEAVES DURING DEEP FREEZE STORAGE Report No. R148, A.62014 Hoechst Schering AgrEvo GmbH, Berlin Not GLP Unpublished	N	N	not protected	TFP
KCA 6.2.1	Boerner, H.	1969	DECOMPOSITION AND TRANSLOCATION OF PHENMEDIPHAM IN BEETS Report No. M4 not available Not GLP Unpublished	N	N	not protected	TFP
KCA 6.2.1	Johnson, B.G.	1969	DISTRIBUTION OF PHENMEDIPHAM FOLLOWING FOLIAR APPLICATIONS TO SUGAR BEETS (BETA VULGARIS L.) ADDENDUM: METABOLISM OF PHENMEDIPHAM FOLLOWING FOLIAR APPLICATIONS TO SUGAR BEETS (BETA VULGARIS L.) Report No. M5, A61823 Industrial Bio-test Laboratories, Inc. Not GLP Unpublished	N	N	not protected	TFP

KCA 6.2.1	Bruehl, R., Celorio, J.	1981	ESTIMATION OF METHYL-N-(3-HYDROXYPHENYL) CARBAMATE RESIDUES IN SUGAR BEETS Report No. M15, A61835 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	not protected	TFP
KCA 6.2.1	Celorio, J.-I.	1983	METABOLISMUS VON PHENMEDIPHAM IN DER ZUCKERRÜBE (BETA VULGARIS L.) Report No. M16, A61836 Schering AG, Berlin, Germany Not GLP Unpublished	N	N	not protected	TFP
KCA 6.2.1	Celorio, J.I., Hoyer, G.A., Iwan, J., Baltes, W.	1984	METABOLISM OF PHENMEDIPHAM IN SUGAR BEET (BETA VULGARIS L.) Report No. M17 Lebensmittelchem. Gerichtl. Chem., 38, 73 Not GLP Published	N	N	not protected	-
KCA 6.2.1	Celorio, J.I., Hoyer, G.A., Iwan, J., Koelsch, L.	1987	METABOLISM OF PHENMEDIPHAM IN SUGAR BEET (BETA VULGARIS L.) Report No. M22 Pesticide Science and Biotechnology, 1987, 495-498 Not GLP Published	N	N	not protected	-
KCA 6.2.2	██████	1991	THE DISPOSITION OF [14C]-PHENMEDIPHAM FOLLOWING REPEATED ORAL ADMINISTRATION TO LAYING HENS ██████ GLP Unpublished	N Y	N	not protected	TFP
KCA 6.2.3	██████	1989	INDICATION OF THE METABOLITES OF PHENMEDIPHAM IN THE MILK AND MEAT OF A COW FOLLOWING ORAL DOSING FOR 3 DAYS ██████ GLP Unpublished	N Y	N	not protected	TFP
KCA 6.6.1	Downey, S.S.	1993	UPTAKE OF [14C]-PHENMEDIPHAM RESIDUES IN SOIL BY ROTATIONAL CROPS UNDER CONFINED CONDITIONS Report No. W267 NOR-AM Chemical Company, USA GLP Unpublished	N	N	not protected	TFP

KCP 10.1.2.2	Diesing, L.	2014	PHENMEDIPHAM. TOXICITY ENDPOINT FOR THE WILD MAMMAL LONG-TERM & REPRODUCTIVE RISK ASSESSMENT not stated Bayer CropScience AG, Monheim, Germany non GLP/GEP Unpublished	N	Y	Data for this new formulation already evaluated at EU level.	TFP
KCP 10.4.2.1/03	Frommholz, U.	2010	Phenmedipham A.S.: Influence On The Reproduction Of The Collembolan Species Folsomia candida Tested In Artificial Soil Report No. FRM-COLL-83/10 Bayer CropScience AG Development Environmental Safety, Ecotoxicology, Germany GLP Unpublished	N	-	Data for this new formulation evaluated at EU level in ongoing process of the renewal a.s.	TFP

TFP: Taskforce Phenmedipham; AGE: AgrEvo (now part of Bayer CropScience)

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review: 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1	Schulte, G.	2013a	ANALYTICAL METHOD 01343 FOR THE DETERMINATION OF RESIDUES OF OPEN-RING-2-KETO ETHOFUMESATE (AE C520645) IN/ON PLANT MATRICES BY HPLC-MS/MS - METHOD FOR STORAGE STABILITY Report No. MR-12/056 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	Schulte, G.	2013b	STORAGE STABILITY OF OPEN-RING-2-KETO ETHOFUMESATE (AE C520645) IN PLANT MATRICES FOR 24 MONTHS - PHASE REPORT AFTER 6 MONTHS Report No. M-459806-01 not available GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	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 AND TOPS FOLLOWING ONE PRE-EMERGENCE APPLICATION; ITALY, 1995 Report No. M-165366-02-1 not available GLP Unpublished	N	N	not protected	TFE
KCP 5.1	Godfrey, T.L.	1996	ETHOFUMESATE AND METABOLITE ANALYTICAL GRADES AE B049913 AND AE C509607 (NC 8438 AND NC 9607) ANALYTICAL METHOD FOR THE DETERMINATION OF ACTIVE SUBSTANCE AND MAJOR METABOLITE IN SUGAR BEET (ROOTS AND TOPS) BY GC/MSD Report No. A89687 not available GLP Unpublished	N	N	not protected	TFE

KCP 5.1	Schulte, G.	2013c	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 Report No. 10-2109 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	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) Report No. M-438402-01-1 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	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 not available not available GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCP 5.1	Schlewitz, P.	2014	FROZEN STORAGE STABILITY OF RESIDUES OF ETHOFUMESATE METABOLITE NC 20645 IN SUGAR BEET (ROOTS AND TOPS WITH LEAVES) Report No. B1312 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 5.1	Perny, A.	2002	VALIDATION OF THE METHOD OF ANALYSIS OF THE RESIDUES OD ETHOFUMESATE AND ITS METABOLITE 2-KETO ETHOFUMESATE (FREE AND CONJUGATED FORM) IN SUGAR BEETS Report No. A0019 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCP 5.1	Huauilmé, J.-M.	2013a	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) - 2012 Report No. BPL12/436/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCP 5.1	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 Report No. BPL11/380/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCP 5.1	Hamberger, R.	2012a	ANALYTICAL PHASE REPORT - 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 not stated not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	Huauilmé, 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 Report No. BPL12/435/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCP 5.1	Spence, Ch.	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) Report No. 34890 Charles River Laboratories, Edinburgh, UK GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCP 5.1	Hamberger, R.	2014	ANALYTICAL PHASE REPORT - 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). not stated not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	██████	1994	ETHOFUMESATE-DERIVED RESIDUES IN THE MEAT AND MILK OF DAIRY COWS; RESULTING FROM ORAL INGESTION OF ETHOFUMESATE ██████ Not GLP Unpublished	Y	N	not protected	BCS
KCP 5.1	██████	2013	FREEZER STORAGE STABILITY OF ETHOFUMESATE IN ANIMAL MATRIX SAMPLES - INTERIM REPORT ██████ GLP Unpublished	N Y	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	██████	2010	ETHOFUMESATE - MAGNITUDE OF THE RESIDUE IN DAIRY COW ██████ GLP Unpublished	Y	Y	Study may have already been submitted for national authorisation, but data protection may still be active	BCS

KCP 5.1	Traub, M.	2011	AE C508493 (ETHOFUMESATE-2-HYDROXY): AEROBIC DEGRADATION IN FOUR EUROPEAN SOILS Report No. S11-00957 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	Traub, M.	2012a	AE C509607: AEROBIC DEGRADATION IN FOUR EUROPEAN SOILS Report No. S11-00958 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	Traub, M.	2012b	ETHOFUMESATE-CARBOXYLIC ACID (AS POTASSIUM SALT: AE C639175): AEROBIC DEGRADATION IN FOUR EUROPEAN SOILS Report No. S11-03264 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.1	Whiteoak, R.J., Crofts, M., Harris, R.J.	1973	ANALYTICAL METHOD FOR RESIDUE IN SUGAR BEET TREATED WITH NORTON Report No. A83491/ M-155727-01 not available Not GLP Unpublished	N	N	not protected	TFE
KCP 5.1	Whiteoak, R.J., Crofts, M., Harris, R.J.	1976	ANALYTICAL METHOD FOR RESIDUES IN SUGARBEET TREATED WITH NORTON Report No. A83492/ M-155728-01 not available Not GLP Unpublished	N	N	not protected	TFE
KCP 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 Report No. M-479926-01 not available GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE




KCP 5.2	Betson, S.	2014	INDEPENDENT LABORATORY VALIDATION (ILV) OF THE ANALYTICAL METHOD 01392 FOR THE DETERMINATION OF THE RELEVANT ETHOFUMESATE METABOLITES IN PLANT MATRICES BY HPLC-MS/MS Report No. M-497682-01-1 not available GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.2	Schlewitz, P.	2013a	validation of the analytical method for the determination of Ethofumesate (free form) and NC 20645 (free and conjugated form) in high protein/starch content, high water content, high oil content, high acid content and difficult commodities Report No. R B3016 Anadiag S.A., Haguenau, France GLP Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 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 GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 5.2	Schlewitz, P.	2013	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	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 5.2	Schneider, E.	2000	CONFIRMATION METHOD FOR THE DETERMINATION OF RESIDUES OF ETHOFUMESATE IN SOIL Report No. PR00/003 UCL Umwelt Control Labor, Köln, Germany GLP Unpublished	N	N	Not protected	FCS
KCP 5.2	Hamberger, R.	2012b	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF ETHOFUMESATE AND ITS METABOLITES NC8493 IN SOIL Report No. 12A04042-01-VMS CIP Chemisches Institut Pforzheim GmbH, Germany GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCP 5.2	Jooß, S.	2011	ETHOFUMESATE - VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE IN WATER Report No. P 2368 G PTRL Europa, Ulm, Germany GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 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 not available Not GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	TFE
KCP 5.2	Hamberger, R.	2012c	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF ETHOFUMESATE AND ITS METABOLITES NC9607 AND NC20645 IN SURFACE WATER Report No. 12A04042-01-VMWA CIP Chemisches Institut Pforzheim GmbH, Germany GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCP 5.2	Brown, D.	2014	ETHOFUMESATE - INDEPENDENT LABORATORY VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE AND ITS METABOLITES NC 20645 AND NC 9607 IN SURFACE WATER Report No. S13-04250 Eurofins Agrosience Services GmbH GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCP 5.2	Wrede-Rücker, A.	1993b	ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE IN AIR Report No. W139 not stated Not GLP Unpublished	N	N	Not protected	AGE
KCP 5.2	Reichert, N.	1994	DEVELOPMENT OF A METHOD FOR THE DETERMINATION OF ETHOFUMESATE AND OXO-METABOLITE OF ETHOFUMESATE IN AIR Report No. C506 not available GLP Unpublished	N	N	Not protected	AGE

KCP 5.2	Schneider, E.	1994a	ETHOFUMESATE: VALIDATION OF AN ANALYTICAL METHOD FOR DETERMINATION IN AIR (INCLUSIVE ETHOFUMESATE-2-KETO) Report No. NC 8438 / W174 not available GLP Unpublished	N	N	Not protected	AGE
KCP 5.2	Schneider, E.	1994b	DETERMINATION OF ETHOFUMESATE IN AIR Report No. PR93/016, method DrK078 not available GLP Unpublished	N	N	Not protected	FCS
KCP 5.2	McKenzie, J.	1994	VALIDATION OF A PLASMA ASSAY, ETHOFUMESATE IN DOG PLASMA Report No. C507 not available GLP Unpublished	N	N	Not protected	AGE
KCA 4.2/26	Klimmek, S.; Gizler, A.	2014	Validation of DFG method S 19 (extended revision) for the determination of residues of desmedipham, phenmedipham and their metabolites EHPC and MHPC in/on plant material by means of liquid chromatography with Tandem mass spectrometric detection (LC-MS/MS) Eurofins Agrosience Services Chem, Hamburg, Germany Amendment No. 1 to Report No. AVE-0201V Edition Number: M-216103-02-1 Date: 2014-11-27 GLP/GEP: yes, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham
KCA 4.2/27	Anspach, T.	2002	Validation of DFG method S 19 (extended revision) for the determination of residues of desmedipham, phenmedipham and their metabolites EHPC and MHPC in/on plant material by means of liquid chromatography with Tandem mass spectrometric detection (LC-MS/MS) Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Report No.: C028890 Date: 2002-12-13 GLP/GEP: no, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham
KCA 4.2/28	Freitag, Th.	2014	Independent laboratory validation of the DFG Method S19 (extended revision) for the determination of residues of medipham, Phenmedipham, and their Metabolites EHPC and MHPC in/on plant material Bayer CropScience, Monheim , Germany Report No.: P612051807 (amendment to Report No. MR-146/05) Edition Number: M-261837-02-1 Date: 2014-08-14; amended 12.5.2016 GLP/GEP: yes, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham

KCA 4.2 /32	Krebber, R.; Braune, M.	2013	Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Bayer CropScience AG, Monheim, Germany Report No.: MR-13/085, Edition Number: M-466732-01-1 Report No.: MR-13/085 Date: 2013-10-09 GLP/GEP: yes, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham
KCA 4.2 /33	Stanislawski, T.	2013	Independent laboratory validation of BCS methods 01333 and 01387 for the determination of various pesticides in surface water by DI-HPLC-MS/MS PTRL Europe, Ulm, Germany Report No.: P3117 G, Edition Number: M-470714-02-1 Date: 2013-12-13 GLP/GEP: yes, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham
KCA 4.2 /34	Kaussmann, M.	2016	Analytical Method 01486 for the determination of various pesticides and selected pesticide metabolites in plasma by HPLC-MS/MS Bayer Report No.: 01486 Edition Number: M-556577-01-1 Method Report No.: P683166504 Date: 2016-06-06 GLP/GEP: Yes, unpublished	N	Y	Study submitted under renewal process of Phenmedipham (RAR, 05.2022)	Task Force on Phenmedipham
KCA 6.1	Whiteoak, R.J.	1975	STABILITY OF RESIDUES DURING STORAGE OF CROP AND SOIL SAMPLES FROM TRIALS WITH NORTON Report No. NC 8438/ R52=W40 not stated Not GLP Unpublished	N	N	Not protected	BCS
KCA 6.1	Cole, M.G.	1995	ETHOFUMESATE: STABILITY OF ETHOFUMESATE, NC 9607 AND NC 8493 IN GRASS DURING FROZEN STORAGE, USA, 1993 Report No. A54281 not available GLP Unpublished	N	N	Not protected	BCS
KCA 6.1	Bright, J.H.M.	1991	STABILITY OF ETHOFUMESATE AND NC 9607 RESIDUES IN SUGAR BEET ROOTS AND TOPS DURING DEEP FREEZE STORAGE Report No. NC 8438 / R171 not stated GLP Unpublished	N	N	Not protected	BCS

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 Report No. 12A04042-01-SSSB CIP Chemisches Institut Pforzheim GmbH GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	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) Report No. B1312 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCA 6.2	Miller, C.A.	1999	SUMMARY OF THE METABOLISM OF ETHOFUMESATE IN PLANTS Report No. C003349 AgrEvo UK Ltd. Not GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Adcock, J.W., Warner, P.A., Challis, I.R.	1976	THE METABOLISM OF 14C-ETHOFUMESATE IN THE ONION Report No. META/76/22 AgrEvo Not GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Adcock, J.W., Lines, D.	1978	THE METABOLISM OF ETHOFUMESATE BY SUGAR BEET UNDER GLASSHOUSE CONDITIONS Report No. META/78/57 AgrEvo Not GLP Unpublished	N	N	not protected	AGE
KCA 6.2.1	Warner, P.A., Adcock, J.W.	1977	THE METABOLISM OF 14C-ETHOFUMESATE IN TOBACCO Report No. META/77/38 AgrEvo UK Ltd. Not GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Lines, D., Adcock, J.W.	1979	THE METABOLISM OF ETHOFUMESATE BY SUGAR BEET UNDER FIELD CONDITIONS Report No. NC 8438/M43 AgrEvo Not GLP Unpublished	N	N	not protected	BCS

KCA 6.2.1	Chapleo, S.	1992a	THE METABOLISM OF 14C-ETHOFUMESATE IN SUGAR BEET - A GLASSHOUSE STUDY Report No. IRI 381174 AgrEvo GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Caley, C.Y., Chapleo, S., Haswell, A.	1994	THE METABOLISM OF 14C-ETHOFUMESATE IN SUGAR BEET Report No. 10056 AgrEvo GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Chapleo, S.	1992b	THE METABOLISM OF 14C-ETHOFUMESATE IN ANNUAL RYEGRASS - A GLASSHOUSE STUDY Report No. IRI 381169 AgrEvo GLP Unpublished	N	N	not protected	BCS
KCA 6.2.1	Mellet, M.	1993	DETERMINATION OF THE RESIDUE OF ETHOFUMESATE, ETHOFUMESATE-2-KETO AND THE CONJUGATIONS IN SUGAR BEETS AFTER APPLICATION OF ETHOSAT 500 SC IN FRANCE, 1992 Report No. RF 2102-1 not stated GLP Unpublished	N	N	not protected	FCS
KCA 6.2.1	Hennecke, D.	2003	METABOLISM OF ETHOFUMESATE IN SUGAR BEETS Report No. GAB-002/7-08 Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCA 6.2.2		1992	THE METABOLISM OF 14C-ETHOFUMESATE IN LAYING HENS  GLP Unpublished	N Y	N	not protected	BCS
KCA 6.2.2		1999	POULTRY METABOLISM, DISTRIBUTION AND NATURE OF THE RESIDUES IN EGGS AND EDIBLE TISSUES. CODE AE B 049913 Report No. C002998 AgrEvo UK Ltd. GLP Unpublished	N Y	N	not protected	BCS

KCA 6.2.3		1976	THE METABOLISM OF 14C-ETHOFUMESATE IN THE SHEEP Not GLP Unpublished	Y	N	not protected	BCS
KCA 6.2.3		1992	THE METABOLISM OF 14C-ETHOFUMESATE IN THE COW GLP Unpublished	Y	N	not protected	BCS
KCA 6.2.3		1999	ETHOFUMESATE RUMIANT: METABOLISM, DISTRIBUTION AND NATURE OF THE RESIDUES IN MILK AND EDIBLE TISSUES. CODE AE B 049913 GLP Unpublished	Y	N	not protected	BCS
KCA 6.3	Tandy, R.	2012	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 Report No. S11-03715 Eurofins Agrosience Services GmbH GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCA 6.3	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 Report No. R A0015 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. R A1114 Anadiag S.A., Haguenau, France GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCA 6.3	Huauilmé, J.-M.	2013a	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) - 2012 Report No. BPL12/436/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. BPL11/380/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. R03-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. R03-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCA 6.3	Waalkens, W.M., Hamberger, R.	2005c	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 SE AND ETHOFUMESATE / PHENMEDIPHAM / DESMEDIPHAM 128/62/21 G/L EC TO SUGAR BEETS IN THE NETHERLANDS AND NORTHERN FRANCE, 2004 Report No. R04-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 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 Report No. R04-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	Anspach T.	2001	MAGNITUDE OF THE RESIDUES OF PHENMEDIPHAM, DESMEDIPHAM, ETHOFUMESATE AND ITS METABOLITE 2-OXO-ETHOFUMESATE IN SUGAR BEETS (ROOTS AND LEAVES/TOPS) AFTER THE APPLICATION OF BETASANA TRIO UNDER FIELD CONDITIONS IN GERMANY, 2000 Report No. AND-0004 Dr. Specht Partner, Chemische Laboratorien GmbH, Germany GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL
KCA 6.3	Tandy, R.	2013	DETERMINATION OF RESIDUES OF ETHOFUMESATE AND ETHOFUMESATE-2-KETO, AFTER ONE OR THREE APPLICATIONS OF ETHOFOL 500SC, OR THREE APPLICATIONS OF BETASANA TRIO SC IN SUGAR BEET (OUTDOOR) AT 5 SITES IN NORTHERN EUROPE AND 5 SITES IN SOUTHERN EUROPE 2010 Report No. S10-00258 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL

KCA 6.3	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 Report No. R03-16-SP-06 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. R03-16-FR-07 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. BPL12/435/GC BIOTEK Agriculture GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.3	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 Report No. S13-03837 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL

KCA 6.4.1	Harris, R.J.	1975	INVESTIGATION OF TISSUE AND EGG RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS Report No. NC 8438/ R57 Fisons Ltd., UK Not GLP Unpublished	N	N	not protected	BCS
KCA 6.4.2	Roberts, N.L., Ross, D.B.	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28 DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS. PART I; FEEDING STUDY AND PREPARATION OF SAMPLES Report No. RESID/77/R28 NC 8438/R29 Huntingdon Research Centre Ltd., Huntingdon, UK Not GLP Unpublished	N	N	not protected	BCS
KCA 6.4.2	Harris, R.J., Whiteoak, R.J.	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28 DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS. PART II ANALYSIS FOR ETHOFUMESATE AND ITS METABOLITES Report No. RESID/77/28 NC 8438/R 78 Fisons Ltd., UK Not GLP Unpublished	N	N	not protected	BCS
KCA 6.4.2	Castro, L.E.	1994a	ETHOFUMESATE-DERIVED RESIDUES IN THE MEAT AND MILK OF DAIRY COWS; RESULTING FROM ORAL INGESTION OF ETHOFUMESATE Report No. B002201 AgrEvo Not GLP Unpublished	N	N	not protected	BCS
KCA 6.5.3	Crofts, M., Whiteoak, R.J.	1973a	CONJUGATED RESIDUES IN FRACTIONS PROCESSED FROM SUGAR BEET TREATED WITH NORTRON Report No. NC 8438/R 5 not stated Not GLP Unpublished	N	N	not protected	BCS
KCA 6.5.3	Crofts, M., Whiteoak, R.J.	1974a	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON-TREATED SUGARBEET Report No. NC 8438/R 19 not available Not GLP Unpublished	N	N	not protected	BCS

KCA 6.5.3	Crofts M., Whiteoak R.J.	1975a	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTON- TREATED SUGARBEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN THE UNITED KINGDOM Report No. NC 8438 / R40 not available Not GLP Unpublished	N	N	not protected	BCS
KCA 6.5.3	Crofts M., Whiteoak R.J.	1975b	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTON- TREATED SUGARBEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN WEST GERMANY Report No. NC 8438 / R41 not available Not GLP Unpublished	N	N	not protected	BCS
KCA 6.6.1	Chapleo, S.	2003	THE UPTAKE OF [14C]-ETHOFUMESATE RESIDUES IN SOIL BY ROTATIONAL CROPS UNDER CONFINED CONDITIONS Report No. 22558 Inveresk Research International, Tranent, Scotland GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM
KCA 6.6.1	Carlton, R., Cordell, P.	1993	THE UPTAKE AND METABOLISM OF ETHOFUMESATE AND ITS SOIL METABOLITES IN A CONFINED ROTATIONAL CROP STUDY Report No. A83396/W153-1 AgrEvo UK Ltd. GLP Unpublished	N	N	not protected	BCS
KCA 6.6.2	Spence, Ch.	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) Report No. 34890 Charles River Laboratories, Edinburgh, UK GLP Unpublished	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ACM

KCA 6.6.2	Castro, L.E.	1994b	ETHOFUMESATE EMULSIFIABLE CONCENTRATE 200G/L CR13678: AT HARVEST RESIDUES OF ETHOFUMESATE AND METABOLITES IN ROTATIONAL CROPS AND SOIL FOLLOWING APPLICATIONS OF NORTON EC TO SUGAR BEETS, USA,1990 Report No. A83117/R178-1 NOR-AM Chemical Company, USA GLP Unpublished	N	N	not protected	BCS
KCA 6.6.2	Crofts, M., Whiteoak, R.J.	1974b	RESIDUE ANALYSIS OF WHEAT GROWN IN THE UK AS A FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTON Report No. NC 8438/R30 AgrEvo Not GLP Unpublished	N	N	not protected	BCS
KCA 6.6.2	Crofts, M., Whiteoak, R.J.	1973b	RESIDUE ANALYSIS OF WHEAT AND CORN (MAIZE) GROWN AS FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTON Report No. NC 8438/R29 AgrEvo Not GLP Unpublished	N	N	not protected	BCS
KCA 6.6.2	Peatman, M.H., Snowdon, P.J.	1991	RESIDUES OF SOIL AND EMERGENCY CROPS FOLLOWING APPLICATIONS OF ETHOFUMESATE AS A 50 SC FORMULATION IN THE UK 1990/91 Report No. NC 8438/W119 = R174 AgrEvo GLP Unpublished	N	N	not protected	BCS
KCA 6.10.1	Lückmann, J.	2013	ETHOFUMESATE - EXPOSURE OF HONEYBEES TO RESIDUES IN NECTAR, POLLEN AND GUTTATION FLUID IN SUGAR AND FODDER BEETS Report No. P13096 RIFCon GmbH, Hirschberg, Germany Not GLP Unpublished	N	N	not protected	UPL

BCS: Bayer CropScience, FCS: Feinchemie Schwebda, UPL: UPL Europe Ltd., TFE : Task Force Ethofumesate, ACM: AgriChem, AGE: AgrEvo (now part of Bayer CropScience)

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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List of data relied on and not submitted by the applicant but necessary for evaluation

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