

REGISTRATION REPORT

Part A

Risk Management

Product code: GF-3969

Chemical active substances:

Rimsulfuron, 148.15 g/kg
Thifensulfuron methyl, 92.6 g/kg
Isoxadifen-ethyl, 111.1 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Corteva/DuPont/DowAgroScience/Pioneer*

Submission date: January 2021

MS Finalisation date: December 2021 (initial National Assessment)

August 2022, updated October 2022 (final National Assessment)

*Corteva Agriscience is new Legal Entity in most of EU countries and should be treated as an Applicant for GF-3969 registration. Information about Applicant for each country is provided in dRR Part A.

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Version history

When	What
January 2021	Initial dRR – Corteva Agriscience
December 2021	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 .
August 2022	Final report (National Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .
October 2022	Correction by zRMS: Eye irritation information revised to be consistent with part B6 (pages 8 and 9). Information no longer relevant is struck through and shaded .

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Unless otherwise specified, endpoints used in this section for thifensulfuron methyl originate from FMC and DuPont has a letter of access. Unless otherwise specified, endpoints used in this section for isoxadifen-ethyl originate from Bayer CropScience and DuPont has a letter of access.

For rimsulfuron: EFSA Scientific Report (2005) 45, 1-61. Conclusion regarding the peer review of the pesticide risk assessment of the active substance rimsulfuron.

For thifensulfuron methyl: EFSA Journal 2015;13(7):4201. Conclusion on the peer review of the pesticide risk assessment of the active substance thifensulfuron-methyl.

The evaluation of the safener isoxadifen-ethyl (IDF) was performed by RMS Germany and resulted in an evaluation report. Unless specified otherwise, endpoints were taken by the RMS Germany document (Summary of the German national evaluation of the safener isoxadifen-ethyl, 14th of August 2002, RMS: Germany - M-263999-01-1).

PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions and the specific conditions of use and labelling required for the registration of the plant protection product GF-3969 in Poland. GF-3969 is a water dispersible granules (WG) containing the existing EU active substances rimsulfuron at 148.15 g/kg, thifensulfuron methyl at 92.6 g/kg and isoxadifen-ethyl at 111.1 g/kg for use as herbicide in maize.

GF-3969 was not a representative formulation reviewed during the Annex I inclusion/Active substance renewal/country-level review of either rimsulfuron, thifensulfuron methyl or isoxadifen-ethyl. The formulated product has not previously been evaluated in any EU countries according to the Uniform Principles.

The risk assessment conclusions on GF-3969 are based on the information, data, and assessments provided in GF-3969 Registration Report, Part B, Sections 1-10 and Part C, and national addenda when appropriate.

1.1 Application background

The application is prepared for the registration of GF-3969 water dispersible granules (WG) in Poland, a new formulation which has been developed to protect maize from grass and broad-leaved weeds (BLW). Poland is also the zRMS for GF-3969.

GF-3969 water dispersible granules (WG), is a homogenous blend of water dispersible granules (WG) and water-soluble granular (SG) formulations: Rimsulfuron 25SG, Thifensulfuron methyl 50SG and Isoxadifen ethyl 50WG (safener). The final blended product contains 148.15 g/kg rimsulfuron, 92.6 g/kg thifensulfuron methyl and 111.1 g/kg isoxadifen-ethyl.

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The intended uses in Poland are summarised in section 2.6.

1.2 Letters of Access

The DuPont data on rimsulfuron and GF-3969 owned by DuPont International Operations Sàrl 2, Chemin du Pavillon, P.O. Box 50, CH-1218 Le Grand-Saconnex, Geneva, Switzerland are listed in the master reference list. A letter of access to this data is provided as appropriate.

DuPont has been granted the right to cite and rely upon thifensulfuron methyl data included in this Registration Report, per Letter of Access by FMC. A copy of the letter of access is included in the Appendix or attached to the cover letter in accordance with Article 34 of Regulation (EC) No. 1107/2009 as appropriate.

DuPont has been granted the right to cite and rely upon isoxadifen-ethyl data included in this Registration Report, per Letter of Access by Bayer. A copy of the letter of access is included in the Appendix or attached to the cover letter in accordance with Article 34 of Regulation (EC) No. 1107/2009 as appropriate.

1.3 Justification for submission of tests and studies

Unless specifically indicated, all tests and studies have been submitted to address mandatory data requirements for the authorisation of the plant protection product.

Unless specifically indicated, all submitted tests and studies, which involve vertebrate animals, address mandatory data requirements which could not be met with alternative methods. Studies were conducted according to prescribed guidelines. Unless specifically justified, this dossier does not contain reports of studies duplicating previous tests on vertebrate animals.

1.4 Data protection claims

Claims for the protection of active substance and plant protection product data supporting the application for authorisation of GF-3969 will be claimed according to Articles 33.4, 59, and, where applicable, 80.2 of Regulation EC No. 1107/2009.

Specific country claims will be provided with each submission.

Appendix 3 of this document contains data protection claims for Poland.

2 Details of the authorization decision

2.1 Product identity

Product code	GF-3969 (DPX-V4B07)
Product name in MS	Dragster®
Authorization number	Not applicable
Function	herbicide
Applicant	Corteva
Active substance(s) (incl. content)	Rimsulfuron; 148.15 g/kg Thifensulfuron methyl; 92.6 g/kg Isoxadifen-ethyl; 111.1 g/kg
Formulation type	Water dispersible granules [WG]
Packaging	Professional user

	200 mL jar, 30-120 g pack, HDPE, 39 mm opening 500 mL jar, 125-250 g pack, HDPE, 39 mm opening 1 L jar, 280-600 g pack, HDPE, 39 mm opening 2 L jar, 625 g to 1 kg pack, HDPE, 39 mm opening 3 L jar, 1.1-1.6 kg pack, HDPE, 52 mm opening 4200 mL jar, 1.7-2 kg pack, HDPE, 52 mm opening 5 L jar, 2-3 kg pack, HDPE, 52 mm opening 8200 mL jar, 3.1-4.5 kg pack, HDPE, 52 mm opening
Coformulants of concern for national authorizations	-
Restrictions related to identity	Not applicable
Mandatory tank mixtures	GF-3969 requires adjuvant
Recommended tank mixtures	The product can be mixed in the tank together with 21 different tank mix partners in two, three, and four-way mixture combinations. For further detail on acceptable tank mix partners, please refer to the product label.

2.2 Conclusion

Based on the performed **updated** evaluation **authorisation of GF-3969 in Poland may be ~~cannot be granted~~** **for the intended uses listed in the GAP table presented in point 2.6 below.** ~~due to not finalised risk assessment for non-target terrestrial plants. Further data must be submitted in order to address the risk.~~

2.3 Substances of concern for national monitoring

Results from available risk assessments indicate that there are no substances of concern for national monitoring.

2.4 Classification and labelling

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

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

Hazard class(es), categories	
Eye Irrit. 2	Eye Irritation Category 2 is applicable in accordance to Annex I – part 3 – points 3.3.3 to 3.3.3.3.6. of Regulation (EC) No. 1272/2008 and its corresponding ATPs.
Acute Aquatic Cat. 1	Aquatic Acute toxicity Category 1 is applicable in accordance to Annex I - part 4 - points 4.1.3 to 4.1.3.6.1., table 4.1.0. (b)(ii) of Regulation (EC) No. 1272/2008 and its corresponding ATPs.
Chronic Aquatic Cat. 1	Aquatic Chronic toxicity Category 1 is applicable in accordance to Annex I - part 4 - points 4.1.3 to 4.1.3.6.1., table 4.1.0. (b)(ii) of Regulation (EC) No. 1272/2008 and its corresponding ATPs.

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:	
GHS07	The pictogram GHS07 is applicable to mixtures classified Eye Irritation Category 2 in accordance to articles 19 and 26, Annex I - Part 3 - point 3.3.4.1 table 3.3.5 of Regulation (EC) No. 1272/2008 and its corresponding ATP's, and ECHA Guidance on labelling and packaging chapter 4, point 4.3

GHS09	The pictogram GHS09 is applicable to mixtures classified Aquatic Acute toxicity Category 1 and Aquatic Chronic toxicity Category 1 in accordance to Articles 19 and 26, Annex I - part 4 - point 4.1.4.1 and table 4.1.4 of Regulation (EC) No. 1272/2008 and corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.3.
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Signal word:	
Warning	The signal word Warning is applicable to mixtures classified eye irritation Category 2, Aquatic Acute toxicity Category 1, Aquatic Chronic toxicity Category 1 in accordance to Article 20, Annex I - Part 3 - point 3.3.4.1. table 3.3.5, point 3.4.4.1, table 3.4.4 and Part 4 - point 4.1.4.1 table 4.1.4, of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, points 4.3 and 4.4.

Hazard statement(s):	
H319	Hazard Statement H319 is assigned to mixtures classified Eye Irritation Category 2 in accordance to Article 3 and Article 21, Annex I - part 3 - point 3.3.4.1. table 3.3.5 of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.5.
H400	Hazard Statement H400 is assigned to mixtures classified Aquatic Acute toxicity Category 1 in accordance to Annex I - part 4 - point 4.1.4.1., table 4.1.4. of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.5.
H410	Hazard Statement H410 is assigned to mixtures classified Aquatic Chronic toxicity Category 1 in accordance to Article 21, Annex I - Part 4 - point 4.1.4.1., table 4.1.0. (a)(ii) of Regulation (EC) No. 1272/2008 and its corresponding ATPs.

Precautionary statement(s):	
P280	Precautionary statement P280 is applicable to mixtures assigned H319 and H317 in accordance to Article 22, Annex I - part 3 - point 3.4.4.1. and table 3.4.7; point 3.3.4.1. and table 3.3.5 of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.6. and chapter 7 point 7.3.3.3. and 7.3.3.4.
P305 + P351 + P338	Precautionary statement P305 + P351 + P338 is applicable to mixtures assigned H319 in accordance to Article 22, Annex I - Part 3 - point 3.3.4.1. table 3.3.5. of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.6. and chapter 7 point 7.3.3.3
P337 + P313	Precautionary statement P337 + P313 is applicable to mixtures assigned H319 in accordance with Article 22, Annex I - Part 3- Point 3.3.4.1. Table 3.3.5. of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.6. and chapter 7 point 7.3.3.3.
P391	Applicable when mixture is classified as H410
P501	Precautionary statement P501 is applicable to mixtures assigned H317 and H373 in accordance to Article 22, Annex I - part 3 - point 3.4.4.1 table 3.4.7, point 3.9.4.1. table 3.9.5.; of Regulation (EC) No. 1272/2008 and its corresponding ATPs, and ECHA Guidance on labelling and packaging chapter 4, point 4.6. and chapter 7 point 7.3.3.4., 7.3.3.9.

Additional labelling phrases:	
EUH 208: Contains Isoxadifen-ethyl. May produce an allergic reaction.	The label on the packaging of mixtures not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in table 3.4.6. of Annex I shall bear EUH208 statement.
To avoid risks to man and the environment, comply with the instructions for use. [EUH401]	Supplemental hazard information assigned to plant protection products subject to 1107/2009/EC.

Special rule for labelling of plant protection product (PPP):	
EUH 208: Contains Isoxadifen-ethyl. May produce an allergic reaction.	The label on the packaging of mixtures not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in table 3.4.6. of Annex I shall bear EUH208 statement.
To avoid risks to man and the environment, comply with the instructions for use. [EUH401]	Supplemental hazard information assigned to plant protection products subject to 1107/2009/EC.

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).	The supplementary advice SP1 is assigned according to Annex III (1) of Regulation (EU) No.547/2011 (amending Regulation (EC) No. 1107/2009) and recommendations stated in ECHA Guidance on labelling and packaging, chapter 3, points 3.2, 3.3 and chapter 4 point 4.8.
SPe3	To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.	Triggered by the risk assessment for aquatic species and non-target terrestrial plants . <i>Most likely mitigation measures will be also required for non-target terrestrial plants, but the risk assessment could not be finalised based on the available data.</i>

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

Not applicable OR Respective code if available	Not applicable OR Appropriate national additional phrases
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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:		
respective code if available	Protective gloves should be worn when handling the concentrate and during maintenance of the sprayer during application.	Triggered by the estimated operator exposure and the sensitising potential of DPX-YYYYY <formulation type>

Worker protection:		
Not applicable or respective code if available	None triggered by the risk assessment Or national PPE requirements	

Integrated pest management (IPM)/sustainable use:		
Not applicable	Not applicable	
Or respective code if available	Or e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.	

Environmental protection		
SPe3	To protect aquatic organisms, respect an vegetated buffer strip of 10 m to surface water bodies. To protect non-target plants, respect an unsprayed buffer zone of 5 m to non-agricultural land, or reduce spray drift by 75% using respective drift reducing techniques	Triggered by the risk assessment for aquatic organisms and terrestrial non-target plants

Other specific restrictions		
Not applicable	Not applicable	
Or respective code if available	Or are there any other national requirements	

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

Integrated pest management (IPM)/sustainable use:		
Not applicable	Not applicable	
Or respective code if available	Or e.g. The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.	

2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
Not applicable	Not applicable	Not applicable
Or respective code if available	Or e.g. The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	Or use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
respective code if available	e.g. The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	use number from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	GF-3969	Formulation type:	WG	GAP rev. 2 1 , date: 08/2022 12/2021
Active substance 1:	Rimsulfuron	Conc. of a.s. 1:	148.15 g/kg	
Active substance 2:	Thifensulfuron methyl	Conc. of a.s. 2:	92.6 g/kg	
Active substance 3:	-	Conc. of a.s. 3.:	-	
Safener:	Isoxadifen-ethyl	Conc. of safener:	111.1 g/kg	
Synergist:	-	Conc. of synergist:	-	
Applicant:	DuPont/Corteva	Professional use:	<input checked="" type="checkbox"/>	
Zone(s):	CEU	Non professional use:	<input type="checkbox"/>	
Verified by MS:	Yes			
Field of use:	Herbicide			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15															
														Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha	Overall conclusions						
														Method/ Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha ^a 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
9	LU	Maize (ZEAMX) (silage and grain)	F	Annual monocotyledonous weeds (TTTMS); Annual dicotyledonous weeds (TTTDS); Perennial grass weeds (GGGPE)	Hydraulic sprayer overall	BBCH 11 to BBCH 18 Spring April-June	a) 1 b) 1	n.a.	a) 0.135 b) 0.135	a) 32.5 (20 + 12.5) b) 32.5 (20 + 12.5)	100 / 400	n.a.	Safener: formulated product contains 111.1 g/kg isoxadifen-ethyl (max. 15 g/ha) Adjuvant: application with max. 0.2% a non-ionic surfactant (ex. KG691) or vegetable oil Dose range: 67.5–135 g product/ha																
10	PL	Maize (ZEAMX) (silage and grain)	F	Annual monocotyledonous weeds (TTTMS); Annual dicotyledonous weeds (TTTDS); Perennial grass weeds (GGGPE) <u>Echinochloa crus-galli (ECHCG)</u>	Hydraulic sprayer overall	BBCH 11 to BBCH 18 Spring April-June	a) 1 b) 1	n.a.	a) 0.135 b) 0.135	a) 32.5 (20 + 12.5) b) 32.5 (20 + 12.5)	100 / 400	n.a.	Safener: formulated product contains 111.1 g/kg isoxadifen-ethyl (max. 15 g/ha) Adjuvant: application with max. 0.2% a non-ionic surfactant (ex. KG691) or vegetable oil	A	A	A	A	A	R Aquatics	A	A								
																			R NTTP R.A not Finalised										
																			A remaining species										

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15															
														Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha	Overall conclusions						
														Method/ Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha ^a 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
27	SK	Maize (ZEAMX) (silage and grain)	F	Annual monocotyledonous weeds (TTMS); Annual dicotyledonous weeds (TTDS); Perennial grass weeds (GGPE)	Hydraulic sprayer overall	BBCH 11 to BBCH 18 Spring March- July	a) 2 b) 2	7	a) 0.0675 b) 0.135	a) 16.25 (10 + 6.25) b) 32.5 (20 + 12.5)	100- 400	n.a.	Safener: formulated product contains 111.1 g/kg isoxadifen-ethyl (max. 15 g/ha) Adjuvant: application with 0.2% a non- ionic surfactant (ex. KG691) or vegetable oil Split application: 2x 67.5 g product/ha																

- * 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
- a Dose expressed as total g active substance (g rimsulfuron + g thifensulfuron methyl)
- b n.a. = not applicable

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

- | | | |
|-------------------------|---|--|
| Remarks columns: | 1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the 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 equipment (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 the column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

3 Background of authorization decision and risk management

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

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of the plant protection product.

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 mixture of cream, beige and tan granules. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 407.5°C. In aqueous solution, it has a pH value around 7 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active substance content nor the technical properties were changed. **The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE container.** ~~The 2 weeks at 54°C accelerated storage data indicate a shelf life of at least 2 years at ambient temperature when stored in high density polyethylene (HDPE) containers.~~ Its technical characteristics are acceptable for a water dispersible granules (WG) formulation.

The intended concentration of use is 0.0125% to 0.27%.

The product has been tested and can be mixed in the tank together with 21 different partners in two, three and four-way mixture combinations. For further detail on acceptable tank mix partners, please refer to product label.

Tank mix with adjuvants is mandatory for GF-3969 (Dragster). During spraying it is recommended to add non-ionizing surfactant in a ratio of 0.2% v/v or vegetable oil.

~~There are no mandatory recommendations for tank mixtures.~~

Physical-chemical properties of product GF-3969 do not trigger any classification in accordance with Regulation (EC) No. 1272/2008.

3.2 Efficacy (Part B, Section 3)

GF-3969 is an herbicide effective for the control of grasses and broadleaved weeds in maize.

This document has been prepared to support the application of GF-3969 (DuPont experimental code, DPX-V4B07) in mixture with a non-ionic surfactant for the control of weeds in field crops of maize.

There were 37 field trials conducted across the Central Regulatory zone between 2017 and 2018 on various grasses and broadleaf weeds in maize.

The zonal GAP envelope for CEU countries foresees the application of 135 g fp/ha GF-3969 (32.5 g a.s./ha + 15 g isoxadifen ethyl) between BBCH 11-18 of maize. GF-3969 should be tank mixed with surfactant (non-ionic or vegetable oil). Certain countries (BE, HU, NL, LU, RO, and SK) apply for a dose range, which is why also lower doses (67.5 g fp/ha) are presented within the efficacy section. Furthermore, split application of GF-3969 in the ratio of 50:50 (67.5 g fp/ha GF-3969 per application: AT, BE, CZ, DE, HU, NL, LU, PL, RO, SK) and/or as **63:37** ~~60:40~~ (85 g fp/ha first application, 50 g fp/ha second application: AT, CZ, DE) is intended.

Trials were carried out by DuPont and contractor companies, all of which follow the EPPO standards

and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

3.2.1 Efficacy data

A total of 37 trials were conducted across various countries and years to support the different chapters of this biological assessment dossier. Trial details are revealed in the upcoming tables.

Applications were done between BBCH 11 and BBCH 18 of the maize using randomized complete block design, 4 replicates, plot sizes between 15 and 30 m² in various commercial maize hybrids between 2017 and 2018. Thereby, multiple target weeds in densities >5 individuals per m² were assessed until ~50 days after the treatment. Usually the final assessment was taken into consideration and is presented in the upcoming section(s). Trials were carried out by contract companies which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP) and following the published EPPO guidelines standards, PP 1/50 (Weeds in maize), PP 1/152 (Design and analysis of efficacy evaluation trials), PP 1/135 (Phytotoxic assessment), PP 1/181 (Conduct and reporting of efficacy evaluation trials including good experimental practice), PP 1/214 (Principles of acceptable efficacy) and PP 1/225 (Minimum effective dose).

Summary and conclusions on the preliminary trials

Overall it was demonstrated that the inclusion of rimsulfuron as contained in GF-3969 was clearly justified by grass control, whereas thifensulfuron methyl provided broad leaf weed control in maize. A non-ionic surfactant clearly increased the efficacy of GF-3969 against all major target weeds in maize whereas the inclusion of isoxadifen did not affect efficacy at all. The ratio for both actives as contained within GF-3969 were chosen to provide highest and most reliable control to the farmer against all major target weeds in maize under various climatic conditions.

Minimum effective dose

37 field trials were established to determine the minimum effective dose of GF-3969 for the control of annual monocotyledonous weeds, annual dicotyledonous weeds and perennial grass weeds in maize. GF-3969 was tested at 67.5 g fp/ha, 101.25 g fp/ha and 135 g fp/ha (target rate) in maize for the control of major target weeds. The rates tested reflect, respectively, 50%, 75% and 100% of the full recommended rate of GF-3969 in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'.

Summary and conclusions on the minimum effective dose

According to the trial results, it can be concluded that the dose rate of 135 g fp/ha is the most effective to control of all weed species submitted in this dossier. Taking into account that the dose range of 67,5-135 g fp/ha is the indicated doses for Belgium, Netherlands, Luxemburg, Hungary, Romania and Slovakia, it can be concluded that 67,5 g fp/ha is the minimum effective dose rate of GF-3969.

Efficacy trials

There were 37 field trials conducted across ten countries within the Central Regulatory zone between 2017 and 2018 to determine the efficacy and weed spectrum of GF-3969 + surfactant in maize. Trials were carried out by contractor companies, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Only trials with significant weed infestation were considered and included in the analysis in this report.

The zonal GAP envelope for CEU countries foresees the application of 135 g fp/ha GF-3969 (20 g a.s./ha rimsulfuron + 12.5 g a.s./ha thifensulfuron methyl + 15 g a.s./ha isoxadifen ethyl) plus a

surfactant (non-ionic or vegetable oil) between BBCH11-18 of maize. Certain countries (BE, HU, LU, NL, RO, and SK) apply for a dose range, which is why also lower doses (67.5 g fp/ha) are presented within this efficacy section. Furthermore, split application of GF-3969 in the ratio of 50:50 (67.5 g fp/ha GF-3969 per application: AT, BE, CZ, DE, HU, LU, NL, PL, RO, SK) and/or as 63:37 ~~60:40~~ (85 g fp/ha first application, 50 g fp/ha second application: AT, CZ and DE) is intended.

The biological performance of GF-3969 was evaluated for post-emergence application at the proposed label rate of 135 g f.p./ha and was compared with the most important commercial reference products available in the market at the time of trial execution, such as Equip Ultra™ and Laudis®.

Assessments were carried out according to the EPPO guidelines PP 1/135 “Phytotoxicity assessment”, PP 1/152 “Design and analysis of field evaluation trials”, PP 1/50 “weeds in maize” and PP 1/181 “Conduct and reporting of efficacy evaluation trials including good experimental practice”. The EPPO guideline PP 1/050(3) was followed in all trials, visual assessments were conducted approximately 2, 4, and 8 weeks after application. The percentage of visual control was estimated on a 0-100 linear scale with: 0% = no control and 100% = plant death.

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

GF-3969 contains rimsulfuron and thifensulfuron methyl, both active substances are members of the sulfonylurea herbicides family, and controls weeds through both root and foliar activity. It controls weeds by blocking biosynthesis of the plant enzyme acetolactate synthase (ALS), which is needed to make the branched-chain amino acids: leucine, isoleucine and valine, essential building blocks of proteins and other plant components.

GF-3969 is a systemic herbicide, entering the plant through the roots and the leaves and being quickly distributed in the plant. Weed growth ceases within as little as six hours after application. Activity begins in the young growing points, which turn yellow or chlorotic within a few days. Weed death normally occurs within one to three weeks after application, depending on the species and environmental conditions. GF-3969 performs best when applied to actively growing weeds.

- Target site resistance: This is the basis for most of the weed biotypes with resistance to ALS inhibitor herbicides. A mutation in the gene encoding the ALS enzyme renders the weed less sensitive to sulfonylurea. The ability for other ALS inhibitor herbicides to bind at this site and hence their activity could also be affected, and it depend directly of the mutated gene position on the ALS genome. The single site of action means that sulfonylureas pose a relatively high resistance risk.
- No-target site resistance: This type of resistance includes several mechanisms like overexpression of the enzymes, transportation and accumulation of the chemical in vacuole, etc..., but the most commonly found is the enhance of metabolism, which is based on the plant’s ability to metabolize the herbicide to non-phytotoxic compounds rapidly enough to prevent the build-up of lethal herbicide levels. This mechanism is present in grass resistant populations. Resistant biotypes can metabolize sulfonylurea herbicides into non-toxic metabolites.

The resistance to weeds arising from treatment with sulfonylurea herbicides was first detected in *Alopecurus myosuroides* in 1984 in the United Kingdom, several years after the first widespread commercial use of chlorsulfuron.

Since that discovery, resistance to ALS inhibitors (sulfonylureas, triazolopyrimidine, imidazolinone, pyrimidinylthiobenzoates and sulfonyl-amino-carbonyl-triazolinones) has been documented in 168 ~~165~~ weeds species (102 ~~101~~ broadleaves weeds and 66 ~~64~~ grass weeds) in a total of 40 countries world-wide. ALS inhibitors-resistant weeds have appeared in cereals, maize/soybeans rotation, rice, highway right-of-way, and forestry. In these situations, the use of long residual ALS inhibitors and/or frequent

application (more than one per season) and extensive use of one mode of action herbicide has contributed to the development of resistance.

In 2020, there were 44 confirmed and published cases of weeds resistant to ALS inhibitors in Europe, Middle East and Africa.

Resistance has almost exclusively arisen in situations where ALS inhibitor herbicides have been used repeatedly to control specific weeds in non-crop areas (e.g. roadsides, railways) and monoculture (cereals, maize, rice, highway right-of-way, and forestry). In these situations, the use of ALS inhibitors and/or frequent application (more than one per season) has contributed to the development of resistance. Both long-term residuality and multiple applications of the same mode of action exert a strong selection pressure on target weeds.

Cross-resistance occurs in biotypes that are resistant to one or more herbicides due to either one of the mechanisms outlined in section 3.3.2. The modification of the target site or the enhanced metabolism renders the plant less susceptible/resistant to chemicals that have the same mode or site of action or in the case of enhanced metabolism a similar molecular structure or part of the molecular structure. For example, a modification of the target site, as is the case in certain sulfonylurea resistant biotypes, will result in cross-resistance to other sulfonylureas and other groups of ALS inhibitors, e.g. Imidazolinones. The presence of cross-resistance between sulfonylureas and other ALS inhibitors means that sulfonylureas pose a relatively high resistance risk. Please note that, ALS resistant biotypes are easily controlled by products based on an alternative mode of action. The implications of cross resistance between groups of herbicides with the same mode of action and the susceptibility of resistant biotypes to products with alternative modes of action are important factors in the management of resistant biotypes. This includes the prevention/delay of the appearance of resistant biotypes.

Baseline sensitivity data is not presented in this dossier due to the large number of years that the active substances, rimsulfuron and thifensulfuron methyl, present in GF-3969, were present on the maize market, and because already resistant biotypes to sulfonylurea have been reported on *Echinochloa crus-galli*, *Setaria viridis*, *Digitaria sanguinalis*, *Sorghum halepense*, *Chenopodium album* and *Amarantus retroflexus*.

Based on the information presented the commercial use of GF-3969 has the risk to develop resistance on the weeds which have been identified, and this risk is considered unacceptable, therefore a management strategy to prevent the resistance development and to manage those individual already resistance is provided.

To protect the value of the sulfonylurea herbicides, and the inhibitors of the ALS herbicides in general, Applicant will recommend the use of GF-3969 in tank mix or in sequential applications with a suitable product with an alternative mode of action for the control of weeds with high risk.

Herbicides with a different mode of action to the ALS inhibitors have been evaluated in in-vivo tests to propose chemical alternatives for the control in post emergence of *Echinochloa crus-galli*, *Setaria viridis*, *Digitaria sanguinalis*, *Sorghum halepense*, *Chenopodium album* and *Amarantus ssp.* resistant populations and give practical recommendations/advice to farmers and distributors. Results from the monitoring tests are presented in the chapters below.

As a result, the following resistant management strategy will be communicated for the use of GF-3969, and the following guidelines will be recommended:

- The principles of good plant protection practices will be promoted. These include the use of cultural and mechanical practices to ensure that herbicide application is made under favorable environmental conditions, facilitating good even coverage, to prevent resistance appearance by avoiding monoculture situations, ploughing before crop drill, etc...
- Use of GF-3969 in tank mix or sequential applications with effective products on the target weeds with a different mode of action. As examples, and if the weed pressure is high and resistance is suspected, GF-3969 may be tank mix in post emergence or apply in sequences with

herbicides based on the following active substances:

- In the case of *Echinochloa crus-galli* it is recommended to tank mix or alternate with herbicide belonging to the HPPD mode of action (27 (legacy F2) group according to the HRAC classification) like mesotrione, sulcotrione, tembotrione.
 - In the case of *Sorghum halepense* it is recommended to tank mix or alternate with herbicide belonging to the ACCase mode of action (1 (legacy A) group according to the HRAC classification) like cycloxydim, fluazifop
 - In case of *Setaria viridis* is recommended to tank mix or alternate with herbicide belonging to the ACCase mode of action (1 (legacy A) group according to the HRAC classification) like cycloxydim and also with herbicide belonging to the Chloroacetamid mode of action (K3 group according to HRAC classification) like dimethenamid.
 - In case of *Digitaria sanguinalis* is recommended to tank mix or alternate with herbicide belonging to the HPPD mode of action (27 (legacy F2) group according to the HRAC classification) like mesotrione, sulcotrione, tembotrione and also with herbicide belonging to the Chloroacetamid mode of action (15 (legacy K3) group according to HRAC classification) like dimethenamid
 - In case of *Amaranthus retroflexus* is recommended to tank mix or alternate with herbicide belonging to the HPPD mode of action (27 (legacy F2) group according to the HRAC classification) like mesotrione, sulcotrione, tembotrione.
- Destroy all the seeds produce by no-controlled weeds using mechanical control or effective herbicides with a different mode of action.

The use of GF-3969 in tank mix with herbicides with a different mode of action for the control of grass weeds (see above) is recommended to prevent and manage the presence of weed resistant biotypes to sulfonylureas.

The resistance management strategy is implemented / communicated via:

- label statements
- leaflets
- training courses
- CORTEVA customer meetings

Part of the management strategy is to monitor the product performance to determine any shifts in sensitivity towards the product. This will help determine the success of the management strategies implemented.

The monitoring strategies employed will be based on the investigation of complaints from growers of apparent loss of field performance. Providing that all other aspects negatively impacting field performance can be ruled out samples will be taken and tested for resistance according to an “in vivo” resistant method develop by Applicant or by the conventional whole-plant soil bio-assay.

Monitoring studies have been and will be conducted on GF-3969 from the moment that the product will be re-authorized. Monitoring studies will continue for this high resistant risk species like *Echinochloa crus-galli*, *Sorghum halepense*, *Digitaria sanguinalis* and *Amaranthus retroflexus* to sulfonylureas herbicides.

Seed samples will be collected in the fields following weed control failure. Resistant “in vivo” test under growth chamber conditions and is appropriated PCR analysis will be performed to confirm if the population is resistant or not.

3.2.3 Adverse effects on treated crops

Crop phytotoxicity after application of GF-3969 to maize was assessed in 29 selectivity trials across multiple climatic conditions and farming systems across the central registration zone. Trials were carried out by contractor companies, all of which follow the EPPO standards (PP 1/135 and 1/226) and are officially recognized by the competent authorities to carry out field registration trials in accordance with

the principles of Good Experimental Practice (GEP).

Effects on the quality of plants

Twenty-two selectivity trials analysed to test different quality parameters. Studies were conducted in seven different countries between 2017 and 2018 on maize and revealed no negative impact compared to the untreated or compared to the included reference products.

3.2.4 Observations on other undesirable or unintended side-effects

Impact on succeeding crops

The impact of GF-3969 on succeeding crops is presented following the EPPO Guidance PP1/207 (2) which describe the methods used to examine whether an herbicide cause negative effect on crops grown as rotational or replacement crops after a crop treated with that product. A greenhouse study was conducted in 2017 by the laboratory “Rheinland-Pfalz (RLP) AgroScience GmbH” in order to determine the EC₁₀ values of GF-3969, also coded as DPX-V4B07 containing rimsulfuron and thifensulfuron methyl. Doses of GF-3969 also coded as DPX-V4B07 from 0 to 135 g fp/ha including thifensulfuron methyl at the highest dose of 12.5 g a.s./ha and rimsulfuron at the high dose of 20 g a.s./ha were used as the doses to calculate the TER value as well as the maximum dose of the final product GF-3969 to determine the EC₁₀ values of each selected crops.

Results show that alfalfa and sugarbeet are the most sensitive species tested for GF-3969 followed by potatoes. Cereals shown in general high EC₁₀ values. And from the most tolerant crops to GF-3969 peas, soybean and tomatoes were identified. None of the tested plant species was affected in seedling emergence.

In the case of a normal crop rotation the following crops can be planted after application of GF-3969: winter cereals (barley, rye, wheat and triticale) in the same calendar year and spring barley, spring oil seed rape, potatoes, sugar beet, sunflower, soybean, peas, cotton, alfalfa and tomatoes on the following springs.

Impact on other plants including adjacent crops

Studies on the toxicity to non-target terrestrial plants have been carried out with GF-3969.

Based on the risk assessment provided above, as well as considering the drift mitigation technologies, the proposed mitigation measures for GF-3969 formulation for adjacent crops should therefore be:

- for onion, oat, corn, oilseed rape, cucumber, soybean, tomato and pea: neither buffer zones, nor drift reduction technology is needed,
- for sorghum, a 3-m buffer or 50% drift reduction technology is required whereas
- Sugar beet requires at least 75% drift reducing technology or a 3-m buffer

Acceptable risk to each of the species tested is shown based on the maximum application rate of 1 x 135 g product/ha, when appropriate mitigation is applied. Full details of the terrestrial plant studies are provided in DuPont 50803 CEU: SECTION 9.

Effects on beneficial and other non-target organisms

For an herbicide, where beneficial are not important in controlling the plant species, further testing is not required. As such no specific considerations are required for beneficial arthropods.

The risk to arthropods is presented in Part B Section 9 (Ecotoxicology). A low risk was identified for the standard indicator arthropod species *Aphidius* and *Typhlodromus* for both in-field and off-field exposure and so a low risk to arthropods from the intended use.

The Tier I laboratory studies showed acceptable in-field and off-field effects for *Aphidius rhopalosiphi* and *Typhlodromus pyri* from applications of GF-3969 according to the proposed use pattern. All details are given in DuPont 50803 CEU: SECTION 9.

3.2.5 Physical and chemical compatibilities

The product has been tested and can be mixed in the tank together with 21 different partners in two, three and four-way mixture combinations. For further detail on acceptable tank mix partners, please refer to product label.

Tank mix with adjuvants is mandatory for GF-3969 (Dragster).
During spraying it is recommended to add non-ionizing surfactant in a ratio of 0.2% v/v or vegetable oil.

~~There are no mandatory recommendations for tank mixtures.~~

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for determination of the active substances in GF-3969 were not evaluated as part of the EU review of rimsulfuron, thifensulfuron methyl or safener isoxadifen-ethyl. Therefore, all relevant data were provided and are considered adequate.

3.3.1 Analytical method for the formulation

The method for assay of rimsulfuron, thifensulfuron methyl and safener isoxadifen-ethyl in GF-3969 formulated product is based on analysis by reversed-phase liquid chromatography and detection at 230 nm using an UV detector.

The validation results for the analytical method to test for rimsulfuron, thifensulfuron methyl and isoxadifen-ethyl, DuPont Method No. X4145.220.03.ST, contained in DuPont-50247, meet the following test and reporting guidelines: (1) U.S. Environmental Protection Agency (EPA), (2) European Union (EU), (3) Health Canada Pest Management Regulatory Agency (PMRA), and (4) Australian Pesticides and Veterinary Medicines Authority (APVMA) for selectivity (interferences), linearity, accuracy (recovery) and repeatability (precision). The method can be used to support the registration of GF-3969.

There are no impurities known to be of toxicological or environmental significance in rimsulfuron, thifensulfuron methyl and safener isoxadifen-ethyl as manufactured which would justify the submission and disclosure of enforcement methods. There are no formulating ingredients in GF-3969 of toxicological or ecotoxicological concern that justify the need for the submission and disclosure of enforcement methods.

3.3.2 Analytical methods for residues

Rimsulfuron

The residue definition for primary crops both for risk assessment and monitoring is set as rimsulfuron. The current residue definition set in Regulation (EC) No 396/2005 (Reg. (EU) No 617/2014) is identical to the residue definition for enforcement derived in the peer review.

In EFSA Scientific Report (2005) 45, 1-61, Conclusion on the peer review of rimsulfuron it is stated that “Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. rimsulfuron in food of plant origin, soil, water and air.”

The methodology used is HPLC with UV or MS/MS detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable due to the nature of the residues. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.”

Residue definitions

Soil

Definitions for risk assessment: rimsulfuron, IN-70941;IN-70942; IN-E9260

Definitions for monitoring: rimsulfuron

Water

Ground water

Definitions for exposure assessment: rimsulfuron, IN-70941, IN-E9260, IN-70942, INJ-290

Definitions for monitoring: rimsulfuron

Surface water

Definitions for risk assessment:

surface water and sediment: rimsulfuron, IN-70941, IN-70942

surface water only: IN-E9260 (where surface water is fed by groundwater)

sediment only: IN-JF999

Definitions for monitoring: rimsulfuron

Air

Definitions for risk assessment: rimsulfuron

Definitions for monitoring: rimsulfuron

Food of plant origin

Definitions for risk assessment: rimsulfuron

Definitions for monitoring: rimsulfuron

Food of animal origin

Definitions for risk assessment: no residue definition needed

Definitions for monitoring: no residue definition needed

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-UV 0.05 mg/kg (maize, potato, tomato) LC-MS/MS 0.01 mg/kg (maize, potato, tomato)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant, no residue definition is proposed
Soil (analytical technique and LOQ)	LC-MS/MS 0.2 µg/kg
Water (analytical technique and LOQ)	HPLC-UV 0.1 µg/L LC-MS/MS 0.05 µg/L (drinking- and surface water)
Air (analytical technique and LOQ)	LC-MS/MS 3 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Not relevant, the active substance is not classified as toxic or very toxic

According to the EFSA Journal 2012;10(10):2911 “During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS was submitted and validated with an LOQ of 0.01 mg/kg in dry (maize grain) and high water content (potato, tomato) commodities and 0.05 mg/kg for maize forage and stover (Germany, 2003). This method was taken into account by the RMS, but an ILV fully validated with an LOQ of 0.01 mg/kg is missing.

In addition, after Annex I inclusion, France evaluated an LC-MS/MS method and its ILV which were validated for the determination of rimsulfuron with an LOQ of 0.01 mg/kg in high water content (apple, cherry and plum), acidic (grape, lemon and lime) and dry (corn grain) commodities (France, 2012). The HPLC-MS/MS method from the DAR reported above can be used as confirmatory method for dry and high water content commodities.

Hence, it is concluded that parent rimsulfuron can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in dry and high water content commodities.

No analytical method is available for food of animal origin. As there is no significant intake of residues by livestock, no residue definition and no MRL were proposed for commodities of animal origin. Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.”

The summary and evaluation of new methods for the determination of rimsulfuron in food of plant origin, soil, water, air and in body fluids provided for renewal of active substance were presented in Renewal Assessment Report for Review of Annex I Inclusion of Rimsulfuron, in B.5 – Methods of Analysis, October 2017. The conclusions were published in EFSA Journal 2018;16(5):5258. The available methods are acceptable and sufficient to support the proposed use.

In EFSA Journal 2018;16(5):5258 it is stated that “*Rimsulfuron residue can be monitored in food and feed of plant origin by high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Rimsulfuron residue in dry and high water content commodities can be determined also by the quick, easy, cheap, effective and safe method (QuEChERS) using HPLC–MS/MS with a LOQ of 0.01 mg/kg. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.*

Rimsulfuron residue in soil can be monitored by HPLC–MS/MS with a LOQ 0.05 µg/kg. Rimsulfuron residue in water can be monitored by QuEChERS HPLC–MS/MS or single HPLC–MS/MS with LOQs 0.05 µg/L and 0.1 µg/L, respectively. An appropriate HPLC–MS/MS method exists for monitoring of rimsulfuron residue in air with a LOQ of 3.0 µg/m³.

The HPLC-MS/MS method can be used for monitoring of rimsulfuron in body fluids (urine and plasma) with LOQ of 0.01 mg/kg. Rimsulfuron residue in body tissues can be determined by HPLC-MS/MS with LOQ of 0.01 mg/kg.”

Furthermore the Applicant submitted a number of methods for analysis of residues of rimsulfuron for the generation of pre-authorization data. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Thifensulfuron methyl

In EFSA Journal 2015;13(7):4201 it is stated that “*For plants, soil, water and air LC-MS/MS methods are available. A method of analysis for products of animal origin is not required as no MRLs are proposed. A method of analysis for body fluids and tissues is not required.*”

Residue definitions for monitoring purposes

Food/feed of plant origin	For oilseeds and cereals (weed-control use): Thifensulfuron-methyl (parent only) Although currently no EU MRLs are set for feed commodities, for possible future applicability it is proposed: For Animal feed items (grass / alfalfa): Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl
Food/feed of animal origin	Thifensulfuron-methyl (parent only)
Soil	Thifensulfuron-methyl
Water (surface, drinking/ground)	Thifensulfuron-methyl
Air	Thifensulfuron-methyl
Body fluids and tissues	Thifensulfuron-methyl

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DuPont: LC-MS/MS – LOQ = 0.01 mg/kg for soybean seed, olives, corn grain, oranges and lettuce.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no MRLs are proposed
Soil (analytical technique and LOQ)	DuPont: LC-MS/MS – LOQ = 0.05 µg /kg for soil
Water (analytical technique and LOQ)	DuPont: LC-MS/MS – LOQ = 0.05 µg/L for both drinking and surface water
Air (analytical technique and LOQ)	DuPont: LC-MS/MS – LOQ = 2.8 µg/m ³ for air

Body fluids and tissues (analytical technique and LOQ)	Not required.
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Excerpt from EFSA Journal 2015;13(7):4201:

Plant residue definition for monitoring - Thifensulfuron-methyl (parent only) (for oilseeds and cereals),
Plant residue definition for risk assessment - Thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (for oilseeds and cereals).

Remark: The risk assessment definition is not finalised with regard to metabolites IN-A4098 and IN-B5528. The consumer exposure assessment is moreover pending further clarification on the toxicological properties of IN-W8268 and IN-A5546.

Furthermore the Applicant submitted a number of methods for analysis of residues of thifensulfuron-methyl for the generation of pre-authorization data and for post-authorization control and monitoring purposes. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part 5.

According to the EFSA Journal 2015;13(7):4201 a method of analysis for body fluids and tissues is not required. However in Reg (EU) No 283/2013 it is stated that “*methods, with a full description, shall be submitted for the analysis in body fluids and tissues for active substance and relevant metabolites*”.

Applicant provided analytical method for the determination of thifensulfuron methyl in plasma and urine (R. M. Henze, J. J. Stry, 2016, Dupont-47394).

The analytical method was developed and validated for the detection, quantitative analysis and confirmation of residues of thifensulfuron methyl (DPX-M6316) in plasma and urine. The determined limit of quantitation (LOQ) was 1.0 µg/kg (ppb) for plasma and 3.0 µg/kg for urine. The study is acceptable. The details of the evaluation of additional study is referred in Appendix 2 of Part 5.

Additionally Applicant provided analytical method for the determination of thifensulfuron methyl in drinking, ground and surface water (R. M. Henze, J. J. Stry, 2013, DuPont-35704) and independent laboratory validation of DuPont-35704 (Mason, B., 2013 (DuPont-36531)).

The analytical method (DuPont-35704) was developed and validated for the detection, quantitative analysis and confirmation of residues of thifensulfuron methyl (DPX-M6316) in water using LC/MS/MS. The determined limit of quantitation (LOQ) was 0.1 µg/kg (ppb) for water. The DuPont-35704 analytical method was successfully independently validated for the determination of residues of thifensulfuron methyl in drinking, ground and surface water with a LOQ of 0.10 µg/kg using LC-MS/MS. The studies are acceptable. The details of the evaluation of additional studies are referred in Appendix 2 of Part 5.

Isoxadifen-ethyl

It should be pointed out that formulation GF-3969 contains 111.1 g/kg of safener, isoxadifen-ethyl. Isoxadifen-ethyl is not considered as an active substance and at present MRLs are not set in the EU for safeners.

The Applicant provided the data for safener reviewed by Germany. According to Regulation 1107/2009, data for safener should be evaluated in line with requirements relevant for active substances and EU agreed and peer-reviewed endpoints should be generated. Such evaluation, however, is outside the scope of the product registration and should be carried out at the EU level in order to derive uniform endpoints that may be used in evaluation of various formulations. For this reason studies provided for isoxadifen-ethyl were not validated by the zRMS.

3.4 Mammalian toxicology (Part B, Section 6)

Mammalian toxicology for GF-3969 has not been evaluated as part of the EU reviews of rimsulfuron, thifensulfuron methyl. Therefore, all relevant data were provided and are considered adequate.

GF-3969 is a mixture of two active substances and a safener. Therefore, a first tier combined exposure assessment has been presented. The Hazard Index was <1, thus combined exposure to all active substances in GF-3969 is not expected to present a risk for operators, workers, bystanders and residents.

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

3.4.1 Acute toxicity

GF-3969 is a water dispersible granules formulation containing rimsulfuron, 148.15 g/kg, thifensulfuron methyl, 92.6 g/kg, and isoxadifen-ethyl, 111.1 g/kg. A summary of the toxicological evaluation for GF-3969 is given in the following table.

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of the plant protection product.

Some of the submitted tests and studies which involve vertebrate animals and which address mandatory data requirements could have been met with alternative methods or by the calculation methods according to the CLP Regulation (EC No. 1272/2008); however, since this formulation is also being registered in regions that do not accept these alternative tests, the traditional tests were performed. These studies were included in the submission and used as a basis for the classification of the product when applicable as they provide representative data for the actual formulation. Studies were conducted according to prescribed guidelines.

Unless specifically indicated, this section does not contain reports of studies duplicating previous tests on vertebrate animals.

Regarding skin corrosion/irritation based on *in vitro* studies it was consider following outcome. In the Test Guideline No. 439 *In Vitro* Skin Irritation: Reconstructed Human Epi-dermis Test Methods; revision 14 June 2021; section “Initial considerations and limitations” point 8, has been stated: (..) A study comparing *in vitro* and *in vivo* data for 65 agrochemical formulations re-vealed an overall accuracy of 54% (based on 65 agrochemical formulations), a sensitivity of 44% (based on 25 formulations) and a specificity of 60% (based on 40 formulations). This data indicates a lack of applicability of the RhE based *in vitro* skin irritation test for agrochemical formulations. (..).

In addition this is supported by following paper included in the references TG OECD 439: Kolle S.N, van Ravenzwaay B. and Landsiedel R. (2017). Regulatory accepted but out of domain: *In vitro* skin irritation tests for agrochemical formulations. Regul.Toxicol. Pharmacol 89, 125-130.

Thus regarding mentioned above information, it was decided not to take into account *in vitro* study Costin, G.E., Pham, R., Sadowski, N., 2018 and conclude hazard assessment for skin irritation potential considering available *in vivo* study (Slonina, M., 2018). (*refer Table 3.4 1).

Predictions for eye corrosion/irritation based on *in vitro* studies is not relevant due to inconclusive outcome. This approach is supported by following paper: Kolle S.N., van Cott A., van Ravenzwaay B. and Landsiedel R. (2017): Lacking applicability of *in vitro* eye irritation methods to identify seriously eye irritating agrochemical formulations: Results of bovine cornea opacity and permeability assay, isolated chicken eye test and the EpiOcular™ ET-50 method to classify according to UN GHS. Regulatory Toxicology and Pharmacology 85 (2017) 33-47. ~~However *in vivo* study showed no eye irritation properties but considering WoE and precautionary approach, ZRMS in this particular case (eye corrosion/irritation) decided to take into account for hazard assessment predictions for eye corrosion/irritation based on composition of the product which estimation is indicative of eye irritation. (**refer Table 3.4 1).~~

Considering comments and suggestions sent by the CMS during the commenting period on the dRR,

ZRMS PL decided to take into account all proposals and reclassified the PPP Dragster in terms of eye irritation.

Based on the discussion regarding CLP classification final conclusions reflecting irritating potential was made on the basis of an *in vivo* test (Slonina, M., 2018 (DuPont-49964)), which confirmed the absence of eye irritation effect after exposure to the tested formulation.

For hazard assessment all information obtained from *in vivo* studies and one prediction based on composition (eye corrosion/irritation) has been taken into account. All these results are considered as complete data package relevant to conclude hazard assessment. Product classification has been agreed using all accepted end-points.

Table 3.4-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GF-3969

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral, rat (OECD 425)	>5000 mg/kg bw	Not classified.
LD ₅₀ dermal, rat (OECD 402)	>5000 mg/kg bw	Not classified.
LC ₅₀ inhalation, rat (OECD 403)	>5.4 mg/L air	Not classified.
Skin irritation, rabbit (OECD 404)	Non-irritant	Not classified.
Skin irritation, EpiDerm SIT model (OECD 439) ¹	Non-irritant	Not classified.
Eye irritation, rabbit (OECD 405)	Non-irritant	Not classified.
Eye irritation, EpiOcular EIT (OECD 492) ²	Irritant	Inconclusive EpiOcular eye irritation test. Classification based on calculation. H319 Causes serious eye irritation.
Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Not classified.
Supplementary studies for combinations of plant protection products. Induction of antioxidant-response-element dependent gene activity and cytotoxicity (using MTT) in the keratinocyte ARE-reporter cell line keratinosens	Non-sensitising	Not classified.

Note:

1) In the Test Guideline No. 439 In Vitro Skin Irritation: Reconstructed Human Epidermis Test Methods; revision 14 June 2021; in section “Initial considerations and limitations” point 8, has been stated: (...) A study comparing *in vitro* and *in vivo* data for 65 agrochemical formulations revealed an overall accuracy of 54% (based on 65 agrochemical formulations), a sensitivity of 44% (based on 25 formulations) and a specificity of 60% (based on 40 formulations). This data indicates a lack of applicability of the RhE based *in vitro* skin irritation test for agrochemical formulations. (...).

In addition this is supported by following paper: Kolle S.N, van Ravenzwaay B. and Landsiedel R. (2017). Regulatory accepted but out of domain: *In vitro* skin irritation tests for agrochemical formulations. Regul.Toxicol. Pharmacol 89, 125-130.

Thus regarding mentioned above information, ZRMS decided not to take into account *in vitro* study Costin, G.E., Pham, R., Sadowski, N., 2018 and conclude hazard assessment skin irritation potential considering available *in vivo* study (Slonina, M., 2018).

2) Predictions for eye corrosion/irritation based on *in vitro* studies is not relevant due to inconclusive outcome, thus ZRMS in this particular case (eye corrosion/irritation) decided to take into account for hazard assessment purpose predictions for eye corrosion/irritation based on *in vivo* study.

3.4.2 Operator exposure

No unacceptable risk for operators from the supported uses of GF-3969 and the adjuvant was identified based on exposure estimates from the EFSA Model. However, eyewear must be worn when handling the concentrated product due to GF-3969 being classified as an eye irritant. Gloves should also be worn during mixing, loading, and application due to the skin sensitization hazard classification for GF-3969. Thus, the predicted operator exposure to rimsulfuron, thifensulfuron methyl, isoxadifen-ethyl (safener), and isodecyl alcohol ethoxylate (adjuvant) from tractor mounted applications was $\leq 5\%$ of the respective AOEL values, based on normal work wear and gloves worn during mixing, loading, and application.

A summary of the exposure models used for estimation of operator exposure to the active substances during application of GF-3969 according to the critical use(s) is presented in Table 3.4-2. Outcome of the estimation is presented in Table 3.4-3.

Table 3.4-2: Exposure models for intended uses

Critical use(s)	<ul style="list-style-type: none"> GF-3969: Maize (max. per application and per season = 0.135 kg product/ha, Minimum water volume = 100 L/ha) DPX-KG691: Maize (max. rate = 0.8 L adjuvant/ha in maximum water volume of 400 L/ha at 0.2% v/v)
Model(s)	EFSA model Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874)

Table 3.4-3: Estimated operator exposure: GF-3969

Spray application: Tractor mounted boom spray application outdoors to maize Area Treated: 50 ha/day (AOEM; 75 th percentile) Body weight: 60 kg						
Model Information	Rimsulfuron		Thifensulfuron methyl		Isoxadifen-ethyl (safener)	
Number of applications and application rate	1 × 0.02 kg a.s./ha		1 × 0.0125 kg a.s./ha		1 × 0.015 kg a.s./ha	
Level of PPE	Total absorbed dose (mg/kg/day)	% of AOEL	Total absorbed dose (mg/kg/day)	% of AOEL	Total absorbed dose (mg/kg/day)	% of AOEL
Work wear (arms, body and legs covered) M/L & A (no PPE)	0.0042	6%	0.0029	4%	0.0033	17%
Work wear (arms, body and legs covered) + Gloves for M/L & A	0.0011	2%	0.0009	1%	0.0010	5%

Table 3.4-4: Estimated operator exposure: DPX-KG691

Spray application: Tractor mounted boom spray application outdoors to maize Area Treated: 50 ha/day Body weight: 60 kg		
Model Information	Isodecyl alcohol ethoxylate (IAE)	
Number of applications and application rate	1 × 0.720 kg IAE/ha	
Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Work wear (arms, body and legs covered) M/L & A (no PPE)	0.1784	36% 24%
Work wear (arms, body and legs covered) + Gloves for Mixing/Loading only and application	0.0093	2% 1%

Since the operator exposure estimations carried out indicated that the respective acceptable operator exposure levels (AOEL) for all active substances in GF-3969 and DPX-KG691 will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.4.3 Worker exposure

Since the maximum single application rate is the same as the maximum seasonal application rate (0.135 kg product/ha), the highest dislodgeable foliar residue, and hence the highest dermal exposure risk upon re-entry, is when the maximum amount of product is applied in one single application. When the product is split into two lower application rates with a 7-day interval in-between the two applications, some of the foliar residue from the first application will degrade before the second application resulting in re-entry exposure to foliar residue after the first or second application being lower than exposure from a single application at maximum dose rate. As such, the single application at maximum dose rate scenario represents the worst-case exposure scenario and, therefore, considered to be the most appropriate way of assessing re-entry worker exposure.

No unacceptable risk for workers from the supported uses of GF-3969 and DPX-KG691 was identified based on exposure estimates from the EFSA Model. The predicted operator exposure to rimsulfuron, thifensulfuron methyl, isoxadifen-ethyl (safener), and isodecyl alcohol ethoxylate (adjuvant) was ≤10% ≤7% of the respective AOEL values, based on normal work wear and no additional PPE.

Table 3.4-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GF-3969 according to the critical uses. Outcome of the estimation is presented in Table 3.4-6.

Table 3.4-5: Exposure models for intended uses

Critical use(s)	<ul style="list-style-type: none"> GF-3969: Maize (max. per application and per season = 0.135 kg product/ha, Minimum water volume = 100 L/ha) DPX-KG691: Maize (max. rate = 0.8 L adjuvant/ha in maximum water volume of 400 L/ha at 0.2% v/v)
Model	EFSA model Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874)

Table 3.4-6: Estimated worker exposure: GF-3969

Inspection and irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha							
Model Information		Rimsulfuron		Thifensulfuron methyl		Isoxadifen-ethyl (safener)	
Number of applications and application rate		1 × 0.02 kg a.s./ha		1 × 0.0125 kg a.s./ha		1 × 0.015 kg a.s./ha	
Level of PPE	Total absorbed dose (mg/kg/day)	% of AOEL	Total absorbed dose (mg/kg/day)	% of AOEL	Total absorbed dose (mg/kg/day)	% of AOEL	
Work wear (arms, body and legs covered) TC ^a : 1400 cm ² /person/h (no PPE ^b)	0.0014	2%	0.0009	1%	0.0011	5%	

a EFSA default for crop inspection. TC: Transfer coefficient

b No PPE: Worker wearing long sleeved shirt, long trousers

Table 3.4-7: Estimated worker exposure: DPX-KG691

Inspection and irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Model Information		Isodecyl alcohol ethoxylate (IAE)	
Number of applications and active substance single application rate		1 × 0.720 kg IAE/ha	
Model data	Level of PPE	Total absorbed dose (mg/kg/d)	% of systemic AOEL
Work wear (arms, body and legs covered) TC ^a : 1400 cm ² /person/h (no PPE ^b)		0.0504	10% 7%

a EFSA default for crop inspection. TC: Transfer coefficient

b No PPE: Worker wearing long sleeved shirt, long trousers

A refinement of the generic dislodgeable foliar residues (DFR) was not necessary since the worker exposure estimations carried out indicated that the respective acceptable operator exposure levels (AOEL) for all active substances in GF-3969 and DPX-KG691 (adjuvant) will not be exceeded under conditions of intended uses.

Since the worker exposure estimations carried out indicated that the acceptable worker exposure levels (AOEL) for all active substances in GF-3969 will not be exceeded under conditions of intended uses and considering above mentioned PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.4.4 Bystander and resident exposure

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

The toxicological assessment of the formulation GF-3969 based on Acute Toxicity Exposure (ATE) calculations triggers a category 1B skin sensitizer classification. Therefore, an assessment to confirm that the in use-spray dilution would not be classified as a skin sensitizer is required. There is a current understanding that if a formulation which is classified as a sensitizer (as in the case of GF-3969) is diluted to less than 1%, then the resulting mixture would not be considered a sensitizer. Considering the worst-case scenario GAP where the maximum product application rate (0.135 kg product/ha) is diluted in the minimum water volume (100 L water/ha), the product will constitute 0.14% of the in-use spray dilution ($[0.135 \text{ product/ha} \div 100 \text{ L water/ha}] \times 100\%$), which is less than the 1% cut-off. As such, the in-use spray dilution is not considered to be a skin sensitizer and therefore does not present a risk to bystanders/residents.

Resident exposure estimations carried out using the EFSA Model indicated that the acceptable exposure level will not be exceeded under conditions of intended use. Using the EFSA Model, the highest estimated all pathways mean exposure for residents (children) to rimsulfuron, thifensulfuron methyl, isoxadifen-ethyl (safener), isodecyl alcohol ethoxylate (adjuvant) was 6%, 4%, 16%, and 13% ~~9%~~ of the respective AOELs.

Table 3.4-8 shows the exposure model(s) used for estimation of bystander and resident exposure to rimsulfuron, thifensulfuron methyl, and isoxadifen-ethyl (safener). Outcome of the estimation is presented in

Table 3.4-9.

Table 3.4-8: Exposure models for intended uses

Critical use(s)	<ul style="list-style-type: none">• GF-3969: Maize (max. per application and per season = 0.135 kg product/ha, Minimum water volume = 100 L/ha)• DPX-KG691: Maize (max. rate = 0.8 L adjuvant/ha in maximum water volume of 400 L/ha at 0.2% v/v)
Model	EFSA model Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874)

Table 3.4-9: Estimated resident exposure (longer term exposure): GF-3969

Tractor mounted boom spray Buffer zone: 2-3 (m) Drift reduction technology: No DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha							
Model data		Rimsulfuron		Thifensulfuron methyl		Isoxadifen-ethyl (safener)	
		Total absorbed dose (mg/kg/d)	% of systemic AOEL	Total absorbed dose (mg/kg/d)	% of systemic AOEL	Total absorbed dose (mg/kg/d)	% of systemic AOEL
Number of applications and application rate		1 × 0.02 kg a.s./ha		1 × 0.0125 kg a.s./ha		1 × 0.015 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0027	4%	0.0017	2%	0.0020	10%
	Vapour (75 th perc.)	0.0011	2%	0.0011	2%	0.0011	5%
	Deposits (75 th perc.)	0.0002	0.2%	0.0001	0.1%	0.0001	0.6%
	Re-entry (75 th perc.)	0.0017	2%	0.0011	2%	0.0013	6%
	Sum (mean)	0.0040	6%	0.0033	4%	0.0033	16%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0006	1%	0.0004	0.6%	0.0005	2%
	Vapour (75 th perc.)	0.0002	0.3%	0.0002	0.3%	0.0002	1%
	Deposits (75 th perc.)	0.0001	0.1%	0.0000	0.06%	0.0001	0.3%
	Re-entry (75 th perc.)	0.0009	1%	0.0006	1%	0.0007	4%
	Sum (mean)	0.0013	2%	0.0011	1%	0.0011	5%

Table 3.4-10: Estimated resident exposure (longer term exposure): DPX-KG691

Tractor mounted boom spray Buffer zone: 2-3(m) Drift reduction technology: No DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Model data		Isodecyl alcohol ethoxylate	
		Total absorbed dose (mg/kg/d)	% of systemic AOEL
Number of applications and application rate		1 × 0.720 kg IAE/ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0242	3% 5%
	Vapour (75 th perc.)	0.0011	0.1% 0.2%
	Deposits (75 th perc.)	0.0058	1%
	Re-entry (75 th perc.)	0.0608	8% 12%
	Sum (mean)	0.0671	9% 13%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0058	1%
	Vapour (75 th perc.)	0.0002	0.03% 0.05%
	Deposits (75 th perc.)	0.0025	0.3% 0.5%
	Re-entry (75 th perc.)	0.0338	5% 7%
	Sum (mean)	0.0317	4% 6%

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure levels (AOEL) for rimsulfuron, thifensulfuron methyl, isoxadifen-ethyl (safener), and isodecyl alcohol ethoxylate (adjuvant) will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.4.5 Combined exposure

The product is a mixture of two active substances (rimsulfuron and thifensulfuron methyl) and a safener (isoxadifen-ethyl). In the tank mix, GF-3969 is mixed with water (application rate of 0.135 kg fp/ha with spray volumes 100-400 L/ha). DPX-KG691 is then added (label rate of 0.2 L/ha – 0.8 L/ha) to the diluted formulation, resulting in dilution of the adjuvant in the tank mix with its overall concentration in the tank mix very low and thus reducing its hazard profile. Therefore, it is highly unlikely that the addition of DPX-KG691 will significantly change the toxicological profile of the product due to the very low concentrations of the adjuvants as well as the active substances. Furthermore, default dermal absorption values have been applied for all components in the risk assessment which presents a highly precautionary approach. Based on the specified use pattern, any cause for concern related to acute exposure to this tank mixture is not expected to lead to additional acute toxicity concerns for the user relative to that posed by the neat products individually.

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. The Hazard Index (HI) is the sum of the individual HQs.

Table 3.4-11: Risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure/ AOEL (HQ)
Operators – Tractor mounted boom spray application (Gloves only worn during mixing, loading, and application)	Rimsulfuron	0.02
	Thifensulfuron methyl	0.01
	Isoxadifen-ethyl	0.05
	Isodecyl alcohol ethoxylate (adjuvant)	0.01 0.02
	Cumulative risk Operators (HI)	0.09 0.1
Workers – crop inspection and irrigation	Rimsulfuron	0.02
	Thifensulfuron methyl	0.01
	Isoxadifen-ethyl	0.05
	Isodecyl alcohol ethoxylate (adjuvant)	0.07 0.1
	Cumulative risk Workers (HI)	0.15 0.18
Resident Child – All pathways (mean)	Rimsulfuron	0.06
	Thifensulfuron methyl	0.04
	Isoxadifen-ethyl	0.16
	Isodecyl alcohol ethoxylate (adjuvant)	0.09 0.13
	Cumulative risk Resident Child – sum (mean) of all pathways (HI)	0.35 0.39
Resident Adult – All pathways (mean)	Rimsulfuron	0.02
	Thifensulfuron methyl	0.01
	Isoxadifen-ethyl	0.05
	Isodecyl alcohol ethoxylate (adjuvant)	0.04 0.06
	Cumulative risk Resident Adult – sum (mean) of all pathways (HI)	0.12 0.14

The Hazard Index is <1 for all subpopulations. Thus, combined exposure to all active substances and safener in GF-3969 + adjuvant is not expected to present a risk for operators, workers, bystanders and residents provided that the PPE/ risk mitigation measures stated in the table below are applied. No further refinement of the assessment is required.

	Result	PPE/ Risk mitigation measures
Operators	Acceptable	None; however, eyewear and gloves are required for mixing, loading, and application based on the hazard classification of the product.
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

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

The preparation GF-3969 is composed of three active ingredients; rimsulfuron, thifensulfuron methyl and the safener isoxadifen-ethyl.

Table 3.5-1: Toxicological reference values for the dietary risk assessment of rimsulfuron, thifensulfuron methyl and isoxadifen-ethyl

Rimsulfuron				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.1	2-year rat study	100	EFSA Scientific Report (2005) 45, 1–61
Acute Reference Dose (ARfD)	1.7	Rabbit, developmental study	100	EFSA Journal 2018;16(5):5258
Thifensulfuron methyl				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.01	2-year rat study	100	EFSA Journal 2015;13(7):4201
Acute Reference Dose (ARfD)	2	Developmental toxicity rat study	100	
Isoxadifen-ethyl				
End-Point	Value (mg/kg/day)	Study	Uncertainty factor	Reference
Acceptable Daily Intake (ADI)	0.03	1-year dog study	100	2002 German national Evaluation*
Acute Reference Dose (ARfD)	0.5	Rabbit developmental toxicity study	100	

* Summary of the German national evaluation of the safener isoxadifen-ethyl, 14 August 2002, RMS: Germany. BCS document ID: M-263999-01-1

3.5.1 Residues

Endpoints for the active substances in GF-3969, rimsulfuron and thifensulfuron methyl, relevant for the metabolism and residue evaluation are derived from the respective EFSA conclusions for these actives as indicated below.

For rimsulfuron: EFSA Scientific Report (2005) 45, 1-61. Conclusion regarding the peer review of the pesticide risk assessment of the active substance rimsulfuron.

EFSA Journal 2018;16(5):5258 - Peer review of the pesticide risk assessment of the active substance rimsulfuron.

For thifensulfuron methyl: EFSA Journal 2015;13(7):4201. Conclusion on the peer review of the pesticide risk assessment of the active substance thifensulfuron methyl.

Rimsulfuron

The nature and magnitude of residues in corn/maize were previously evaluated in the Rimsulfuron Draft Assessment Report, Volume 3, Annex B7 (2005).

As residues of rimsulfuron do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Thifensulfuron methyl

As residues of thifensulfuron methyl do not exceed the trigger values defined in Reg (EU) No 283/2013,

there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Isoxadifen-ethyl (safener)

It should be pointed out that formulation GF-3969 contains 111.1 g/kg of safener, isoxadifen-ethyl. Isoxadifen-ethyl is not considered as an active substance and at present MRLs are not set in the EU for safeners.

The Applicant provided the data for safener reviewed by Germany. According to Regulation 1107/2009, data for safener should be evaluated in line with requirements relevant for active substances and EU agreed and peer-reviewed endpoints should be generated. Such evaluation, however, is outside the scope of the product registration and should be carried out at the EU level in order to derive uniform endpoints that may be used in evaluation of various formulations. For this reason studies provided for isoxadifen-ethyl were not validated by the zRMS.

GF-3969 formulation

One new study on the magnitude of residue has been submitted by the applicant in the framework of this application. Eleven field trials (6 trials in N-EU and 5 trials in S-EU) were conducted to determine residues of rimsulfuron and thifensulfuron methyl in commodities derived from maize treated with DPX-TNS43 (a blend of rimsulfuron 25SG/thifensulfuron methyl 50SG/mesotrione 50WG plus isoxadifen-ethyl 50WG (safener; not active)) during the 2017 and 2018 growing seasons in EU. **Trend 90 (0.2% (v/v)) adjuvant was added to the tank mix.** DPX-TNS43 was applied once on maize at growth stage BBCH 19 at a nominal rate of 20 g ai/ha for rimsulfuron and 15 g ai/ha for thifensulfuron methyl. The data were generated to support the proposed use of GF-3969, which includes use of maize grain and stover as animal feed items. These data show that application of GF-3969 according to the proposed cGAP will not exceed the current EU MRLs of 0.01* mg/kg (Reg. (EU) No 617/2014) for rimsulfuron or thifensulfuron methyl. According to the available data, the intended uses on maize are considered acceptable.

While the number of residue trials was not compliant with the data requirements for maize, the reduced number of residue trials was considered acceptable for rimsulfuron and thifensulfuron methyl because all residues were below the LOQ and a no residue situation was expected.

(* Limit of analytical determination)

3.5.2 Consumer exposure

Rimsulfuron

The highest Theoretical Maximum Daily Intake (TMDI) predicted using EFSA PRIMo is 2% of the ADI for the NL Toddler. ~~The highest contribution is from cattle milk. In the UK, infants are the most exposed population at 1% of the ADI based on EFSA PRIMo exposure estimates.~~

~~Estimates of potential dietary exposure were also calculated using the UK CRD's ten consumer model (version 1.1). The highest predicted total National TMDI (NTMDI) is 3% of the ADI for the UK infant.~~

~~These estimates indicate that no health effects due to chronic exposure are expected in UK consumers.~~

Table 3.5-2: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	2% (based on NL Toddler)
NTMDI (% ADI) according to UK Model	3% (UK Infant)
IESTI (% ARfD) according to EFSA PRIMo	No acute reference dose was set therefore IESTI is not required.
NESTI (% ARfD)	Not required.
IESTI (% ARfD) according to EFSA PRIMo ^a	<p>Unprocessed Commodities: 0.1% based on consumption of milk</p> <p>Processed Commodities: 0.01% based on consumption of maize/oil</p>

^a Based on all listed EU MRLs.

Acute risk assessment not required as an ARfD is not necessary (EFSA, 2005).

EFSA concluded in EFSA Journal 2018;16(5):5258 that „*The acceptable daily intake (ADI) of rimsulfuron is 0.1 mg/kg bw per day with no change in the ADI value compared to SANCO/10528/2005-rev.2 (European Commission, 2006), based on decreased body weight and body weight gain, decreased food efficiency and increased in relative testes weight in the rat 2-year study by applying an uncertainty factor (UF) of 100.*

The acute reference dose (ARfD), which was not set in the review report assessment (European Commission, 2006) following the previous evaluation, is 1.7 mg/kg bw based on decreased food consumption, and mortality observed in the developmental study in the rabbit and applying an UF of 100.”

Additionally, the evaluator performed an acute consumer risk assessment using STMR/HR (0.01 mg/kg) for maize and MRLs for animal commodities and using a new value of ARfD of 1.7 mg/kg bw.

The highest International Estimated Short-Term Intake (IESTI) is at 0.1% and 0.05% of the ARfD for the consumption of Milk: Cattle by children and by adults respectively.

The proposed use of rimsulfuron in the product GF-3969 do not represent unacceptable acute and chronic risks for the consumer.

Thifensulfuron methyl

The highest Theoretical Maximum Daily Intake (TMDI) is 12% of the ADI for the Netherlands toddler. The highest contribution (6% ADI) is from cattle milk. The acute risk assessment was undertaken only for the crops under consideration. Children have the highest International Estimated Short-Term Intake (IESTI) for unprocessed commodities at 0.01% of the ARfD for the consumption of maize, and for processed commodities at 0.01% of the ARfD for the consumption of maize/oil.

Estimates of potential dietary exposure were also calculated using the UK CRD’s ten consumer model (version 1.1). The highest predicted total National Estimate of Dietary Intake (NEDI) is 15% of the ADI for UK infants. The acute dietary assessment performed using the UK model for the consumption of commodities for which GAPs are notified (maize) estimates the highest National Estimate of Short-Term Intake (NESTI) to be <0.01% of the ARfD for all population groups.

These estimates indicate that no health effects due to chronic and acute dietary exposure are expected in UK consumers.

Table 3.5-3: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo ^a	12% (based on NL toddler)
NTMDI (% ADI) according to UK Model ^a	15% (based on UK infant)
IESTI (% ARfD) according to EFSA PRIMo ^b	<u>Unprocessed Commodities:</u> 0.01% based on consumption of maize by UK infant
	<u>Processed Commodities:</u> 0.01% based on consumption of maize/oil by NL toddler
NESTI (% ARfD) according to UK Model ^b	<0.01% based on consumption of maize by all population groups.

a Based on all listed EU MRLs.

b Based on crops under consideration, *i.e.* maize

The proposed uses of thifensulfuron methyl in the formulation GF-3969 do not represent unacceptable acute and chronic risks for the consumer.

GF-3969

Based on the different calculations made to estimate the risk for consumer through diet and other means it can be concluded that the use of product GF-3969 does not lead to unacceptable risk for consumer when applied according to the recommendations.

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

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

The soil exposure was estimated for the intended use pattern of GF-3969 in line with FOCUS methodology. Obtained PEC_{SOIL} values were used in the risk assessment for soil organisms.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The groundwater modelling was performed for the intended use pattern of GF-3969 in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models.

On the basis of the obtained results rimisulfuron and metabolite IN-J0290 are not expected to migrate to groundwater at concentrations exceeding 0.1 µg/L when GF-3969 is used according to the intended use pattern.

PEC_{GW} for toxicologically non-relevant metabolite IN-70941 were >0.75 µg/L (max 4.3 µg/L) and the consumer risk assessment has been performed in the Core Assessment, Part B, Section 10 resulting with predicted exposure <1.0% ADI indicating acceptable risk.

PEC_{GW} for toxicologically non-relevant metabolite IN-70942 were >0.1 µg/L, but <0.75 µg/L (max 0.314 µg/L) so no further assessment for this compound is deemed necessary.

PEC_{GW} for IN-E9260 were >0.75 µg/L (max 1.913 µg/L) and the consumer risk assessment has been performed in the Core Assessment, Part B, Section 10 resulting with predicted exposure <1.0% ADI indicating acceptable risk. It should be noted that this metabolite was indicated as potentially toxicologically relevant in EFSA Journal 2018;16(5):5258, however based on additional data provided in support of evaluation of GF-3969 the zRMS toxicology expert concluded that IN-E2960 should be considered as toxicologically not relevant.

On the basis of the obtained results thifensulfuron-methyl and metabolites IN-A4098, IN-U5F72, IN-L9226, IN-A5546, IN-V7160 and IN-W8268 are not expected to migrate to groundwater at concentrations exceeding 0.1 µg/L when GF-3969 is used according to the intended use pattern.

PEC_{GW} for metabolites IN-L9225 and IN-JZ789 were >0.1 µg/L, but <0.75 µg/L (max 0.110 and 0.328 µg/L, respectively) so no further assessment for these compounds is deemed necessary. It should be

noted that both metabolites were indicated as toxicologically relevant in EFSA Journal 2015:13(7):4201. However RAC opinion of December 2016 changed harmonised classification of thifensulfuron-methyl and in consequence metabolites IN-L9225 and IN-JZ789 may be considered as toxicologically non-relevant. For more details, please refer to the Core Assessment, Part B, Section 10.

PEC_{GW} for IN-L9225 were >0.75 µg/L (max 0.831 µg/L) and the consumer risk assessment has been performed in the Core Assessment, Part B, Section 10 resulting with predicted exposure <2.0% ADI indicating acceptable risk. It should be noted that this metabolite was indicated as potentially toxicologically relevant in EFSA Journal 2015:13(7):4201. However RAC opinion of December 2016 changed harmonised classification of thifensulfuron-methyl and in consequence metabolites IN-L9225 and IN-JZ789 may be considered as toxicologically non-relevant. For more details, please refer to the Core Assessment, Part B, Section 10.

Overall, based on the performed evaluation no unacceptable risk to groundwater from rimsulfuron, thifensulfuron and their metabolites is expected following the intended uses of GF-3969.

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

The groundwater modelling was performed for the intended use pattern of GF-3969 in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PEC_{SW/SED} values were used in the risk assessment for aquatic organisms.

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

No unacceptable contamination of the atmosphere is expected following the intended uses of GF-3969.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The risk assessment for effects on birds and mammals was carried out according to the “Guidance of EFSA. Risk Assessment for Birds and Mammals” (EFSA, 2009)¹.

To achieve a concise risk assessment, a risk envelope approach was applied.

Birds

Regulatory testing for birds has been conducted with rimsulfuron and thifensulfuron methyl in accordance with EU requirements. The risk to birds was assessed based on the maximum single application rate of 1 × 135 g GF-3969/ha as this is protective of all intended uses.

For each of the active substances, the calculated TER values exceeded the relevant acute and chronic trigger values at the screening step and Tier 1, and so acceptable risk can be concluded. The risk to birds from exposure via drinking water was assessed and an acceptable risk was concluded.

An assessment of the risks via secondary poisoning was not triggered for the active substances rimsulfuron and thifensulfuron methyl, as they have log K_{ow} values of <3 and the potential for bioaccumulation is considered to be low.

As an acute study with birds is not available with the product GF-3969, therefore, acute combination toxicity assessment was conducted. None of the active substances was found to contribute to >90% of

¹ EFSA, 2009: Risk Assessment for Birds and Mammals, European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2009: 7(12):1438

the mixture toxicity and, therefore, acute risk was assessed by deriving the TER between the predicted endpoint by the concentration addition model and the sum of application rates of active substances. The TER exceeded the relevant trigger value (10); therefore, acceptable risk was concluded.

The combined long-term risk was concluded to be low based on TERmix exceeding the trigger of 5.

Calculations performed for isoxadifen-ethyl were presented for informative purposes only, since no EU agreed endpoints exist for this compound. In case the endpoints were confirmed at the EU level, acceptable acute and long-term risk from exposure to isoxadifen-ethyl would be concluded.

Mammals

Regulatory testing has been conducted with rimsulfuron and thifensulfuron methyl in accordance with EU requirements. The risk to mammals was assessed based on the maximum single application rate of 1×135 g GF-3969/ha as this is protective of all intended uses.

For each of the active substances, the calculated TER values exceeded the relevant acute and chronic trigger values at the screening step and Tier 1, and so acceptable risk can be concluded. The risk to mammals from exposure via drinking water was assessed and an acceptable risk was concluded.

An assessment of the risks via secondary poisoning was not triggered for the active substances rimsulfuron and thifensulfuron methyl, as they have log K_{ow} values of <3 the potential for bioaccumulation is considered to be low.

An acute toxicity with GF-3969 has been conducted and reported the LD_{50} to be >2000 mg product/kg bw. The acute combination toxicity assessment was conducted. None of the active substances was found to contribute to $>90\%$ of the mixture toxicity and, therefore, acute risk was assessed by deriving the TER between the predicted endpoint by the concentration addition model and the sum of application rates of active substances. The TER exceeded the relevant trigger value (10), therefore, acceptable risk was concluded. According to the Central Zone requirement, long-term combination toxicity assessment was conducted. None of the active substances was found to contribute to $>90\%$ of the mixture toxicity and, therefore, long-term risk was assessed by deriving the TER between the predicted endpoint by the concentration addition model and the sum of application rates of active substances. The TER exceeded the relevant trigger value (5), therefore, acceptable risk was concluded.

The combined long-term risk was concluded to be low based on TERmix exceeding the trigger of 5.

Calculations performed for isoxadifen-ethyl were presented for informative purposes only, since no EU agreed endpoints exist for this compound. In case the endpoints were confirmed at the EU level, acceptable acute and long-term risk from exposure to isoxadifen-ethyl would be concluded.

3.7.2 Effects on aquatic species

The maximum PEC_{sw} values resulted from the single application at a rate of 135 g GF-3969/ha (equivalent to a rate of 20 g rimsulfuron/ha, 12.5 g thifensulfuron methyl/ha and 15 g isoxadifen-ethyl/ha).

For rimsulfuron acceptable acute and chronic risk to fish, aquatic invertebrates and algae is shown at FOCUS Step 1.

For *Lemna gibba*, mitigation at FOCUS Step 4 is required to show acceptable risk for each of the uses. For the maximum application of 20 g rimsulfuron/ha, a 10-m buffer with 10 m vegetative filter strip is required to show acceptable risk in scenarios R1, R3 and R4. For remaining scenarios acceptable risk with no need for risk mitigation measures may be concluded.

An acceptable aquatic risk is concluded from the exposure to rimsulfuron metabolites at FOCUS Step 1

and 2.

For thifensulfuron methyl acceptable acute and chronic risk to fish, aquatic invertebrates, algae and sediment organisms is shown at FOCUS Step 1 and 2.

For aquatic plants a potential risk was triggered and so a refinement based on the agreed RMS geomean endpoint (from the review of confirmatory data) of 0.53 µg a.s./L was applied to the risk assessment. Acceptable risk could be concluded in scenarios relevant for Poland provided that 10 m vegetated filter strip to surface water bodies is respected.

An acceptable aquatic risk is concluded from the exposure to thifensulfuron methyl metabolites at FOCUS Step 1 and 2.

The combined toxicity assessment demonstrated that measured and estimated toxicity endpoints for *Lemna gibba* are comparable. For fish and *Daphnia magna* the formulated product was more toxic than predicted based on data for individual active substances and for this reason measured formulation endpoints were concluded to be relevant for the risk assessment purposes in case of these two groups of species.

For algae the estimated toxicity of the mixture was clearly lower than measured. Nevertheless, in case of algae the TU analysis demonstrated that thifensulfuron-methyl contributes at >90% to the toxicity of the mixture and hence no additional calculations were deemed necessary and risk assessment for this species based on active substance data was sufficient.

Bases on measured endpoints and calculated product PEC_{sw} values, an acceptable risk was concluded following the use of GF-3969 in maize at 135 g prod/ha with the inclusion of a 10 m buffer zone.

Overall, in order to protect aquatic organisms 10 m vegetated filter strip to surface water bodies must be respected in case of application of GF-3969 in Poland.

3.7.3 Effects on bees

Regulatory testing to assess the acute toxicity to bees has been conducted with rimsulfuron, thifensulfuron methyl and GF-3969 in accordance with EU requirements. HQ values for each of the active substances and product were calculated to be less than the trigger of 50, indicating acceptable risk to bees from acute oral and contact routes of exposure based on a single maximum application rate of 135 g GF-3969/ha to maize.

Regulatory testing is being conducted with the product to assess the chronic toxicity to honey bee larvae and adults and the studies will be provided as soon as possible.

3.7.4 Effects on other arthropod species other than bees

Regulatory testing has been conducted with the product. The Tier I laboratory studies showed acceptable in-field and off-field effects for *T. pyri* and *A. rhopalosiphi* from applications of GF-3969 according to the maximum exposure without the need for risk mitigation measures.

3.7.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (EU, 2002), as provided by the Commission Services.

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have

been carried out with rimsulfuron, thifensulfuron methyl and the formulated product GF-3969.

Earthworms

The risk to earthworms and other soil organisms was assessed using the toxicity exposure ratios (TERs) between the toxicity endpoints for GF-3969, rimsulfuron, thifensulfuron methyl, formulation GF-3969 and relevant metabolites, and the maximum PEC_{soil} or $PEC_{accumulation}$ resulting from the single application rate of 1×135 g product/ha. Acceptable risk could be concluded.

Other soil macro-organisms

For each of the active substances and metabolites the chronic TER values were greater than the trigger of 5, indicating acceptable risk to non-target soil macro-organisms following use of GF-3969 according to the proposed use pattern. A low toxicity of the product to soil organisms was shown and acceptable risk concluded based on maximum predicted exposure.

Soil microbial activity

The risk of GF-3969, the active substances and relevant metabolites to soil micro-organisms was evaluated by comparison of the reported concentrations with effects <25% derived from laboratory tests, with maximum initial PEC_{soil} or $PEC_{accumulation}$ based on the highest single application rate of 135 g product/ha. No significant effects of >25% effect were reported at soil concentrations where exceeded the relevant PEC_{soil} values, indicating that the risk to soil micro-organisms is acceptable following the use of GF-3969 according to the proposed use pattern.

3.7.6 Effects on non-target terrestrial plants

Regulatory testing has been conducted with the product, GF-3969 to assess effects on vegetative vigour and seedling emergence. The seedling emergence study was accepted by the zRMS, but the vegetative vigour study was agreed after exclusion of control replicates of oilseed rape and sorghum which exhibited phytotoxic effects and recalculation of endpoints for these two species. The risk assessment was performed using deterministic and probabilistic approach. Overall, acceptable risk to non-target terrestrial plants could be concluded from the intended uses of GF-3969 in Poland, provided that following risk mitigation measures are respected:

- 5 m unsprayed buffer zone to non-agricultural land, or
- 90% drift reduction.

~~invalidated due to phytotoxic effects observed in control replicates and their potential impact on growth parameters of control plants at the test termination and in consequence on the endpoints calculated for the test item groups.~~

~~Since no other data exist, the risk assessment for non-target plants could not be finalised and no final conclusion may be taken.~~

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species were not required.

3.8 Relevance of metabolites (Part B, Section 10)

The ground water concentration of metabolites of two active substances rimsulfuron and thifensulfuron methyl and the safener isoxadifen-ethyl were simulated using the latest version of FOCUS groundwater models – PEARL 4.4.4 and PELMO 5.5.3.

The application scenarios of the formulated product GF-3969 are provided in the Part B, Section 10. Simulations were conducted with EU-reviewed endpoints for rimsulfuron (EFSA, 2005; EFSA, 2018) and thifensulfuron methyl (EFSA, 2015).

The EFSA conclusion for active substance renewal of rimsulfuron in Europe was published in 2018, although its approval is still pending. As supplemental information, the PEC_{gw} of rimsulfuron metabolites simulated with both 2005 and 2018 EFSA endpoints are provided.

In the simulation with the 2018 EFSA endpoints, the Tier 2 PEC_{gw} of rimsulfuron IN-E9260 was refined with the field-derived degradation endpoints, and demonstrated to be $<0.1 \mu\text{g/L}$.

The maximum concentrations of metabolites in ground water for rimsulfuron (EFSA, 2005), rimsulfuron (EFSA, 2018), thifensulfuron methyl (EFSA, 2015), and the safener isoxadifen-ethyl are summarized in the Part B, Section 10.

Based on the trigger concentration of $>0.1 \mu\text{g/L}$, the following metabolites require toxicological relevance assessment:

Rimsulfuron (EFSA, 2005): IN-70941, IN-70942 and IN-E9260;
Rimsulfuron (EFSA, 2018): IN-70941, IN-70942 and IN-E9260;
Thifensulfuron (EFSA, 2015): IN-L9225, IN-L9223, and IN-JZ789;
Isoxadifen-ethyl (safener): None.

The details of groundwater simulation can be found in Core Part B, Section 8 (Environmental fate and behaviour).

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

Not required.

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

All respective information to address issues related to non-target terrestrial plants raised by the zRMS was provided by the Applicant and for this reason no further data are deemed necessary. The request below was thus struck through as being no longer relevant.

~~Further data to address effects of GF 3969 on vegetative vigour. Respective information on effects of GF 3969 plus both surfactants (DPX KG691 and Codacide) should be made available.~~

Copy of the product authorization

Appendix 1 Copy of the product label

Komentarz oceniających:

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

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie dwuletnich badań stabilności dla środka przechowywanego w opakowaniach wykonanych z HDPE. 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 (Comb. T., 2020, 190492). 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 zapisów nazw grup chemicznych, do których przyporządkowano substancje czynne oraz ich zawartości. Dodano zawartości substancji czynnych wyrażone w procentach i skorygowano zawartość sejfnera.
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego potwierdzono zgodność łącznego stosowania środka ochrony roślin Dragster/GF-3969, ze środkami: Actirob B, Adigor, Astuss, Auxo, Banvel 4 S, Biathlon, Callisto, Cambio, Camix SE 460 g/L, Casper, Conquerant, Dakota P, Dual gold, Gondor, Helisol, Isard, Peak, Roundup Extra, Silwet L77, Surf 2000, DPX-V4B07. Przedstawiono również wyniki badań potwierdzające zgodność stosowania środka ochrony roślin z adjuwantem oraz koncentratem oleju:
 - 0,2 % v/v *Trend 90 spray tank adjuvant*;
 - 1,5 % v/v *crop oil (Codacide) - crop oil - Vegetable oil (rape seed oil)*;
 - 0,135 kg produktu/ha w mieszaninie z adjuwantami 0,2% v/v *Vivolt* i 1,245%v/v *Codacide* w 50 i 400L wody/ha.

Sekcja skuteczność:

1. Na podstawie danych przedłożonych przez wnioskodawcę w zakresie sekcji skuteczność, możliwa jest rejestracja środka Dragster przeznaczonego do zwalczania chwastnicy jednostronnej i chwastów dwuliściennych w kukurydzy w dawce 135 g pr/ha, 1 raz w sezonie wegetacyjnym lub w systemie dawek dzielonych w stosunku 50:50, czyli w dawce 67,5 g pr/ha dwa razy w sezonie wegetacyjnym, zgodnie z informacjami zawartymi w tabeli GAP.
2. Zgodnie z ustaleniami harmonizacyjnymi w zakresie wymaganej liczby badań (6 badań dla gatunków ważnych i 3 badania w przypadku chwastów mniej istotnych) i ich lokalizacji (obligatoryjnie badania ze strefy NE oraz badania z krajów ościennych stref MAR lub SE jako wspierające rejestrację środka w Polsce) dla poszczególnych gatunków chwastów w przypadku nowej mieszaniny znanych substancji, w etykiecie pozostawiono następujące gatunki chwastów: chwastnica jednostronna, szarłat szorstki, komosa biała, rdestówka powojowata, gwiazdnica pospolita, przetacznik perski i maruna bezwonna.
3. Nie zaakceptowano następujących chwastów z uwagi na niewystarczającą liczbę badań: ambrozja bylicolistna (brak badań ze strefy NE), bodziszek drobny (brak badań ze strefy NE), fiołek polny (przedłożono 1 badanie ze strefy NE, brak badań z krajów ościennych), jasnota purpurowa (brak badań ze strefy NE), ketmia południowa (brak badań ze strefy NE), komosa wielonasienna (brak badań ze strefy NE), perz właściwy (brak badań ze strefy NE), rdest kolankowaty (brak badań ze strefy NE), rdest plamisty (przedłożono 1 badanie ze strefy NE, brak badań z krajów ościennych), rdest ptasi (brak badań ze strefy NE), rumianek pospolity (brak badań ze strefy NE), rzepień pospolity (brak badań ze strefy NE), sorgo alepskie (brak badań ze strefy NE), tobołki polne (brak badań ze strefy NE), wiechlina roczna (brak badań ze strefy NE), włośnica zielona (brak badań ze strefy NE), zaślaz pospolity (brak badań ze strefy NE),

żółtlica drobnokwiatowa (brak badań ze strefy NE), palusznik krwawy (brak badań ze strefy NE), przytulia czepna (przedłożono 2 badania ze strefy NE, brak badań z krajów ościennych), słonecznik (przedłożono 1 badanie ze strefy NE, brak badań z krajów ościennych), bielun dziędzierzawa (brak badań ze strefy NE), psianka czarna (przedłożono 1 badanie ze strefy NE, brak badań z krajów ościennych). Zgodnie z ustaleniami do ważnych chwastów w uprawie kukurydzy należą: rdest plamisty oraz psianka czarna, dla których należy przedłożyć 6 badań skuteczności. Dla pozostałych gatunków wymagane są 3 badania skuteczności.

4. Z uwagi na to, że w zaakceptowanym zakresie chwastów brak jest chwastów wieloletnich, a wśród chwastów jednoliściennych pozostała jedynie chwastnica jednostronna, z części OPIS DZIAŁANIA wykreślono odpowiednie rekomendacje.
5. W części STOSOWANIE ŚRODKA, w przypadku zastosowania jednorazowego, usunięto zalecenia dotyczące perzu właściwego oraz chwastów jednoliściennych (oprócz chwastnicy jednostronnej), tak aby informacje zawarte w tej części były zgodne z wnioskami końcowymi przeprowadzonej oceny.
6. W części dotyczącej następstwa roślin, zweryfikowano zapis dotyczący gatunków uprawnych. W przypadku roślin wysiewanych jesienią doprecyzowano gatunki zbóż ozimych (jęczmień, żyto, pszenica i pszenżyto). W przypadku roślin wysiewanych wiosną wymieniono właściwe gatunki uprawne, które zgodnie z wynikami badań mogą być bezpiecznie wysiewane po zastosowaniu środka Dragster.
7. W części dotyczącej strategii zarządzania odpornością dodano informację o przynależności substancji czynnych zawartych w środku do właściwej grupy HRAC oraz zalecenie o przestrzeganiu liczby zabiegów wskazanej w etykiecie.
8. Doprecyzowano rodzaj przemijających objawów fitotoksyczności, które mogą się pojawić na roślinach kukurydzy po zastosowaniu środka Dragster.
9. Dodano zalecenia dotyczące wpływu środka na uprawy sąsiednie. Określono wymiar stref buforowych oraz technik ograniczających znoszenie cieczy środka na te uprawy.
10. Doprecyzowano zalecenia dotyczące procedury mycia opryskiwacza.

Sekcja metody analityczne:

Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W zakresie klasyfikacji zagrożeń wynikających z potencjalnego działania drażniącego na oko, zaproponowana klasyfikacja została zmieniona zgodnie zaakceptowanymi punktami końcowymi z badań *in vivo*.

W części etykiety dotyczącej klasyfikacji zagrożeń zmodyfikowano zwrot określający środki ostrożności zapobieganie P280 zgodnie z zaakceptowanym punktem końcowym dotyczącym właściwości drażniących dla oka.

2. W części etykiety dotyczącej zalecanych środków ostrożności dla osób stosujących produkt, zapis został zmodyfikowany z uwzględnieniem klasyfikacji CLP ~~działania drażniącego na oko~~ oraz szacowania NDE.

Sekcja pozostałości:

1. Z punktu widzenia pozostałości zaakceptowano stosowanie środka Dragster w mieszaninie z adiuwantem.
2. Na podstawie badań polowych możliwe jest zastosowanie dawki 135 g/ha dla jednorazowego zastosowania, bądź zastosowanie dawki dzielonej, tak jak proponuje Wnioskodawca, przy czym nie można przekroczyć łącznie dawki 135 g/ha środka.
3. Zaakceptowano proponowany okres karencji dla kukurydzy wynoszący 60 dni.
4. Zaakceptowano zapisy dotyczące roślin następczych.
5. Zaakceptowano zapis dotyczący braku możliwości stosowania środka w ochronie kukurydzy cukrowej i pękającej.

Sekcja los i zachowanie:

Brak uwag.

Sekcja ekotoksykologia:

1. Dodano zwrot P501 oraz wskazano, że przypisano symbol P391 do zwrotu „Zebrać rozsypany produkt”.
2. Wprowadzono odpowiednie zwroty dotyczące zarządzania ryzykiem w celu ochrony organizmów wodnych oraz roślin niebędących celem zwalczania. Należy zauważyć, że zwroty ograniczające ryzyko dla roślin lądowych pokrywają standardowe zwroty wprowadzane w celu ochrony stawonogów lądowych, gdy ocena wykazuje dopuszczalne ryzyko (tzn. standardowa strefa ochronna o szerokości 1 m od terenów nieużytkowanych rolniczo).

Projekt etykiety nie został zweryfikowany pod kątem oceny w zakresie ekotoksykologii, gdyż ocena nie mogła zostać zakończona ze względu na niewystarczające dane dotyczące toksyczności środka dla roślin lądowych niebędących celem działania.

Posiadacz zezwolenia:

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

DRAGSTER

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

tifensulfuron metylu (związek z grupy pochodnych sulfonilomocznika) – **92,6 g/kg (9,26%)**,
rimsulfuron (związek z grupy pochodnych sulfonilomocznika) – **148,15 g/kg (14,82%)**,
isoxadifen (związek nie będący substancją czynną) – **111,1 g/kg (11,11%) (36,0%)**.

Zezwolenie MRiRW nr



UWAGA

~~H319 Działa drażniąco na oczy~~

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

~~EUH 208: Zawiera Isoxadifen-ethyl. Może powodować wystąpienie reakcji alergicznej .~~

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

~~P280 Stosować rękawice ochronne./ochronę oczu/ochronę twarzy~~

~~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.~~

~~P337 + P313 W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza~~

P391 Zebrać rozsypany produkt

P501 Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach

OPIS DZIAŁANIA

DRAGSTER jest środkiem chwastobójczym w formie granul do sporządzania zawiesiny wodnej, stosowanym nalistnie i przeznaczonym do powschodowego zwalczania ~~jednorocznych chwastów jednoliściennych (w tym chwastów prosowatych)~~ **chwastnicy jednostronnej** oraz chwastów dwuliściennych w kukurydzy. ~~Zwalcza również niektóre wieloletnie chwasty jednoliściennie i dwuliściennie.~~

Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

DZIAŁANIE NA CHWASTY

DRAGSTER jest selektywnym herbicydem o działaniu systemicznym. Pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie i szybko przemieszczany w roślinie, wstrzymując jej wzrost i rozwój. Pierwsze objawy działania są widoczne wkrótce po zastosowaniu, po czym następuje stopniowe przebarwianie się roślin. Chwasty zamierają całkowicie w 10-25 dni po wykonaniu zabiegu.

Środek działa najskuteczniej na młode, intensywnie rosnące chwasty dwuliścienne, w fazach od 2 do 4 liści (BBCH 12-14) i chwasty jednoliścienne, w fazach od 3 do 5 liści (BBCH 13-15).

Wrażliwość	GF-3969 + adjuwant	
	135 g pr/ha	Dawka dzielona 135 g pr/ha (67.5 g pr/ha x 2 zastosowania)
Chwasty wrażliwe 85-100%	Ambrozja bylicolistna, Bodziszek drobny, Chwastnica jednostronna, Fiołek polny, Gwiazdnica pospolita, Jasnota purpurowa, Ketmia południowa, Komosa biała, Komosa wielonasienna, Maruna bezwonna, Perz właściwy, Rdest kolankowaty, Rdest plamisty, Rdest ptasi, Rdestówka powojowata, Rumianek pospolity, Rzepień pospolity, Sorgo alepskie, Szarłat szorstki, Tobolki polne, Wiechlina roczna, Włośnica zielona, Zaślaz pospolity, Żółtlica drobnokwiatowa	Ambrozja bylicolistna, Bieleń dziedzierzawa, Bodziszek drobny, Chwastnica jednostronna, Fiołek polny, Gwiazdnica pospolita, Jasnota purpurowa, Ketmia południowa, Komosa biała, Komosa wielonasienna, Maruna bezwonna, Palusznik krwawy, Perz właściwy, Przytulia czepna, Rdest kolankowaty, Rdest plamisty, Rdest ptasi, Rdestówka powojowata, Rumianek pospolity, Rzepień pospolity, Sorgo alepskie, Szarłat szorstki, Tobolki polne, Wiechlina roczna, Włośnica zielona, Zaślaz pospolity, Żółtlica drobnokwiatowa
Chwasty średniowrażliwe 70-85%	Palusznik krwawy, Przetacznik perski, Przytulia czepna, Słonecznik	Słonecznik, Przetacznik perski
Chwasty średnioodporne 60-69.9%	Bieleń dziedzierzawa	
Chwasty odporne 0-59.9%	Psianka czarna	Psianka czarna

STOSOWANIE ŚRODKA

Środek Dragster stosować wyłącznie w mieszaninie z adjuwantem.

ROŚLINY ROLNICZE

Kukurydza

A: Zastosowanie jednorazowe

Maksymalna dawka dla jednorazowego zastosowania: 135 g/ha.

Zalecana dawka dla jednorazowego zastosowania: 135 g/ha.

Środek stosować w fazie 1-8 liści kukurydzy (BBCH 11 - 18), gdy:

~~większość roślin perzu osiągnęła wysokość 15-20 cm,~~

- rośliny chwastnicy jednostronnej i innych chwastów jednoliściennych znajdują się w fazie 3 liści do końca fazy krzewienia,

- większość chwastów dwuliściennych znajduje się w fazie 2-4 liści.

Herbicyd Dragster należy stosować wyłącznie z adjuwantem

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

B: Dawki dzielone

W przypadku silnej presji ze strony chwastów lub w przypadkach, gdy warunki termiczne mogą potęgować ryzyko ewentualnych uszkodzeń roślin kukurydzy zaleca się stosowanie dawek dzielonych.

Pierwszy zabieg

Termin stosowania: środek należy zastosować w fazie 2-3 liści kukurydzy (BBCH 12-13)
Maksymalna/zalecana dawka dla jednorazowego zastosowania: 67.5 g/ha.
Drugi zabieg
Termin stosowania: środek należy zastosować maksymalnie do końca fazy 8 liścia właściwego (BBCH < 18).
Maksymalna/zalecana dawka dla jednorazowego zastosowania: 67.5 g/ha.
Liczba zabiegów: 2.
Odstęp pomiędzy zabiegami: 7 – 10 dni.
Zalecana ilość wody: 100-400 l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

5.1.2 NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać jedynie kukurydzę (przed siewem należy przeprowadzić orkę).

Jesienią, po zbiorze kukurydzy można wysiewać zboża ozime (jęczmień, żyto, pszenica i pszenżyto) rzepak ozimy, lucernę siewną, groch siewny. Wiosną i jesienią następnego roku można uprawiać wszystkie rośliny rzepak jary, jęczmień jary, ziemniaki, buraki cukrowe, słonecznik, soję, groch, bawełnę, lucernę i pomidory.

ŚRODKI OSTROŻNOŚCI, OKRES KARENCEJ I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

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

Kukurydza - 60 dni

1. Strategia zarządzania odpornością

Środek Dragster zawiera substancje czynne (tifensulfuron metylu i rimsulfuron) klasyfikowane wg mechanizmu działania do herbicydów z grupy inhibitorów ALS (HRAC Grupa 2) (tifensulfuron metylu i rimsulfuron). Stosowanie po sobie herbicydów o tym samym mechanizmie działania może prowadzić do wyselekcjonowania chwastów odpornych. Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane 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, nie przekraczać zalecanej liczby zabiegów,
- 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 mieszaninę herbicydów (substancji czynnych) 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.

2. Po zastosowaniu środka na niektórych odmianach kukurydzy mogą wystąpić przemijające objawy fitotoksyczności (np. przebarwienia, zniekształcenia, nekrozy lub karłowatości).

3. Warunki niekorzystne dla wzrostu i rozwoju kukurydzy w okresie poprzedzającym zabiegi jak i po zabiegu mogą zwiększyć ryzyko wystąpienia objawów fitotoksyczności.
4. Środka nie stosować:
 - w kukurydzy cukrowej, pękającej oraz w uprawie materiałów hodowlanych,
 - na rośliny kukurydzy znajdujące się w fazie powyżej 8 liści,
 - bezpośrednio po okresie długotrwałych chłódów (lub ciągłych opadów), na rośliny, których wzrost został zahamowany. Zabieg można wykonać po wznowieniu intensywnego wzrostu przez rośliny kukurydzy (gdy zostanie odbudowana powłoka woskowa),
 - w temperaturze powietrza poniżej 10°C i powyżej 25 °C oraz podczas silnego nasłonecznienia,
 - gdy różnice temperatur między dniem a nocą są większe niż 15 °C,
 - na plantacjach roślin chorych, osłabionych przez szkodniki, przymrozek, mróz, nadmiar wilgoci, suszę, niedobór składników mineralnych lub inne czynniki powodujące osłabienie wzrostu (stosowanie na glebach bardzo lekkich zwiększa ryzyko wystąpienia i wpływu wymienionych czynników stresowych),
 - na mokre rośliny (rosa, deszcze),
 - przed spodziewanymi opadami, przymrozkami lub bezpośrednio po nich,
 - gdy przewiduje się wystąpienie opadu w przeciągu 3 godzin po zabiegu.
5. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych:
 - a. w przypadku uprawy sorga wymagane jest zachowanie strefy buforowej 3 m lub stosowanie technik ograniczających znoszenie cieczy środka o 50%
 - b. w przypadku uprawy buraka cukrowego wymagane jest zachowanie strefy buforowej 3 m lub stosowanie technik ograniczających znoszenie cieczy środka o co najmniej 75%
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

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 zakończeniu pracy należy niezwłocznie wmyć wodą zbiornik oraz wszystkie części składowe opryskiwacza, zgodnie z fabryczną instrukcją obsługi. Do mycia opryskiwacza należy używać odpowiednich środków myjących. Wypłukać wnętrze zbiornika czystą wodą, używając co najmniej jednej dziesiątej objętości zbiornika opryskiwacza. Po przepłukaniu przez pompę i przewody opryskowe, opróżnić zbiornik i powtórzyć cały proces jeszcze dwukrotnie, aby zapewnić procedurę potrójnego płukania. Do drugiego płukania zaleca się dodać środek czyszczący do opryskiwacza.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

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

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

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.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie **zadarnionej** strefy ochronnej o szerokości **10 metrów** ~~±m~~ od zbiorników i cieków wodnych.

W celu ochrony roślin lądowych niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 metrów od terenów nieużytkowanych rolniczo lub redukcja znosu z chmurą oprysku o 90% za pomocą odpowiednich technik antyznoszeniowych.

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie od terenów nieużytkowanych rolniczo strefy ochronnej o szerokości: 1m~~

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

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

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

Okres ważności - 2 lata

Data produkcji

Zawartość netto

Nr partii

Appendix 2 Letter of Access

Letters of Access are provided for thifensulfuron methyl, isoxadifen-ethyl and nicosulfuron (studies not owned by Corteva Agriscience). A Letter of Ownership is provided for the rimsulfuron studies.

Appendix 3 Lists of data considered for national authorization

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of active substance.

Unless specifically indicated, all tests submitted in this section, which involve vertebrate animals, address mandatory data requirements which could not be met with alternative methods. Studies were conducted according to prescribed guidelines.

Unless specifically indicated, this section does not contain reports of studies duplicating previous tests on vertebrate animals.

List of data submitted by the applicant and relied on

This list refers to new studies, submitted and summarised in the dRR for support of the authorisation of GF-3969. The studies for which data protection is claimed were conducted according to GLP or GEP standards and have not been protected before in this Member State. A 10-year protection is claimed from the date on which the authorization is granted, according to paragraph 18 of the Guidance Document on Data Protection SANCO/12576/2012-rev1.1.

B0 Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

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, 2.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.2/01	Jones, J.S.	2017	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50PX (DPX-V4B07) 24.08 WG blend of water dispersible granules (14.82% + 9.26% + 11.11%): Laboratory study of explosive and oxidizing properties, flammability of solids and the relative self ignition temperature DuPont-48798 E. I. du Pont de Nemours and Company GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.3/01	Jones, J.S.	2017	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50PX (DPX-V4B07) 24.08 WG blend of water dispersible granules (14.82% + 9.26% + 11.11%): Laboratory study of explosive and oxidizing properties, flammability of solids and the relative self ignition temperature DuPont-48798 E. I. du Pont de Nemours and Company GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.4/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 2.6/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.7/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.7/02	Comb, T.	2021	GF-3969 (DPX-V4B07) blend of paste extruded granules: ambient storage stability in HDPE – Two Years. 190496 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont/Corteva
KCP, 2.8.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.8.2/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 2.8.3/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.8.5.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.8.5.2/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.8.5.3/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 2.8.7/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 2.9/01	Huby, J.P.	2017	DPX-V4B07 35.18% WG: Laboratory study of physical compatibility in water AT-18-004 DuPont de Nemours ERDC GLP: No Published: No	N	N		DuPont
KCP, 2.9/02	Huby, J.P., Callemeyn, J.	2021	GF-3969 + Vivolt® and GF-3969 + Codacide®: Physical and Chemical Compatibility evaluation Corteva Agriscience Laboratory Report No: AT-21-023 GLP: No Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Corteva
KCP, 2.11/01	Huby, J.P.	2021	Practical value test in a 200L sprayer to evaluate procedure to mitigate foaming created by a mixture made of GF-3969 + Vivolt® (DPX-KG691) AT-21-021 Corteva Agriscience™ Agriculture division of DowDupont Application Technology service GLP: No Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Corteva
KCP, 4.2/01	Huby, J.P.	2018	Rimsulfuron 14.8% + Thifensulfuron-methyl 9.25% + Isoxadifen 11.11% WG (DPX-V4B07 35.18% WG) laboratory study of spray tank clean out AT-18-009 DuPont de Nemours (France) S.A.S. GLP: No Published: No	N	N		DuPont

Part B3

Efficacy data and information

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, 6.0/01	Freitag, N.	2020	Biological assessment dossier Detailed summary Product name: GF-3969 Chemical active substance(s): Rimsulfuron, 148.15 g/kg Thifensulfuron methyl, 92.6 g/kg Isoxadifen-ethyl, 111.1 g/kg Central registration zone Zonal rapporteur member state: Poland Core assessment DuPont-51169 CEU DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.0/02	Freitag, N.	2020	GF-3969 (rimsulfuron 148.15 g/kg, thifensulfuron methyl 92.6 g/kg, isoxadifen-ethyl 111.1 g/kg): Trial reports efficacy, selectivity, and yield (central zone) DuPont-51170 CEU DuPont European Research and Development Centre (ERDC) GEP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.1/01	Monteix, B.	2017	Field efficacy trial to evaluate DPX-V4B07 at different water volumes in corn PEH-17-108 DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	N		DuPont
KCP, 6.1/02	Notter, J.-S.	2018	Growth chamber studies to justify each rate of active ingredient in GF-3969 (rimsulfuron + thifensulfuron + isoxadifen) on major corn weeds (2017 & 2018 Studies) PEH-18-101 DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	N		DuPont

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, 6.5.1/01	Siemoneit-Gast, S.	2017	DPX-V4B07 35.18WG + surfactant Trend90. Standardised bioassay for the determination of the EC ₁₀ (NOEL) and EC ₅₀ values for herbicides and selected following crops in soil GEP03 Rheinland-Pfalz (RLP) AgroScience GmbH GEP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.5.2/01	Arnie, J.R., McKelvey, R.A., Aufderheide, J.A., Lockard, L.A., Zhang, L.	2020	DPX-V4B07 24 WG: Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure 49942 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.5.2/02	Spatz, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on terrestrial (non-target) plants: Seedling emergence and seedling growth test DuPont-49939 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.5.3/01	Huby, J.P.	2018	DPX-V4B07 35.18WG: Laboratory study of physical compatibility in water AT-18-004 DuPont de Nemours (France) S.A.S. GLP: No Published: No	N	N		DuPont

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, 6.5.3/02	Huby, J.P.	2018	Rimsulfuron 14.8% + Thifensulfuron methyl 9.25% + Isoxadifen ethyl 11.11% WG (DPX-V4B07 35.18% WG) laboratory study of spray tank clean out AT-18-009 DuPont de Nemours ERDC GLP: No Published: No	N	N		DuPont
KCP, 6.5.3/03	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron 50SG/Isoxadifen ethyl 50WG (DPX-V4B07). A blend paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate response test to evaluate the effect on the parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49972 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.5.3/04	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49973 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 6.5.3/05	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49934 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 6.5.3/06	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 Surfactant: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (acari, phytoseiidae) DuPont-49935 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

B5 Analytical methods

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP, 5.1.1/01	Robson, D.D.	2017	Validation of the analytical method for determination of thifensulfuron methyl (DPX-M6316), dicamba (DPX-Y0727), nicosulfuron (DPX-V9360), rimsulfuron (DPX-E9636) and isoxadifen ethyl (DPX-X4145) in DPX-V4B07 24.08WG and DPX-VRF36 60.42 blends of paste-extruded products DuPont-44927 DuPont Stine-Haskell Research Center GLP: Yes Published: No	N	DuPont
KCP, 5.1.1/02	Robson, D.D.	2017	Determination of thifensulfuron methyl (DPX-M6316), dicamba (DPX-Y0727), nicosulfuron (DPX-V9360), rimsulfuron (DPX-E9636) and isoxadifen ethyl (DPX-X4145) in DPX-V4B07 24.08WG and DPX-VRF36 60.42WG blends of paste-extruded products DuPont-50247 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont
KCP, 5.1.1/03	Baker L.	2022	GF-3969 (DPX-V4B07) - Example Chromatograms E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont
KCP, 5.1.2/01	Arnie, J.R., Aufderheidie, J, Lockard, L., Zhang, L.	2020	Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure 49942 Eurofins EAG Agrosience LLC GLP: Yes Published: No	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP, 5.1.2/02	Bergfield, A.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49944 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/03	Cornement, M.	2018	Rimsulfuron-toxicity to Honey bees (<i>Apis mellifera</i> L.) larvae after repeated exposure under <i>in vitro</i> laboratory conditions 20170301 Innovative Environmental Services (IES) Ltd GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/04	xxxxxxxxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions DuPont-49948, Revision No. 1 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont
KCP, 5.1.2/05	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 48-Hour static renewal, acute toxicity test with the cladoceran, <i>Daphnia magna</i> DuPont-49949, Revision No. 1 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/06	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus crop oil (Codacide): 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49978 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP, 5.1.2/07	Hoover, E.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) a blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> DuPont-49943 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/08	Spence, C.	2020	Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active) – EU, initiated 2017 DuPont-49732 Charles River Laboratories Edinburgh Ltd GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/09	Verge, E.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + codacide oil: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48951 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont
KCP, 5.1.2/10	Verge, E.	2019	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + surfactant DPX-KG691: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48899, Revision No. 1 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
CP, 5.2	Charles, E., Doran, A. M., Klems, J. P.	2017	Independent laboratory validation of analytical method DuPont-13412 for the determination of thifensulfuron methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in olives and soybean seed using SPE purification and LC/MS/MS detection DuPont-13398, Supplement No. 1 Inveresk GLP: Yes Published: No	N	DuPont
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2012	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont
CP, 5.2	Gant, A.G.	2012	Independent laboratory validation of DuPont-30449 "Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS" DuPont-30450 ABC Laboratories, Inc. (Missouri) GLP: Yes Published: No	N	DuPont
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont
CP, 5.2	Henze, R. M., Stry J. J.	2016	Analytical method for the determination of chlorsulfuron, metsulfuron methyl, thifensulfuron methyl and tribenuron methyl in plasma and urine by LC/MS/MS DuPont-47394 Stine-Haskell Research Center GLP: No Published: No	N	FMC*

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 5.2/02	Henze, R.M., Stry, J.J.,	2013	Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-35704 GLP: No Published: No	N	DuPont
KCP 5.2/07	Mason, B.J.	2013	Independent laboratory validation of DuPont-35704, "Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS" Morse Laboratories, Inc. DuPont-36531 GLP: Yes Published: No	N	DuPont

*FMC Letter of Access available

B6 Mammalian toxicology

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, 7.1.1/01	xxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute oral toxicity study in rats - up-and-down procedure DuPont-49958 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.2/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute dermal toxicity study in rats DuPont-49959 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.3/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Inhalation median lethal concentration (LC ₅₀) study in rats DuPont-49960 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.4/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary skin irritation in rabbits DuPont-49965 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 7.1.4/02	Costin, G.E., Pham, R., Sadowski, N.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50 SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Skin irritation test (SIT) using the epiderm skin model DuPont-50172 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.5/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary eye irritation in rabbits DuPont-49964 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.5/02	Wilt, N., Pham, R., Sadowski, N.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50 SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): epiocular™ eye irritation test (EIT) for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage DuPont-50173 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 7.1.6/01	xxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Local lymph node assay (LLNA) in mice DuPont-49966 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 7.1.7/01	Clare, K.	2018	Rimsulfuron metabolite (IN-E9260) (CAS # 117671-01-9): Genetic toxicity evaluation using a micronucleus test in TK6 human lymphoblastoid cells MNT00515 Gentronix Limited GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Helm AG, SAPEC AGRO S.A., DuPont
KCP, 7.1.7/02	Ruwona, T., Sheehan, D., Koch, W.T.	2018	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Induction of antioxidant- response-element dependent gene activity and cytotoxicity (using MTT) in the keratinocyte ARE-reporter cell line keratinosens DuPont-50245 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP 7.4/01	Dxxxxxxxxxxxxxxxxxxxx	1999	Oral toxicity test after 28-day repeated administration in the rat. TF375/99-0777 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC

B7 Metabolism and residues

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
KCA, 6.3.1/01	Spence, C.	2020	Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active)-EU, initiated 2017 DuPont-49732 Charles River Laboratories (UK) GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

B8 Environmental fate

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
KCP, 9.1.1.1/01	Huber, A.	2007	The degradation of rimsulfuron in soil and aquatic systems – Summary of kinetic calculations DuPont 23315 DuPont de Nemours (Deutschland) GmbH GLP: No Published: No	N	N		DuPont
KCP, 9.1.2.1/01	Khanijo, I., Huang, M.X.	2015	Degradation of rimsulfuron (DPX-E9636) and its metabolites IN 70941, IN 70942, IN E9260 and IN J0290 in field dissipation studies – a kinetic calculation report DuPont 41948 E. I. du Pont de Nemours and Company GLP: No Published: No	N	N		DuPont
KCP, 9.2.4.1/01	Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in groundwater following application to maize – A modelling assessment for Europe using the 2018 EFSA endpoints DuPont-51202 EU E. I. du Pont de Nemours and Company GLP: No Published: No	N	N		DuPont
KCP, 9.2.4.1/02	Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron (DPX- E9636) and metabolites in groundwater: A modeling study conducted for maize with FOCUS PEARL 4.4.4 and PELMO 5.5.3 with the 2005 EFSA-recommended endpoints DuPont-51201 EU, Revision No. 1 E. I. du Pont de Nemours and Company GLP: No Published: No	N	N		DuPont

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
KCP, 9.2.5/01	Yamsani, S., Mishra, N., Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in surface water following applications to maize - a modelling assessment with the 2018 EFSA endpoints DuPont-51210 EU E. I. du Pont de Nemours and Company GLP: No Published: No	N	N		DuPont
KCP, 9.2.5/02	Yamsani, S., Mishra, N., Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in surface water following applications to maize - a modeling assessment for Europe with the 2005 EFSA endpoint DuPont-51207 EU, Revision No. 1 E. I. du Pont de Nemours and Company GLP: No Published: No	N	N		DuPont

B9 Ecotoxicological studies

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, 10.2.1/01	xxxxxxxxxxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions DuPont-49948, Revision No. 1 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxGLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.2.1/02	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 48-Hour static renewal, acute toxicity test with the cladoceran, <i>Daphnia magna</i> DuPont-49949, Revision No. 1 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.2.1/03	Hoover, E.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) a blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> DuPont-49943 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.2.1/04	Bergfield, A.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49944 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.2.1/05	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus crop oil (Codacide): 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49978 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.1.1.1/01 and KCP, 10.3.1.1.2/01	Tome, H.V.V.	2018	Isoxadifen ethyl 50WG / Rimsulfuron 25SG / Thifensulfuron methyl 50SG (DPX-V4B07), a blend of paste extruded granules (11.11% + 14.82% + 9.26 active) plus codacide oil surfactant: An acute oral and contact toxicity study with the honey bee DuPont-48892 EAG Laboratories GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.1.1.1/02 and KCP, 10.3.1.1.2/02	Tome, H.V.V., Porch J.R.	2018	Isoxadifen ethyl 50WG / Rimsulfuron 25SG / Thifensulfuron methyl 50SG/ (DPX-V4B07), a blend of paste extruded granules (11.11% + 14.82 + 9.26% active) plus Trend 90 surfactant: An acute oral and contact toxicity study with the honey bee DuPont-48950 EAG Laboratories GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.3.1.1.1/03 and KCP, 10.3.1.1.2/03	Verge, E.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + codacide oil: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont 48954 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.1.1.1/04 and KCP, 10.3.1.1.2/04	Verge, E.	2019	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + surfactant DPX-KG691: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont 48899, Revision No. 1 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.1.2/01	Porch, J.R., Riles, B.	2021a	GF-3969 (DPX-V4B07) + DPX-KG691 (VIVOLT): A Chronic Dietary Toxicity test with the Honey Bee (<i>Apis mellifera</i>) Rep. No. 112H-131A DAS Study No. 200439 Eurofins EAG Agroscience, LLC, USA GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Corteva
KCP, 10.3.1.3/01	Cornement, M.	2018	Rimsulfuron toxicity to Honey bees (<i>Apis mellifera</i> L.) larvae after repeated exposure under <i>In Vitro</i> laboratory conditions 20170301 Innovative Environmental Services (IES) LtdKC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.3.1.3/02	Porch, J.R., Riles, B.	2021b	GF-3969 (DPX-V4B07) + DPX-KG691 (VIVOLT): A Chronic Larval Toxicity Study with the Honey Bee (<i>Apis mellifera</i>) Rep. No. 112H-130 DAS Study No. 200438 Eurofins EAG Agrosience, LLC, USA GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Corteva
KCP, 10.3.2.1/01	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49972 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.2.1/02	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49973 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.3.2.1/03	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 Surfactant: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49934 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.3.2.1/04	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: A laboratory rate-response test to evaluate the effects on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49935 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.4.1.1/01	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on reproduction and growth of the earthworm, <i>Eisenia andrei</i> , in artificial soil DuPont-49950 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.4.1.1/02	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on reproduction and growth of the earthworm, <i>Eisenia andrei</i> , in artificial soil DuPont-49980 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.4.2.1/01	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil DuPont-49955 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.4.2.1/02	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on the collembola <i>Folsomia candida</i> in artificial soil DuPont-49954 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.4.2.1/03	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil DuPont-49982 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.4.2.1/04	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on the collembola <i>Folsomia candida</i> in artificial soil with 5% peat DuPont-49981 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.5/01	Hammesfahr, U.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus KG691 surfactant: Assessment of the effects on soil microflora DuPont-49938 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont

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, 10.5/02	Hammesfahr, U.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Assessment of the effects on soil microflora DuPont-49976 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.6.2/01	Spatz, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on terrestrial (non-target) plants: Seedling emergence and seedling growth test DuPont-49939 IBACON GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.6.2/02	Arnie, J.R., McKelvey, R.A., Aufderheide, J.A., Lockard, L.A., Zhang, L.	2020	Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A Blend of Paste Extruded Granules Plus Isodecylalcohol Ethoxylated (DPX-KG691) Surfactant: A Greenhouse Study to Investigate the Effects on Vegetative Vigor of Ten Terrestrial Plants Following Foliar Exposure 49942 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
KCP, 10.6.2/03	Ellis, S.	2022	Position paper to address zRMS comments on the risk to non-target plants from GF-3969 GLP: Not relevant, position paper Published: No	N	N Not relevant for position paper		Corteva

B10
Assessment of the Relevance of metabolites in groundwater

No studies submitted.

List of data relied on, but not submitted and not evaluated at EU peer review

The following studies are relied upon and have not been evaluated at the EU level, but are not submitted in this dossier.

B0

Product background, regulatory Context and GAP information

Not applicable.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

Not applicable.

B3

Efficacy data and information

Not applicable.

B5 Analytical methods

Isxadifen ethyl – not evaluated by zRMS

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
CP, 5.1.2	Dacus, S.C., Neal, J. L., Cole, M.	2001	An analytical method for the determination of residues of Isoxadifen-ethyl (AE F122006) and its major metabolites AE F129431 in corn and rice and AE C637375 in rice by gas chromatography using ion trap mass selective detection, M-238876-02-1 (B003344) GLP: No Published: No	N	N		Bayer
CP, 5.1.2	Dacus, S.C., Neal, J. L.	2000	An analytical method for the determination of residues of AE F122006 and its major metabolites AE F129431 and AE F162241 in field corn by gas and liquid chromatography using ion trap mass selective detection: AE F122006 M-238556-01-1 (B002825) GLP: No Published: No	N	N		Bayer
CP, 5.1.2	Kaune, A.	2002	Validation of the analytical method AM01/08 for the determination of AE F122006 and its metabolites in maize using LC/MS/MS M-206994-01-1 (C018951) GLP: Yes Published: No	N	N		Bayer

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
CP, 5.1.2	Freitag, Th.,	2016	AM01/08 - Analytical method AM01/08 for the determination of AE F122006 and its metabolites in maize using LC/MS/MS M-206993-02-1 (C018950) GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Bayer
CP, 5.2	Bacher, R.	2006	Isoxadifen-ethyl: Analytical method for the determination of isoxadifen-ethyl in air (validation) M-217537-01-1 (C029624) PTRL Europe GmbH GLP: Yes Published: No	N	N		Bayer
CP, 5.2	Cole, M. G.; Neal, J. L.; Dacus, S. C.	2001	An Analytical Method for the Determination of Residues of Residues of Isoxadifenethyl (AE F122006) and its Major Metabolite AE F129431 in Soil by Gas Chromatography Using Nitrogen-Phosphorous or Ion Trap Mass Selective Detection, Revision 1 M-185178-02-1 (B003389) AgrEvo USA Company GLP: No Published: No	N	N		Bayer
CP, 5.2	Meseguer, C.	2017	Independent laboratory validation of modification M029 of the analytical method 01300 (based on QuEChERS) for the determination of residues of isoxadifen-ethyl and its metabolites in different matrices of plant origin M-590984-01-1 (S16-04195) Eurofins Agrosience Services, Chem SAS GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Bayer

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
CP, 5.2	Winter, O., Amann, S.	2016	Modification M029 of the analytical method 01300 (based on QuEChERS) for the determination of residues of isoxadifen-ethyl and its metabolites in different matrices of plant origin M-573745-01-1 (S16-03605) Eurofins Agrosience Services Chem GmbH GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Bayer

**B6
Mammalian toxicology**

Not applicable.

**B7
Metabolism and residues**

Not applicable.

**B8
Environmental fate**

Not applicable.

B9 Ecotoxicological studies

Please note that below studies were agreed by the RMS (UK) in the course of the evaluation of the confirmatory data (for details, please refer to EFSA Supporting publication 2020:EN-1627).

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, 10.2.1	xxxxxxxxxxxxxxxx	2010	Thifensulfuron Methyl (DPX-M6316) Technical: Early Life-Stage Toxicity Test with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Under Flow-Through Conditions ABC Laboratories, Inc. (USA) GLP: Yes xxxxxxxxxxxxxxxx Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.2.1	Brougher, D.S., Lockard, L., Gallagher, S.P.	2017	Thifensulfuron methyl (DPX-M6316) technical: A 48-hour static acute toxicity test with the cladoceran (<i>Daphnia magna</i>) Wildlife International Ltd (USA) DuPont-46007, Revision No. 1 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.2.1	Hutton, D.G.	1989	Chronic toxicity of IN-M6316-25 to <i>Daphnia magna</i> DuPont Haskell Laboratory HLR 70-89 GLP: Yes Published: No	N	N		FMC*
KCP, 10.2.1	Arnie, J.R., Lockard, L., Martin, K.H., Porch, J.R.	2017	Thifensulfuron methyl (DPX-M6316) technical: A 72-hour toxicity test with the freshwater alga (<i>Pseudokirchneriella subcapitata</i>) Wildlife International Ltd (USA) DuPont-46004, Revision No. 1 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam

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, 10.2.1	Arnie, J.R., Zhang, L., Porch, J.R., Martin, K.H.	2016	IN-D8858: A 72-hour toxicity test with the freshwater alga (<i>Pseudokirchneriella subcapitata</i>) Wildlife International Ltd. (USA) DuPont-42163, Revision No. 1 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.2.2	Arnie, J.R., Zhang, L., Porch, J.R., Martin, K.H.	2016	IN-D8858: A 7-day static-renewal toxicity test with duckweed (<i>Lemna gibba</i> G3) Wildlife International Ltd. (USA) DuPont-42164, Revision No. 1 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.4.2.1	Lührs, U.	2015a	IN-JZ789: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-42165 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.4.2.1	Lührs, U.	2015b	IN-U5F72: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-42481 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC*, Rotam
KCP, 10.7.1/01	Pur, A. Ochoa-Acuna, H.	2015	Herbicide non-relevance screen results for Thifensulfuron methyl metabolites (IN-JZ789 and IN-U5F72) DuPont-43667 E.I. du Pont de Nemours and Company GLP: No Published: No	N	N		FMC*

B10
Assessment of the Relevance of metabolites in groundwater

Not applicable.

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

B0

Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

No studies submitted.

B3

Efficacy data and information

No studies submitted.

B5 Analytical methods

Rimsulfuron

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
CP, 5.1.2	Siripriya, G.	2014	DPX-E9636 (Rimsulfuron): Laboratory study of n-octanol/water partition coefficient DuPont-36445 Advinus Therapeutics Limited GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.1.2	Bacher, R.	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air (Amended) DuPont-4560 Amended PTRL Europe GmbH GLP: Yes Published: No	N	N		DuPont
CP, 5.2	Cabusas, M.E.Y., Rodgers, C.	2012	Analytical method for the determination of rimsulfuron (DPX-E9636), nicosulfuron (DPX-V9360), and IN-V9367 in crop matrices by HPLC/ESI-MS/MS DuPont-32277 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

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
CP, 5.2	Rogers, P.	2012	Independent laboratory validation of DuPont-32277 "Analytical method for the determination of rimsulfuron (DPX-E9636), nicosulfuron (DPX-V9360), and IN-V9367 in crop matrices by HPLC/ESI-MS/MS" DuPont-32278 Alliance Pharma, INC. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Cabusas, M.E.Y.	2012	Analytical method for the determination of rimsulfuron (DPX-E9636) in watery, acidic, and dry crop matrices by HPLC/ESI-MS/MS DuPont-15033, Revision No. 2 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont
CP, 5.2	Connolly, P.	2005	Independent laboratory validation of the analytical method; DuPont-15033, Analytical method for the determination of rimsulfuron in watery and dry crop matrices by HPLC/ ESI-MS/MS DuPont-15029, Revision No. 1 Exygen Research GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Cabusas, M.E.Y.	2012	Analytical method for the determination of rimsulfuron in oily crop matrices by HPLC/ESI-MS/MS DuPont-15027, Revision No. 2 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

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
CP, 5.2	Plastridge, B.	2005	Independent laboratory validation of the analytical method, DuPont-15027, Analytical method for the determination of rimsulfuron in oily crop matrices by HPLC/ESI MS/MS DuPont-15030 Exygen Research GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2012	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont
CP, 5.2	Gant, A.G.	2012	Independent laboratory validation of DuPont-30449 "Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS" DuPont-30450 ABC Laboratories, Inc. (Missouri) GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

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
CP, 5.2	xxxxxxxxxxxxxxxxxxxx	1991	Metabolism study of DPX-E9636 in laying hens AMR 1808-90 xxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N		DuPont
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of rimsulfuron (DPX-E9636) and its metabolites in soil and water using HPLC/ESI-MS/MS DuPont-38604 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont
CP, 5.2	Fiorito, B.	2014	Independent laboratory validation of DuPont-38604 "Analytical method for the determination of rimsulfuron (DPX-E9636) and its metabolites in soil and water using HPLC/MS/MS" DuPont-38605 Alliance Pharma GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Taoudi, M.	2015	Method validation – Determination of residues of rimsulfuron and its metabolites IN-70941, IN-70942, IN-J290, IN-E9260, IN-T5831 and IN-JF999 in water FH/14/012 Battelle UK Ltd GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Helm AG, Sapac Agro SA, DuPont*

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
CP, 5.2	Benotti, M.J.	2015	Independent laboratory validation (ILV) of an analytical method for the determination of rimsulfuron, IN-70941, IN-70942, IN-J290, IN-T5831, IN-JF999 and IN-E9260 in drinking water Report No. 100060226B Battelle, USA GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Helm AG, Sapec Agro SA, DuPont*
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2017	Analytical method for the determination of rimsulfuron (DPX-E9636) in plasma and urine by HPLC/ESI-MS/MS DuPont-48528 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

*DuPont has Letter of Co-Ownership

Thifensulfuron methyl

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
CP, 5.2	Devine, T.J., Nanita, S.C.	2007	Multiresidue analytical method for the determination of sulfonyurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection DuPont-13412, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

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
CP, 5.2	Pentz, A.M., Bramble, F.Q.	2005	Analytical method for the determination of nicosulfuron, thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl, and chlorimuron ethyl in oily crop matrices using SPE purification and LC/MS/MS detection DuPont-13412, Revision No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont
CP, 5.2	Pentz, A. M., Bramble, F. Q., Devine, T. J., Nanita, S. C., Henze, R. M., Stry, J. J.	2014	Summary of multiresidue analytical method for the determination of sulfonylurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection DuPont-13412, Supplement No. 4, Revision No. 1 E.I. du Pont de Nemours and Company GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Plastridge, B.	2006	Independent laboratory method validation of a multi-residue method for the analysis of sulfonyurea herbicides in crops DuPont-17207, Revision No. 1 Exygen Research GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 5.2	Hill, S.J. Stry, J.J	2001	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS DuPont-5082, Revision No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	N		DuPont

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
CP, 5.2	Amoo, J.S., Jones, W.	2001	Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyrsulfuron methyl in cereals (wheat grain, forage and straw) DuPont Stine-Haskell Research Center DuPont-5367 GLP: No Published: No	N			FMC
CP, 5.2	Brooky, F.M., Westberg, G.L.	2007	Analytical method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyrsulfuron methyl in lettuce and tribenuron methyl and bensulfuron methyl in citrus (oranges) Morse Laboratories, Inc. DuPont-5367, Supplement No. 1 GLP: No Published: No	N			FMC
CP, 5.2	Pentz, A.M. Beamble, F.Q.	2002	Independent Laboratory Validation of DuPont-5367 'Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyrsulfuron methyl in cereals (wheat grain, forage and straw)' in wheat grain, barley grain, corn grain and tomato. E.I. du Pont de Nemours and Company DuPont-8054 GLP: Yes Published: No	N			FMC
CP, 5.2	Bacher, R.	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air DuPont-4560 PTRL Europe GLP: Yes Published: No	N	N		DuPont

*FMC Letter of Access available

B6 Mammalian toxicology

Rimsulfuron

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
CP, 7.1.7	xxxxxxxxxxxxx	2016	IN-E9260: Rat alkaline Comet assay 8346539 xxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	Helm AG and Sapec Agro SA DuPont
CP, 7.1.7	Clarke, J.J.	2013	IN-E9260: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) DuPont-36588 BioReliance, Alliance Pharma, Inc. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 7.1.7	Clarke, J.J.	2013	IN-70942: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) DuPont-36586 BioReliance, Alliance Pharma, Inc. GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 7.1.7	Forichon, A.	1992	Test to evaluate the induction of chromosome aberrations in the human lymphocytes 202380 Hazleton (France) GLP: Yes Published: No	N	N		DuPont

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
CP, 7.1.7	Gudi, R., Rao, M.	2004	IN-70941: <i>In vitro</i> mammalian chromosome aberration study in human peripheral blood lymphocytes DuPont-13386, Revision No. 1 BioReliance GLP: Yes Published: No	N	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxx.	2004	IN-E9260: Local lymph node assay (LLNA) in mice DuPont-15258 xxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single cutaneous application (Limit Test) in the rat 110303 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single oral administration (Limit Test) in the rat 110304 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxx	1992	Test to evaluate the acute ocular irritation and reversibility in the rabbit 201336 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxx	1992	Test to evaluate the acute primary cutaneous irritation and corrosivity in the rabbit xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont

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
CP, 7.1.7	xxxxxxxxxxxxxxxx	1992	Test to evaluate sensitizing potential in the guinea-pig (Guinea-Pig Maximization Test) 202355 xxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	Reynolds, V.L.	1989	Mutagenicity testing of IN-E9260-1 in the <i>Salmonella typhimurium</i> Plate Incorporation Assay HLR 108-89 DuPont Haskell Laboratory GLP: Yes Published: No	N	N		DuPont
CP, 7.1.7	Reynolds, V.L.	1989	Mutagenicity testing of IN-70941 in the <i>Salmonella typhimurium</i> Plate Incorporation Assay HLR 344-89 DuPont Haskell Laboratory GLP: Yes Published: No	N	N		DuPont
CP, 7.1.7	Roy, S., Jois, M.	2013	IN-70942: <i>In vitro</i> mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL) DuPont-36585 BioReliance GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 7.1.7	San, R.H.C., Clarke, J.J.	2003	IN-70941: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT Test) DuPont-13387 BioReliance GLP: Yes Published: No	N	N		DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxx	1989	Approximate Lethal Dose (ALD) of IN-70941 in rats HLR 199-89 xxxxxxxxxxxxxxxxxxxxxxxx Published: No	Y	N		DuPont

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
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1989	Ten-dose oral subchronic study of IN-70941 in rats HLR 526-89 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont
CP, 7.1.7	Wagner, V.O., III, VanDyke, M.R.	2013	IN-70942: Bacterial reverse mutation test DuPont-36584 BioReliance GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1992	DPX-E9260 - 4 Week oral (gavage) toxicity study in the rat 35291 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N		DuPont

Thifensulfuron methyl

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
CP, 7.1.7	Myhre, A.	2011	IN-L9225: Bacterial reverse mutation test DuPont Haskell Laboratory DuPont-30758 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC

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
CP, 7.1.7	Glover, K.P.	2011	IN-L9225: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes DuPont Haskell Laboratory DuPont-30759 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC
CP, 7.1.7	Clarke, J.J.	2011	IN-L9225: In vitro mammalian cell gene mutation test (CHO/HGPRT assay) BioReliance DuPont-30760, Revision No.1 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC
CP, 7.1.7	Donath, C.	2011	Reverse mutation using bacteria (Salmonella typhimurium and Escherichia coli) with thifensulfuron acid. BSL Bioservice Scientific Laboratories GmbH, Germany. Study No.: 110127 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	Donath, C.	2011	Reverse mutation using bacteria (Salmonella typhimurium and Escherichia coli) with 2-acid-3-sulfonamide BSL Bioservice Scientific Laboratories GmbH, Germany. Study No.: 110128 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	Lloyd, M.	2011	2-acid-3-sulfonamide: Induction of chromosome aberrations in cultured human peripheral blood lymphocytes Covance Laboratories Ltd, Harrogate, UK. Study No.: 8243962 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force

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
CP, 7.1.7	Lloyd, M.	2011	2-acid-3-sulfonamide: Mutation at the thymidine kinase (tk) locus of mouse lymphoma L5178Y cells (MLA) using the microtitre® fluctuation technique Covance Laboratories Ltd, Study No: 8243963 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	xxxxxxxxxxxxxx	2011	Acute oral toxicity (fixed dose procedure) - Limit test with Thifensulfuron acid Report No: 206 GLP: Yes Published: No	Y	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	Myhre, A.	2011	IN-L9223: Bacterial reverse mutation test DuPont Haskell Laboratory DuPont-31622 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC
CP, 7.1.7	Glover, K.P.	2011	IN-L9223: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes DuPont Haskell Laboratory DuPont-31623 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC
CP, 7.1.7	Clarke, J.J.	2011	IN-L9223: In vitro mammalian cell gene mutation test (CHO/HGPRT assay) DuPont Haskell Laboratory DuPont-31624 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	FMC

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
CP, 7.1.7	May, K.	2012	Thifensulfuron Acid (IN-L9225): In vitro micronucleus test in human lymphocytes Huntingdon Life Sciences, Report No.: DGV0080 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	May, K.	2012	O-Desmethyl Thifensulfuron Acid (IN-JZ789): Bacterial reverse mutation test Huntingdon Life Sciences, Report No.: DGV0081 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*
CP, 7.1.7	May, K.	2012	O-Desmethyl Thifensulfuron Acid (IN-JZ789): In vitro micronucleus test in human lymphocytes (amended report) Huntingdon Life Sciences, Report No.: DGV0082 GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	EU TSM AIR 2 Task Force*

* Cheminova (now FMC) is owner of the study.

B7
Metabolism and residues

No studies submitted.

B8
Environmental fate

No studies submitted.

B9
Ecotoxicological studies

No studies submitted.

B10
Assessment of the Relevance of metabolites in groundwater

No studies submitted.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Reason for rejection
KCP, 10.3.1.1.1/03 and KCP, 10.3.1.1.2/03	Verge, E.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + codacide oil: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48951 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont	Not a data requirement
KCP, 10.3.1.1.1/04 and KCP, 10.3.1.1.2/04	Verge, E.	2019	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + surfactant DPX-KG691: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48899, Revision No. 1 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont	Not a data requirement
KCP, 10.3.1.3/01	Cornement, M.	2018	Rimsulfuron-toxicity to Honey bees (<i>Apis mellifera</i> L.) larvae after repeated exposure under <i>In Vitro</i> laboratory conditions 20170301 Innovative Environmental Services (IES) LtdKC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont	Active substance study, not relevant for zonal evaluation
KCP, 10.6.2/02	Arnie, J.R., McKelvey, R.A., Aufderheide, J.A., Lockard, L.A., Zhang, L.	2020	Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A Blend of Paste Extruded Granules Plus Isodecylalcohol Ethoxylated (DPX-KG691) Surfactant: A Greenhouse Study to Investigate the Effects on Vegetative Vigor of Ten Terrestrial Plants Following Foliar Exposure DuPont-49942 Eurofins EAG Agroscience, LLC GLP: Yes Published: No	N	Y	Necessary for the regulatory decision, conducted according to GLP and not previously protected or submitted in this Member State	DuPont	Study not valid

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
-	-	-	-	-	-	-	-