

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: GF-3969

Chemical active substances:

Rimsulfuron, 148.15 g/kg

Thifensulfuron methyl, 92.60 g/kg

Isoxadifen-ethyl, 111.1 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva/DuPont/DowAgroScience/Pioneer*

Submission date: 07/December/2020

MS Finalisation date: November 2021(initial Core Assessment)

May 2022 (final Core 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.

This document is the property of the applicant and contains confidential and trade secret information. Except as required by law, this document should not be, partially or fully (i) photocopied or released in any form to any outside party without the prior written consent of the applicant or its affiliates, or (ii) used by a registration authority to support the registration of any other product without the prior written consent of the applicant or its affiliates.

Version history

When	What
December 2021	Applicant initial dRR
December 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
May 2022	Final report (Core 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 .

Table of Contents

1	Section 1: Identity of the plant protection product.....	5
1.1	Applicant (KCP 1.1).....	5
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	5
1.2.1	Producer(s) of the preparation.....	5
1.2.2	Producer(s) of the active substance(s).....	5
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s).....	5
1.2.3.1	Rimsulfuron	5
1.2.3.2	Thifensulfuron methyl.....	5
1.2.3.3	Isoxadifen-ethyl	5
1.3	Trade names and producer’s development code numbers for the preparation (KCP 1.3)	6
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4).....	6
1.4.1	Composition of the plant protection product (KCP 1.4.1)	6
1.4.2	Information on the active substance(s) (KCP 1.4.2)	7
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	7
1.5	Type and code of the plant protection product (KCP 1.5)	7
1.6	Function (KCP 1.6)	7
2	Section 2: Physical, chemical and technical properties of the plant protection product.....	8
3	Section 3 is presented as a separate document	24
4	Section 4: Further information on the plant protection product.....	24
4.1	Safety Intervals and Other Precautions to Protect Humans, Animals and the Environment (KCP 4.1)	24
4.2	Recommended Methods and Precautions (KCP 4.2)	24
4.3	Emergency Measures in the Case of an Accident (KCP 4.3).....	24
4.4	Packaging and Compatibility with the Preparation (KCP 4.4)	25
4.5	Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging (KCP 4.5).....	28
4.5.1	Neutralisation Procedure (KCP 4.5.1).....	28
4.5.2	Controlled Incineration (KCP 4.5.2).....	28
Appendix 1	Lists of data considered in support of the evaluation	29
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance	34
A 2.1	Rimsulfuron	34
A 2.2	Thifensulfuron methyl.....	34
A 2.3	Isoxadifen-ethyl	34
Appendix 3	Additional information provided by the applicant	35
A 3.1	Study 1, AT-18-009	35

Thifensulfuron methyl information belongs to FMC, but all datapoints originate from the EFSA conclusion. Unless otherwise specified, endpoints used in this section for isoxadifen-ethyl originate from Bayer CropScience and Corteva has a letter of access.

Confidential information or data are provided separately (Part C). Please see Part C, Section 1.4.5.1 Description of formulation process, for additional details of blended formulation components and % active substances in the finished blend.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are:

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

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: See cover letter, zonal/country application form and/or Part A country
Address: As above

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Rimsulfuron

Rimsulfuron min. 960 g/kg

There are no impurities in technical rimsulfuron that are considered relevant from a toxicological or ecotoxicological perspective in GF-3969.

1.2.3.2 Thifensulfuron methyl

Thifensulfuron methyl min. 979 g/kg

There are no impurities in technical thifensulfuron methyl that are considered relevant from a toxicological or ecotoxicological perspective in GF-3969.

1.2.3.3 Isoxadifen-ethyl

Isoxadifen-ethyl min. 970 g/kg

There are no impurities in technical isoxadifen-ethyl that are considered relevant from a toxicological or ecotoxicological perspective in GF-3969.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country

Company code number: GF-3969; DPX-V4B07

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

GF-3969 was not the representative formulation for the approval of rimsulfuron and thifensulfuron methyl. The formulation is produced to meet FAO specifications in relation to allowable limits. The limits for each active substance of GF-3969 are included in Table 1.4-1 and safener in Table 1.4-2. The limits are determined based on Appendix K of the FAO/WHO Manual – Calculation of expanded tolerances for the active ingredient content of mixed solid formulations (Section 4.3.3) as follows:

Calculation

(i) Calculate the upper and lower limits for each active substance present in each formulation component of the blend, referring to the tolerances given in Section 4.3.2 of FAO/WHO Manual.

Active substance upper limit in its formulation (EH) = g/kg declared + tolerance

Active substance lower limit in its formulation (EL) = g/kg declared – tolerance

ii) Calculate the upper and lower limits for each component in the blend, applying the tolerances intended for active substance content in Section 4.3.2 of FAO/WHO Manual.

Blend component upper limit (FH) = g/kg declared + tolerance

Blend component lower limit (FL) = g/kg declared – tolerance

(iii) Calculate the upper and lower limits for each active substance in the blend.

Active substance upper limit in the blend = (EH x FH)/1000 g/kg

Active substance lower limit in the blend = (EL x FL)/1000 g/kg

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance/ variant	Declared content of the pure active substance/ variant (g/kg)	FAO Limits (min – max) (g/kg)	Technical content* (g/kg)	Technical content (%w/w)
Rimsulfuron	148.15	133.4 – 163.7	154.3	15.43
Thifensulfuron methyl	92.60	82.7 – 103.1	94.59	9.46

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

Table 1.4-2: Safener and synergists

Safener/ synergist	Declared content of the safener/ synergist (g/kg)	FAO Limits (min – max) (g/kg)	Technical content* (g/kg)	Technical content (%w/w)
Isxadifen-ethyl	111.1	99.2 – 123.7	114.5	11.45

* Based on the minimum purity of the safener/synergist declared for registration

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable	—

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on rimsulfuron

Type	Name/Code Number
ISO common name	Rimsulfuron
CAS No.	122931-48-0
EC No.	none
CIPAC No.	716

Table 1.4-5: Information on thifensulfuron methyl

Type	Name/Code Number
ISO common name	Thifensulfuron methyl
CAS No.	79277-27-3
EC No.	EINECS or ELINCS not assigned- ECHA assigned list number 616-673-4
CIPAC No.	452

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-6: Information on safener

Type	Name/Code Number
Safener/synergist	Safener
ISO common name	Isoxadifen-ethyl
CAS No.	163520-33-0
EC No.	--
CIPAC No.	666.202

Information on co-formulants is CONFIDENTIAL information and provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water dispersible granules [Code: WG]

1.6 Function (KCP 1.6)

Herbicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

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.~~

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

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

For further information refer to the SDS provided in the Part C.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None proposed, as no classification under Regulation (EC) No 1272/2008 is triggered by the physical chemical properties of GF-3969.

Compliance with FAO specifications:

The product GF-3969 complies with FAO specifications.

Formulation used for tests

Information on formulation composition is CONFIDENTIAL and provided separately (Part C).

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Colour and physical state (KCP 2.1)	Visual	GF-3969 (Test item number TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	GF-3969 is a mixture of cream, beige and tan granules	Y	Comb, T., 2020 (190492)	Accepted.
Explosive properties (KCP 2.2)	EEC A.14	GF-3969 (Test item DPX-V4B07-001 [Rimsulfuron 25SG Lot – MAR14EL004; Thifensulfuron methyl 50SG – APR15EL002; Isoxadifen ethyl 50WG – DEC15EL001]; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Not explosive	Y	Jones, J.S., 2017 (DuPont-48798)	Accepted. GF-3969 has no explosive properties.
Oxidizing properties (KCP 2.2)	EEC A.17	GF-3969 (Test item DPX-V4B07-001 [Rimsulfuron 25SG Lot – MAR14EL004; Thifensulfuron methyl 50SG – APR15EL002; Isoxadifen ethyl 50WG – DEC15EL001]; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Not an oxidizer	Y	Jones, J.S., 2017 (DuPont-48798)	Accepted. GF-3969 has no oxidising properties
Flash point (KCP 2.3)	-	-	Not applicable to solid formulations	-	-	-
Flammability (KCP 2.3)	EEC A.10	GF-3969 (Test item DPX-V4B07-001 [Rimsulfuron 25SG Lot – MAR14EL004; Thifensulfuron methyl 50SG – APR15EL002; Isoxadifen ethyl 50WG – DEC15EL001]; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Not a flammable solid	Y	Jones, J.S., 2017 (DuPont-48798)	Accepted.

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Self-heating (KCP 2.3)	EEC A.16	GF-3969 (Test item DPX-V4B07-001 [Rimsulfuron 25SG Lot – MAR14EL004; Thifensulfuron methyl 50SG – APR15EL002; Isoxadifen ethyl 50WG – DEC15EL001];; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	The lowest temperature at which ignition occurred was 407.5°C.	Y	Jones, J.S., 2017 (DuPont-48798)	Accepted.
Acidity or alkalinity and pH (KCP 2.4)	-	-	Not applicable, because the pH value of a 1% dispersion was between 4 and 10	-	-	-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4)	CIPAC MT 75.3	GF-3969 (Test item number TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	pH of a 1% (at 20°C) test solution = 7.0 and 7.3 (adjuvant/crop oil)	Y	Comb, T., 2020 (190492)	Accepted.
Viscosity (KCP 2.5)	-	-	Not applicable to solid formulations	-	-	-
Surface tension (KCP 2.5)	-	-	Not applicable to solid formulations	-	-	-
Relative density (KCP 2.6)	-	-	Not applicable to solid formulations	-	-	-
Bulk density (KCP 2.6)	CIPAC MT 186	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Loose: 0.64 g/mL Tapped: 0.68 g/mL	Y	Comb, T., 2020 (190492)	Accepted.
Storage Stability after 14 days at 54° C (KCP 2.7)	CIPAC MT 46.3.1 Active substance content: Method number X4145.220.03.ST, validation details please refer to the Section 5.	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Storage conditions: 2 weeks at 54°C in high density polyethylene (HDPE) container. GF-3969 is a mixture of cream, beige and tan granules. Product showed no changes during storage. 1-L HDPE containers showed no indications of significant weight loss or physical deterioration.	Y	Comb, T., 2020 (190492)	The product showed no significant physical changes after accelerated storage. The spontaneity of dispersibility of one active substance, thifensulfuron methyl, was reduced following

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
	Visual		<p>pH (at 20°C): 7.0 and 7.3 (adjuvant/crop oil)</p> <p>Suspensibility: Within 60-105% at both 0.2% v/v and 0.135 kg/50 L GF-3969 with and without adjuvant/crop oil</p> <p>Spontaneity of dispersion: Within 60-105% with and without adjuvant/crop oil with the exception of spontaneity of thifensulfuron methyl (59% after storage, 55% after storage tests with adjuvant and crop oil)</p> <p>Wet sieve: <2% retention on a 75 µm sieve with and without adjuvant/crop oil</p>			<p>storage.</p> <p>It is recommended to include the following phrase on the GF-3969 label: 'Keep stirring during the application'.</p> <p>No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material and that HDPE was satisfactory for the storage of GF-3969.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.</p>

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments										
	CIPAC MT 53.3 CIPAC MT 170 CIPAC MT 171 CIPAC MT 178.2		Wettability: <60 seconds with and without adjuvant/crop oil Dry sieve: 99.9% in the range 500 to 2000 µm Dust content: Nearly dust-free Attrition resistance: 100.0%													
Stability after storage for other periods and/or temperatures (KCP 2.7)	-	-	Not conducted as the formulation is stable after 14 days at 54°C.	-	-	-										
Minimum content after heat stability testing (KCP 2.7)	DuPont HPLC (Method No. X4145.220.03.ST)	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Assay as made: Rimsulfuron 14.6% Thifensulfuron methyl 9.39% Isoxadifen-ethyl 11.0% Assay after 2 weeks at 54°C Rimsulfuron 14.5% Thifensulfuron methyl 9.37% Isoxadifen-ethyl 10.7%	Y	Comb, T., 2020 (190492)	Accepted.										
Effect of low temperatures on stability (KCP 2.7)	-	-	Not applicable to solid formulations	-	-	-										
Ambient temperature shelf life (KCP 2.7)	CIPAC MT 46.3.1 X4145.220.03.ST Appearance CIPAC MT 75.3 CIPAC MT 184	TSN400969 (Lot number: BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Study in progress; 2-year results will be available September 2021 Assay after 2 years storage: Rimsulfuron 15.3% Thifensulfuron methyl 9.16% Isoxadifen-ethyl 10.1% GF-3969 is a mixture of cream, beige and tan granules. GF-3969 was found to be chemically and physically stable when stored in 1-L HDPE containers after two years under ambient conditions. The packaging was observed to be stable with no signs of corrosion. It can therefore be concluded that the test item was not corrosive to the container material and that HDPE was satisfactory for the storage of GF-3969 for two years. pH of a 1% test solution = 6.7 pH of a 1% test solution = 6.9 – 7.1 (adjuvant/crop oil) Suspensibility: Within 60-105% at both 0.2% v/v and 0.135 kg/50 L (0.27% w/v) GF-3969 with and without adjuvant/crop oil Results without adjuvant/oil: <table border="1"> <tr> <td>@ 0.2% v/v</td> <td></td> </tr> <tr> <td>Rimsulfuron</td> <td>99%</td> </tr> <tr> <td>Thifensulfuron methyl</td> <td>101%</td> </tr> <tr> <td>Isoxadifen ethyl</td> <td>86%</td> </tr> <tr> <td>@ 0.135kg/50L (0.27% w/v)</td> <td></td> </tr> </table>	@ 0.2% v/v		Rimsulfuron	99%	Thifensulfuron methyl	101%	Isoxadifen ethyl	86%	@ 0.135kg/50L (0.27% w/v)		Y	Comb, T., 2021 (190496)	Accepted. The HDPE container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Period of validity: 2 years.
@ 0.2% v/v																
Rimsulfuron	99%															
Thifensulfuron methyl	101%															
Isoxadifen ethyl	86%															
@ 0.135kg/50L (0.27% w/v)																

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments																																		
			<table border="1" data-bbox="819 276 1373 357"> <tr><td>Rimsulfuron</td><td>95%</td></tr> <tr><td>Thifensulfuron methyl</td><td>98%</td></tr> <tr><td>Isoxadifen ethyl</td><td>96%</td></tr> </table> <p>Results with adjuvant/oil:</p> <table border="1" data-bbox="819 432 1373 639"> <tr><td>@ 0.2% v/v</td><td></td></tr> <tr><td>Rimsulfuron</td><td>97-100%</td></tr> <tr><td>Thifensulfuron methyl</td><td>100 - 101%</td></tr> <tr><td>Isoxadifen ethyl</td><td>87-92%</td></tr> <tr><td>@ 0.135kg/50L (0.27% w/v)</td><td></td></tr> <tr><td>Rimsulfuron</td><td>97 - 99%</td></tr> <tr><td>Thifensulfuron methyl</td><td>99 - 102%</td></tr> <tr><td>Isoxadifen ethyl</td><td>90 - 93%</td></tr> </table> <p>Spontaneity of dispersion: Within 60-105% with and without adjuvant/crop oil. The test was conducted in duplicate at a concentration of 10 g/L (as specified in the test method) in Standard Water D.</p> <p>Results without adjuvant/oil:</p> <table border="1" data-bbox="819 786 1214 895"> <tr><td>Rimsulfuron</td><td>99%</td></tr> <tr><td>Thifensulfuron methyl</td><td>96%</td></tr> <tr><td>Isoxadifen ethyl</td><td>96%</td></tr> </table> <p>Results with adjuvant/oil:</p> <table border="1" data-bbox="819 946 1252 1023"> <tr><td>Rimsulfuron</td><td>96 - 97%</td></tr> <tr><td>Thifensulfuron methyl</td><td>86 – 91%</td></tr> <tr><td>Isoxadifen ethyl</td><td>94 - 96%</td></tr> </table> <p><2% retention on a 75 µm sieve with (0.19%) and without adjuvant/crop oil (0.17-0.61%)</p> <p><60 seconds with and without adjuvant/crop oil</p> <p>Test result without adjuvant/crop oil: 4 seconds Test result with adjuvant/crop oil: 1-6 seconds</p> <p>100.0% in the range 500 to 2000 µm sieve</p> <p>Nearly dust-free (0.4mg)</p> <p>100.0%</p> <p>Please refer to the Table 2-4.</p>	Rimsulfuron	95%	Thifensulfuron methyl	98%	Isoxadifen ethyl	96%	@ 0.2% v/v		Rimsulfuron	97-100%	Thifensulfuron methyl	100 - 101%	Isoxadifen ethyl	87-92%	@ 0.135kg/50L (0.27% w/v)		Rimsulfuron	97 - 99%	Thifensulfuron methyl	99 - 102%	Isoxadifen ethyl	90 - 93%	Rimsulfuron	99%	Thifensulfuron methyl	96%	Isoxadifen ethyl	96%	Rimsulfuron	96 - 97%	Thifensulfuron methyl	86 – 91%	Isoxadifen ethyl	94 - 96%			The final Ambient temperature study is currently ongoing, and should be provided upon completion.
Rimsulfuron	95%																																							
Thifensulfuron methyl	98%																																							
Isoxadifen ethyl	96%																																							
@ 0.2% v/v																																								
Rimsulfuron	97-100%																																							
Thifensulfuron methyl	100 - 101%																																							
Isoxadifen ethyl	87-92%																																							
@ 0.135kg/50L (0.27% w/v)																																								
Rimsulfuron	97 - 99%																																							
Thifensulfuron methyl	99 - 102%																																							
Isoxadifen ethyl	90 - 93%																																							
Rimsulfuron	99%																																							
Thifensulfuron methyl	96%																																							
Isoxadifen ethyl	96%																																							
Rimsulfuron	96 - 97%																																							
Thifensulfuron methyl	86 – 91%																																							
Isoxadifen ethyl	94 - 96%																																							
	CIPAC MT 174																																							
	CIPAC MT 185																																							
	CIPAC MT 53.3																																							
	CIPAC MT 170																																							
	CIPAC MT 171																																							
	CIPAC MT 178.2																																							

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Shelf life in months (if less than 2 years) (KCP 2.7)	-	-	Based on data from storage stability after 14 days at 54°C (190492), the shelf life at ambient conditions is predicted to be 24 months per the OECD Draft Guidance Document For Storage Stability Testing of Plant Protection and Biocidal Products (6 January 2015).	-	-	Please refer to the point Ambient temperature shelf life. Ambient temperature study is currently ongoing, and should be provided upon completion.
Wettability (KCP 2.8.1)	CIPAC MT 53.3	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	<60 seconds with and without adjuvant/crop oil	Y	Comb, T., 2020 (190492)	Accepted.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Volume of foam after one minute 0 mL at 0.05 kg/400 L 24 mL at 0.135 kg/50 L 60 mL at 0.05 kg/400 L in presence of adjuvant/crop oil 62 mL at 0.135 kg/50 L in presence of adjuvant/crop oil	Y	Comb, T., 2020 (190492)	Volume of foam slightly exceeds the limit of 60 mL after one minute for maximum dilution in the presence of ajuvant, however, since the foam volume decreases over time, no application problems are to be expected. Please refer to the point 2.11. Additional document has been added under KCP 2.11 – Report No AT-21-021. Document presents ‘good’ practices to mitigate foam generation in tank mix of GF-3969 with DPX-KG691.
Suspensibility (KCP 2.8.3)	CIPAC MT 184	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Within 60-105% at both 0.2% v/v and 0.135 kg/50L (0.27% w/v) GF-3969 with and without adjuvant/crop oil. Results without adjuvant/oil: @ 0.2% v/v Rimsulfuron 98%	Y	Comb, T., 2020 (190492)	Accepted.

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments																														
			<table border="1"> <tr> <td>Thifensulfuron methyl</td> <td>99%</td> </tr> <tr> <td>Isoxadifen ethyl</td> <td>76%</td> </tr> <tr> <td colspan="2">@ 0.135kg/50L (0.27% w/v)</td> </tr> <tr> <td>Rimsulfuron</td> <td>98%</td> </tr> <tr> <td>Thifensulfuron methyl</td> <td>101%</td> </tr> <tr> <td>Isoxadifen ethyl</td> <td>75%</td> </tr> <tr> <td colspan="2">Results with adjuvant/oil:</td> </tr> <tr> <td colspan="2">@ 0.2% v/v</td> </tr> <tr> <td>Rimsulfuron</td> <td>99%</td> </tr> <tr> <td>Thifensulfuron methyl</td> <td>99%</td> </tr> <tr> <td>Isoxadifen ethyl</td> <td>74%</td> </tr> <tr> <td colspan="2">@ 0.135kg/50L (0.27% w/v)</td> </tr> <tr> <td>Rimsulfuron</td> <td>100%</td> </tr> <tr> <td>Thifensulfuron methyl</td> <td>99%</td> </tr> <tr> <td>Isoxadifen ethyl</td> <td>77%</td> </tr> </table>	Thifensulfuron methyl	99%	Isoxadifen ethyl	76%	@ 0.135kg/50L (0.27% w/v)		Rimsulfuron	98%	Thifensulfuron methyl	101%	Isoxadifen ethyl	75%	Results with adjuvant/oil:		@ 0.2% v/v		Rimsulfuron	99%	Thifensulfuron methyl	99%	Isoxadifen ethyl	74%	@ 0.135kg/50L (0.27% w/v)		Rimsulfuron	100%	Thifensulfuron methyl	99%	Isoxadifen ethyl	77%			
Thifensulfuron methyl	99%																																			
Isoxadifen ethyl	76%																																			
@ 0.135kg/50L (0.27% w/v)																																				
Rimsulfuron	98%																																			
Thifensulfuron methyl	101%																																			
Isoxadifen ethyl	75%																																			
Results with adjuvant/oil:																																				
@ 0.2% v/v																																				
Rimsulfuron	99%																																			
Thifensulfuron methyl	99%																																			
Isoxadifen ethyl	74%																																			
@ 0.135kg/50L (0.27% w/v)																																				
Rimsulfuron	100%																																			
Thifensulfuron methyl	99%																																			
Isoxadifen ethyl	77%																																			
Spontaneity of dispersion (KCP 2.8.3)	CIPAC MT 174	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Within 60-105% with and without adjuvant/crop oil	Y	Comb, T., 2020 (190492)	Accepted.																														
Dispersion stability (KCP 2.8.3)	-	-	Not applicable to WG formulations	-	-	-																														
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable to WG formulations	-	-	-																														
Particle size distribution/ nominal size range of granules (KCP 2.8.5.1)	CIPAC MT 170	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	100.3% in the range 500 to 2000 µm sieve	Y	Comb, T., 2020 (190492)	Accepted.																														
Wet sieve test (KCP 2.8.5.1)	CIPAC MT 185	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	<2% retention on a 75 µm sieve with and without adjuvant/crop oil	Y	Comb, T., 2020 (190492)	Accepted.																														
Dust content (KCP 2.8.5.2)	CIPAC MT 171	GF-3969 (Test item number: TSN400969; Lot	Nearly dust-free	Y	Comb, T., 2020 (190492)	Accepted.																														

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
		BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl				
Particle size of dust (KCP 2.8.5.2)	-	-	Only applicable to dustable powders	-	-	-
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	99.6%	Y	Comb, T., 2020 (190492)	Accepted.
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable to WG formulations	-	-	-
Emulsifiability (KCP 2.8.6)	-	-	GF-3969 is not an emulsion	-	-	-
Emulsion stability (KCP 2.8.6)	-	-	GF-3969 is not an emulsion	-	-	-
Re-emulsifiability (KCP 2.8.6)	-	-	GF-3969 is not an emulsion	-	-	-
Flowability (KCP 2.8.7)	CIPAC MT 172.1	GF-3969 (Test item number: TSN400969; Lot BP19134-001; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	Flows spontaneously (majority through 4.75 mm sieve and the remainder through the sieve after 1 lift).	Y	Comb, T., 2020 (190492)	Accepted.
Pourability (KCP 2.8.7)	-	-	Not applicable to solid formulations	-	-	-
Dustability following accelerated storage (KCP 2.8.7)	-	-	GF-3969 is not a dustable powder	-	-	-

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments																												
Physical compatibility of tank mixes (KCP 2.9)	ASTM E1518-05 In-house	GF-3969 (DPX-V4B07 35.18% WG; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	GF-3969 was tested with potential tank mix partners in two, three and four-way mixture combinations. Each mixture was tested according to a standardized internal operating procedure, and the following criteria were observed: Compatible: The formulation of a well dispersed mixture of pesticides in water. No non-rinsable residue found on the 300 µm sieve or remaining on bottle walls should be considered compatible. Incompatible: Separation of pesticides in water where flocculation, coagulation, gel, or curd found during or at the end of the test that will not redisperse nor pass through the 300 µm screen should be considered incompatible. Any residue as described previously found remaining on the bottle should be considered incompatible. All the GF-3969 tank mixes, based on two, three and four way mixtures, were found to be physically compatible. Product details please refer to the Table 2-2 and Table 2-3.	N	Huby, J.P., 2017 (AT-18-004)	Accepted. Compatibility has been confirmed.																												
	In-house E-1518-05	GF-3969 (DPX-V4B07 35.18% WG; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl) + DPX-KG691 (Vivolt); GF-3969 + Codacide	The physical compatibility of GF-3969 (148.15 gas/kg of rimsulfuron + 92.6 gas/kg of thifensulfuron-mehtyl + 111.11 g/kg of isoxadifen-ethyl ,WG) at a rate of 0.135 kgcp/ha has been assessed against 2 potential tank mixture adjuvants (Vivolt® and Codacide®) in one single way of introduction and at two water volumes (50 and 400L/ha) (c.p.=commercial product, a.s.=active substance). <table border="1"> <thead> <tr> <th>Sample: Trade Name</th> <th>Formulation Type</th> <th>Formulation Concentration a.s.</th> <th>Sample Rate L or kg cp/ha or % v/v</th> <th>Substance (Including a.s.)</th> <th>Quantity of each formulation (g)/jar (50/400L)</th> <th>Batch number</th> </tr> </thead> <tbody> <tr> <td>GF-3969</td> <td>WG</td> <td>240.75 g/kg</td> <td>0.135</td> <td>Rimsulfuron Thifensulfuron-methyl Isoxadifen-ethyl</td> <td>0.16/0.02 0.05/0.006 0.06/0.007</td> <td>JUN19EL001 MAR18EL007 FEB19EL001</td> </tr> <tr> <td>Vivolt®</td> <td>SI</td> <td>900 g/l</td> <td>0.2 %</td> <td>Fatty Alcohol Ethoxylated</td> <td>2 ml/jar</td> <td>MAR18CE031</td> </tr> <tr> <td>Codacide®</td> <td>EC</td> <td>867.14 g/l</td> <td>1.245</td> <td>Vegetable oil (rape seed oil)</td> <td>2.49/0.311ml</td> <td>040617</td> </tr> </tbody> </table> GF-3969 was found to be physically compatible with Vivolt® and Codacide® either in 50 or 400L/ha of Cipac D water. The 2 tank mix adjuvants are compatible with GF-3969 from ASTM international dynamic test standard operating procedure and DP Corteva SOP test. The test outcomes show that GF-3969 is compatible with key adjuvants for the European Union market.	Sample: Trade Name	Formulation Type	Formulation Concentration a.s.	Sample Rate L or kg cp/ha or % v/v	Substance (Including a.s.)	Quantity of each formulation (g)/jar (50/400L)	Batch number	GF-3969	WG	240.75 g/kg	0.135	Rimsulfuron Thifensulfuron-methyl Isoxadifen-ethyl	0.16/0.02 0.05/0.006 0.06/0.007	JUN19EL001 MAR18EL007 FEB19EL001	Vivolt®	SI	900 g/l	0.2 %	Fatty Alcohol Ethoxylated	2 ml/jar	MAR18CE031	Codacide®	EC	867.14 g/l	1.245	Vegetable oil (rape seed oil)	2.49/0.311ml	040617	N	Huby, J.P., Callemeyn, J.; 2021 (AT-21-023)	The physical compatibility of GF-3969 is confirmed.
Sample: Trade Name	Formulation Type	Formulation Concentration a.s.	Sample Rate L or kg cp/ha or % v/v	Substance (Including a.s.)	Quantity of each formulation (g)/jar (50/400L)	Batch number																												
GF-3969	WG	240.75 g/kg	0.135	Rimsulfuron Thifensulfuron-methyl Isoxadifen-ethyl	0.16/0.02 0.05/0.006 0.06/0.007	JUN19EL001 MAR18EL007 FEB19EL001																												
Vivolt®	SI	900 g/l	0.2 %	Fatty Alcohol Ethoxylated	2 ml/jar	MAR18CE031																												
Codacide®	EC	867.14 g/l	1.245	Vegetable oil (rape seed oil)	2.49/0.311ml	040617																												
Chemical compatibility of tank mixes (KCP 2.9)	ASTM E1518-05 In-house	GF-3969 (DPX-V4B07 35.18% WG; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl)	GF-3969 was tested with potential tank mix partners in two, three and four-way mixture combinations. Each mixture was tested according to a standardized internal operating procedure. pH was measured at T0 and T0 + 2 hours for each single component and each mixture; mixtures were also visually inspected for any signs of gas generation. In addition, the temperature was recorded for single component and corresponding mixtures at T0 and T0 + 2 hours. Within the time frame of the tests no significant variation in pH or temperature was noticed and no gas generation observed, which is considered as evidence of no potentially disadvantageous chemical reaction(s).	N	Huby, J.P., 2017 (AT-18-004)	Please refer to the point 2.9.1.																												
	In-house E-1518-05	GF-3969 (DPX-V4B07 35.18% WG; 14.82% rimsulfuron, 9.26% thifensulfuron methyl, 11.1% isoxadifen ethyl) +	GF-3969 was found to be chemically compatible with Vivolt® and Codacide® either in 50 or 400L/ha of Cipac D water. The 2 tank mix adjuvants are compatible with GF-3969 from ASTM international dynamic test standard operating procedure and DP Corteva SOP test. The test outcomes show that GF-3969 is compatible with key adjuvants for the European Union market.	N	Huby, J.P., Callemeyn, J.; 2021 (AT-21-023)	The chemical compatibility of GF-3969 is confirmed.																												

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
		DPX-KG691 (Vivolt); GF-3969 + Codacide				
Adhesion to seeds (KCP 2.10)	-	-	GF-3969 is not a seed treatment	-	-	-
Distribution to seed (KCP 2.10)	-	-	GF-3969 is not a seed treatment	-	-	-
Other/special studies (KCP 2.11)	-	GF-3969 + DPX-KG691	<p>Good practices to mitigate foam generation when GF-3969 mixed with DPX-KG691:</p> <ul style="list-style-type: none"> • Start with a clean sprayer. • Fill the tank to 50% of its capacity. Be certain that flow back hose end is below the water level. • Use the chemical filler/incorporator as such by closing, the suction valve between introduction of each product and rinsing. • Complete the tank if possible, by the bottom or by the top by avoiding sprinkling the water over the tank surface, e.g. let the hose going down to the bottom of tank. • Slow down or stop the agitation at the bottom of the tank while spraying, by the end of the preparation volume. Regulation will ensure a constant pressure at nozzle level. • As an alternative to direct filling of the main tank, the secondary tank (generally used for tank rinsing) can be filled instead and sprayer's pump can transfer its content to the main tank, this would avoid splashing. <p>Not applicable.</p>	N	Huby, J.P., 2021 (AT-21-021)	Accepted.

Table 2-2: Product details

Sample without Lot	Sample Trade Name	Formulation Type	Formulation Concentration	Sample FieldPro Rate g.a.s./ha	Substance (Including A.S.)
ACTIRB	Actirob B	EW	842.00 g/L	1684.00	Actirob
ADIGOR	Adigor	EC	440.00 g/L	220.00	alcohol ethoxylate methylated seed oil
ASTUSS	Astuss	EC	743.80 g/L	743.80	Surfactant
AUXO	Auxo	EC	337.00 g/L	505.50	bromoxynil octanoate isoxadifen-ethyl tembotrione
BANVEL	Banvel 4S	EC	480.00 g/L	288.00	dicamba
BIATHL	Biathlon	WG	71.40 %Aw/w	50.00	tritosulfuron
CALLIS	Callisto	SC	100.00 g/L	1500.00	mesotrione
CAMBIO	Cambio	SL	410.00 g/L	1025.00	bentazone dicamba
CAMIXWITHBENOX	Camix SE 460 g/L	EC	460.00 g/L	1725.00	benoxacor mesotrione S-metolachlor
CASPER	Casper	WG	55.00 %Aw/w	165.00	dicamba prosulfuron
CONQUERANT	Conquerant	WG	72.50 %Aw/w	290.00	dicamba tritosulfuron
DAKOTA-P	Dakota P	EC	462.50 g/L	1850.00	dimethenamid-P pendimethalin
DUALGO	Dual gold	EC	960.00 g/L	1920.00	S-metolachlor
GONDOR	Gondor	EC	488.00 g/L	122.00	Surfactant
HELIOS	Heliosol	EC	655.00 g/L	1310.00	terpenic alcohol
ISARD	Isard	EC	720.00 g/L	1008.00 1183.00	dimethenamid-P dimethenamid-P
PEAK	Peak	WG	75.00 %Aw/w	15.00	prosulfuron
ROUNDUP EXTRA	Roundup Extra	SL	480.00 g/L	1440.00	glyphosate
SILWET	Silwet L77	EC	840.00 g/L	84.00	Silwet 77
SURF00	Surf 2000	EC	100.00 %Aw/w	100.00	Surfactant
V4B07	DPX-V4B07	WG	35.18 %Aw/w	47.50	isoxadifen-ethyl rimsulfuron thifensulfuron-methyl

Table 2-3: List of mixtures

Mixtures	Trademark	Score	Comments
Mixture 1	[DAKOTA-P + V4B07]	0	Compatible 100L/ha
Mixture 2	[ISARD + V4B07]	0	Compatible 100L/ha
Mixture 3	[ROUNDUP EXTRA + V4B07]	0	Compatible 100L/ha
Mixture 4	[ISARD + V4B07]	0	Compatible 100L/ha
Mixture 5	[DUALGO + V4B07]	0	Compatible 100L/ha
Mixture 6	[AUXO + V4B07 + ACTIRB]	0	Compatible 100L/ha
Mixture 7	[AUXO + PEAK + V4B07 + ACTIRB]	0	Compatible 100L/ha
Mixture 8	[BANVEL + CALLIS + V4B07]	0	Compatible 100L/ha
Mixture 9	[CALLIS + CAMBIO + V4B07]	0	Compatible 100L/ha
Mixture 10	[CALLIS + V4B07]	0	Compatible 100L/ha
Mixture 11	[CALLIS + PEAK + V4B07]	0	Compatible 100L/ha
Mixture 12	[BIATHL + CALLIS + V4B07]	0	Compatible 100L/ha
Mixture 13	[CALLIS + CASPER + V4B07]	0	Compatible 100L/ha
Mixture 14	[CALLIS + CONQUERANT + V4B07]	0	Compatible 100L/ha
Mixture 15	[CAMIXWITHBENOX + V4B07 + ACTIRB]	0	Compatible 100L/ha
Mixture 16	[CAMIXWITHBENOX + V4B07 + HELIOS]	0	Compatible 100L/ha
Mixture 17	[CAMIXWITHBENOX + V4B07 + SILWET]	0	Compatible 100L/ha
Mixture 18	[CAMIXWITHBENOX + V4B07 + GONDOR]	0	Compatible 100L/ha
Mixture 19	[CAMIXWITHBENOX + V4B07 + SURF00]	0	Compatible 100L/ha
Mixture 20	[CAMIXWITHBENOX + V4B07 + ADIGOR]	0	Compatible 100L/ha
Mixture 21	[CAMIXWITHBENOX + V4B07 + ASTUSS]	0	Compatible 100L/ha

Table 2-4: Summary of the results before and after 2-years of storage:

Test	Method reference	Findings
Packaging assessment	N/A	The 1-L HDPE containers showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product
Active substance content	X4145.220.03.ST	Chemically stable in 1-L HDPE ($< 5\%$ change from time zero analysis) Slight reduction in safener, isoxadifen ethyl
Appearance	N/A	Product showed no changes during storage
pH	CIPAC MT 75.3	Time zero = 7.0 and 7.3 (adjuvant/crop oil) 2 years at ambient = 6.7 and 6.9 to 7.1 (adjuvant/crop oil)
Suspensibility	CIPAC MT 184	Within 60 - 105% at both 0.2% v/v and 0.135 kg/50 L GF-3969 with and without adjuvant/crop oil before and after 2 years at ambient
Spontaneity of dispersion	CIPAC MT 174	Within 60 - 105% with and without adjuvant/crop oil before and after 2 years at ambient
Wet sieving	CIPAC MT 185	$< 2\%$ retention on a 75 μm sieve with and without adjuvant/crop oil before and after 2 years at ambient
Wettability	CIPAC MT 53.3	< 60 seconds with and without adjuvant/crop oil before and after 2 years at ambient
Dry sieve analysis	CIPAC MT 170	Time zero = 100.3% in the range 500 to 2000 μm 2 years at ambient = 100.0% in the range 500 to 2000 μm
Dust content	CIPAC MT 171	'Nearly dust-free' before and after 2 years at ambient
Attrition resistance	CIPAC MT 178.2	$> 98\%$ before and after 2 years at ambient

N/A = not applicable

Properties which were assessed by dilution in water were also determined with the presence of an adjuvant and crop oil

Parameter	Results	
	Prior to storage	2 years
Appearance	Cream, beige and tan granules	Cream, beige and tan granules
pH - 1% w/v	7.0	6.7
Suspensibility 0.2%		
Rimsulfuron	98%	99%
Thifensulfuron methyl	99%	101%
Isxadifen ethyl	76%	86%
0.135 kg/50 L		
Rimsulfuron	98%	95%
Thifensulfuron methyl	101%	98%
Isxadifen ethyl	75%	96%
Spontaneity of dispersion		
Rimsulfuron	92%	99%
Thifensulfuron methyl	86%	96%
Isxadifen ethyl	93%	96%
Wet sieving (retention on a 75 µm sieve)	0.07%	0.19%
Wettability	7 seconds	4 seconds
Dry sieve analysis (in the range 500 to 2000 µm)	100.3%	100.0%
Dust content	0.6 mg	0.4 mg
Attrition resistance	99.6%	100.0%

(tests with adjuvant and/or crop oil)

Parameter	Results				
	Prior to storage	2 years			
		Test 2	Test 3	Test 4	Test 5
pH - 1% w/v	7.3	7.1	7.0	6.9	6.9
Suspensibility 0.2%					
Rimsulfuron	99%	100%	99%	97%	-
Thifensulfuron methyl	99%	101%	100%	100%	-
Isoxadifen ethyl	74%	92%	90%	87%	-
0.135 kg/50 L					
Rimsulfuron	100%	99%	97%	-	98%
Thifensulfuron methyl	99%	99%	101%	-	102%
Isoxadifen ethyl	77%	93%	91%	-	90%
Spontaneity of dispersion					
Rimsulfuron	92%	97%	97%	96%	97%
Thifensulfuron methyl	82%	91%	91%	86%	90%
Isoxadifen ethyl	94%	94%	95%	96%	94%
Wet sieving (retention on a 75 µm sieve)	0.34%	0.52%	0.17%	0.39%	0.61%
Wettability	3 seconds	1 second	1 second	3 seconds	6 seconds

Test 2 - adjuvant at 0.2% v/v and crop oil at 1.5% v/v
 Test 3 - adjuvant at 0.2% v/v
 Test 4 - crop oil at 0.31% v/v
 Test 5 - crop oil at 2.49% v/v

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Safety Intervals and Other Precautions to Protect Humans, Animals and the Environment (KCP 4.1)

Pre-harvest interval (in days) for each relevant crop

Pre-harvest intervals are covered by conditions of use/or growing period between application and harvest. Since applications of maize herbicides are made at an early stage in the crop’s development, it is not necessary to establish a pre-harvest interval in days. For full details of all uses please refer to the GAP table displayed in the Core Part B, Section 0.

Re-entry period (in days) for livestock, in areas to be grazed

Maize are not intended for cattle grazing shortly after treatment and exposure of livestock this way is highly unlikely.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated

The risk assessment detailed in the core Part B, Section 6 indicates that it is unlikely that exposures of workers following agricultural use will result in exposure levels approaching the AOEL for the active substances. Therefore, the probability of significant risk for workers exposed to residues on the crop after treatment is low and does not justify the establishment of a re-entry period.

Withholding period (in days) for animal feeding stuffs

There are no specific withholding periods as there is no specific risk for livestock.

Waiting period (in days) between application and handling treated products

Post-harvest treatment is not relevant for this dossier, nor is handling or collection of maize before harvest.

Waiting period (in days) between application and sowing or planting succeeding crops

Please refer to the information displayed in the Core Part B, Section 3.

4.2 Recommended Methods and Precautions (KCP 4.2)

Please refer to the Safety Data Sheet provided in the Core Part C.

4.3 Emergency Measures in the Case of an Accident (KCP 4.3)

Procedures for cleaning application equipment

Immediately after application, completely drain spray equipment. Thoroughly rinse sprayer and flush the hoses, boom and nozzles with clean water. Loosen and physically remove visible deposits. Remove and clean nozzles, screens and strainers. Flush again the entire system with clean water. Take all necessary safety precautions when cleaning equipment. Do not clean near wells or water sources. Consult label tank cleanup procedures for all tank mix partners and be sure to use the most rigorous procedure recommended.

Effectiveness of the cleaning procedures

A laboratory procedure was conducted to simulate the spray tank clean-out of GF-3969 in water. Results indicate that a triple rinse clean-out procedure is effective for the product. A summary is provided in Appendix 3.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	The ambient temperature stability study indicates the shelf life at least 2-years when stored in HDPE containers.
	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.

Table 4.4-1: Packaging information for 200 mL jars (30 to 120 g pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Cylindrical/ approx. 58 mm diameter
Wall thickness:	Min. 0.5 mm
Opening:	Mini 39 mm (inner diameter)
Closure:	Screw cap
Seal:	Aluminium seal
Manner of construction	Injected or extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-2: Packaging information for 500 mL jars (125 to 250 g pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Cylindrical/ approx. 75 mm diameter
Wall thickness:	Min. 0.5 mm
Opening:	Mini 39 mm (inner diameter)
Closure:	Screw cap
Seal:	Aluminium seal or foam gasket
Manner of construction	Injection or extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-3: Packaging information for 1 L jars (280 to 600 g pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Cylindrical approx. 100 mm diameter or rectangular (W x L x H): 105 x 140 x 160 (mm)
Wall thickness:	Min. 0.5 mm
Opening:	Mini 39 mm (inner diameter)

Type	Description
Closure:	Screw cap
Seal:	Aluminium seal or foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-4: Packaging information for 2 L jars (625 g to 1 kg pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Cylindrical approx. 100 mm diameter or rectangular (W x L x H): 105 x 140 x 240 (mm)
Wall thickness:	Min. 0.5 mm
Opening:	Mini 39 mm (inner diameter)
Closure:	Screw cap
Seal:	Aluminium seal or foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-5: Packaging information for 3 L jars (1.1 to 1.6 kg pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Rectangular approx (W x L x H): 107 x 155 x 283 (mm)
Wall thickness:	Min. 0.45 mm
Opening:	Mini 52 mm (inner diameter)
Closure:	Screw cap
Seal:	Foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-6: Packaging information for 4200 mL jars (1.7 to 2 kg pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Rectangular approx (W x L x H): 190 x 142 x 242 (mm)
Wall thickness:	Min. 0.5 mm
Opening:	Mini 52 mm (inner diameter)
Closure:	Screw cap
Seal:	Foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-7: Packaging information for 5 L jars (2 to 3 kg pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Rectangular approx (W x L x H): 151 x 181 x 281 (mm) or 142 x 195 x 317 (mm)
Wall thickness:	Min. 0.5 mm
Opening:	Mini 52 mm (inner diameter)
Closure:	Screw cap
Seal:	Foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

Table 4.4-8: Packaging information for 8200 mL jars (3.1 to 4.5 kg pack size)

Type	Description
Material:	HDPE (High Density Polyethylene)
Barrier material:	None
Shape/size:	Rectangular approx (W x L x H): 179 x 240 x 307 (mm)
Wall thickness:	Min. 0.5 mm
Opening:	Mini 52 mm (inner diameter)
Closure:	Screw cap
Seal:	Foam gasket
Manner of construction	Extruded blow molding
UN/ADR	Compliant
Additional Data (if required)	Not refillable or returnable

The packaging complies with ADR regulations and has been tested using the ADR test methods appropriate to the pack type, material and classification of the contents. Appropriate UN certificates have been issued.

Resistance of the packaging material to its contents

These packaging are standard packaging used by the applicant for similar formulations for more than 10 years. This long period of use has proved its suitability and resistance, which has been confirmed by additional compatibility and permeability tests.

4.5 Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging (KCP 4.5)

4.5.1 Neutralisation Procedure (KCP 4.5.1)

Please refer to the Safety Data Sheet provided in the Core Part C.

4.5.2 Controlled Incineration (KCP 4.5.2)

Please refer to the Safety Data Sheet provided in the Core Part C.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – all documents

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
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	DuPont	Y
KCP, 2.2/01	Jones, J.S.	2017	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isxadifen 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	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y
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	DuPont/Corteva	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
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	DuPont	Y
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	DuPont	Y
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	DuPont	Y
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	Corteva	Y
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	Corteva	Y
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	DuPont	Y

List of data submitted by the applicant and relied on – vertebrate studies

No vertebrate studies submitted.

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

No studies previously submitted and relied upon.

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

No vertebrate studies previously 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	Owner
-	-	-	-	-	-

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Rimsulfuron

No new or additional studies have been submitted.

A 2.2 Thifensulfuron methyl

No new or additional studies have been submitted.

A 2.3 Isoxadifen-ethyl

No new or additional studies have been submitted.

Appendix 3 Additional information provided by the applicant

A 3.1 Study 1, AT-18-009

Comments of zRMS:	Accepted. Taking in to account the results of the study triple rinsing with tap water is recommended.
-------------------	--

Reference:	KCP 4.2/01
Report:	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
DuPont Report No.:	AT-18-009
Testing Facility Report No.:	AT-18-009
Guidelines	EU Reg 284/2013 Annex A Sec 4.2 (2013)
Deviations:	None
GLP:	No
Acceptability:	Yes

Executive summary:

A laboratory procedure was conducted to simulate a spray tank clean-out of a blend containing 14.8% rimsulfuron + 9.25% thifensulfuron-methyl + 11.11 % isoxadifen present in a dispersible granules formulation (GF-3969) and subsequently added to water at a concentration anticipated by the Good Agricultural Practices (GAP). The results show that the TER (Toxicity Exposure Ratio) is superior to EPPO PP 1/292 (1) standard on sensitive crops like sunflower validating as such the tank cleaning procedure proposed made of three times 10% tank capacity wash with clean water.

I. MATERIALS AND METHODS

A. MATERIALS

Test material:	GF-3969
Purity:	Rimsulfuron, 25SG Thifensulfuron methyl, 50SG Isoxadifen ethyl, 50WG
Description:	Water dispersible granules

B. STUDY DESIGN AND METHOD

The EU Reg 284/2013 Annex A Sec 4.2 (2013) protocol was used to evaluate the effectiveness of the recommended cleaning procedure.

A tank mix containing GF-3969 was prepared with rimsulfuron (14.8%), thifensulfuron-methyl (9.25%) and isoxadifen (11.11%) water dispersible granules to achieve an application rate of 135 g commercial product (gcp)/ha delivered in 200 L/ha, *i.e.* 0.8 g of Titus 25WG + 0.25 g of Harmony 50SG + 0.3 g of X4145 (isoxadifen) in 2000 mL of Cipac D water. After two minutes of stirring, four 100-mL aliquots of the tank mix were poured into 125 mL squared High Density Poly Ethylene (HDPE) jars, which were capped and allowed to stand at room temperature overnight.

Each polyethylene bottle was subjected to a standard cleanout:

1. The jar was inverted and shaken to suspend any settled material and the liquid was discarded.
2. 10 mL tap water was added, the bottle was inverted twice, and the rinsate was discarded.
3. Step 2 was repeated twice.
4. 5 mL water and 5 mL acetonitrile were added and the bottle was shaken well to solubilize any residue on the inside wall of the jar.

5. The water and acetonitrile solution was filtered (RC 0.2 µm) and was analysed by liquid chromatography for the active substances.

II. RESULTS AND DISCUSSION

The concentration of active substance found in the water and acetonitrile extract after the cleanout was <0.02 ppm rimsulfuron and thifensulfuron-methyl, and ≤0.17 ppm isoxadifen-ethyl. The TER (Toxicity Exposure Ratio) is superior to 1 on sensitive crops like sunflower. The results indicate that the cleanout procedure prescribed is effective.

III. CONCLUSION

GF-3969 was efficiently removed using a three water rinse procedure.

(Huby, J.P., 2018)