

REGISTRATION REPORT

Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

CLOSER (GF-2626)

120 g/L Sulfoxaflor

Southern Zone

Zonal Rapporteur Member State: France

(Field F)

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

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IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

Sulfoxaflor is a new active substance which is approved according to Article 9 of Regulation (EC) No 1107/2009 (Regulation EU 2015/1295). Ireland (Pesticide Registration and Control Division, PRCD) is the rapporteur Member State (RMS).

The active substance submission followed a zonal approach where the evaluation was shared by four Member States participating under a work-share umbrella as follows: Ireland - RMS, lead reviewer for the sections Toxicology, Residues and Metabolism along with coordination of the work-share project. France: Lead reviewer for the sections Identity/Physical-Chemical properties, Methods of Analysis and Efficacy/Biology. Poland: Lead reviewer for the section Environmental Fate. Czech Republic: Lead reviewer for the section Ecotoxicology.

Dow AgroSciences submitted an EU MRL dossier to the RMS, Ireland, in April 2011. The EU MRL evaluation was integrated with the active substance evaluation under 1107/2009.

There were two representative formulations for the EU active approval submission. These were GF-2372 (500 g/kg WG) and GF-2626 (120 g/L SC).

This current submission is for one of these two formulations, GF-2626. This is the first submission for authorisation of plant protection products containing sulfoxaflor in EU Member States. The proposed zonal RMS for Central Zone and Southern Zone are Ireland and France respectively.

Where appropriate, this document refers to the conclusions of the EFSA review report (EFSA Journal 2014; 12(5):3692) of sulfoxaflor. This will be where: the active substance data are relied upon in the risk assessment of the formulation; or when the EU review concluded that additional data/information should be considered at national registration.

This Part B document only reviews data (active substance or plant protection product) and additional information that has not previously been considered within the EU review process, as part of the active approval decision. Studies for the active substance which have already been evaluated during the approval process are not summarised. New active substance data are only included if they are considered essential for the evaluation and a full study summary is provided.

Details of the active substance, the active approval Regulation are provided in Table #-1.

Table #-1: Details for the active substance

Active Substance	Approval Regulation	EFSA Scientific Report
Sulfoxaflor	2015/1295	EFSA Journal 2014;12(5):3692 revised March 2015

The active approval Regulation for sulfoxaflor provides specific provisions which need to be considered by the applicant in the preparation of their product submissions and by the Member States prior to granting an authorisation:

For sulfoxaflor, Member States shall pay particular attention to [to be defined].

These concerns have been addressed within the current submission.

NOTE

Sulfoxaflor is also referred to as manufacture's code numbers X11422208, XR-208, XDE-208 and DE-208 in the section.

IIIA 1.1 Applicant

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Contact	

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacture(s) of the preparation

The address and contact details of the manufacturer and the location of the manufacturing sites for the preparation are confidential and the data is provided separately in Part C of this Registration Report.

IIIA 1.2.2 Manufacturer(s) of the active substance

The address and contact details of the manufacturers and the location of the manufacturing sites for the active substance are confidential and the data is provided separately in Part C of this Registration Report

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

Information on the purity of the active substance is provided separately in Part C of this Registration Report.

Information on impurities in the active substance is confidential and is provided in Part C of this Registration Report.

Since the active approval, no changes have been made to the manufacturing site or specification of the active substances.

IIIA 1.3 Trade names and manufacturer's code numbers for the preparation

The code number for the preparation is GF-2626. Refer to Registration Report Part A for trade names.

IIIA 1.4 Detailed quantitative and qualitative information on the composition of the preparation

IIIA 1.4.1 Content of active substances and formulants

Information on the content of the active substance and formulants are provided separately in Part C of this Registration Report.

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by Regulation 1107/2009.

IIIA 1.4.3 Common names and code numbers of the active substance

Active	Data Point	Type	Name/Code Number
Sulfoxaflor	1.4.3.1	ISO common name	Sulfoxaflor

Active	Data Point	Type	Name/Code Number
	1.4.3.2	CAS No.	946578-00-3
	1.4.3.2	EINECS No.	not available
	1.4.3.2	CIPAC No.	820
	1.4.3.2	ELINCS	not available
	1.4.3.3	Salt, ester anion or cation present	none

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function

CONFIDENTIAL information - data provided separately (Part C).

Formulation process

IIIA 1.4.1.1 Description of formulation process

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.1.2 Discussion of the formation of impurities of toxicological concern

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.5 Type of preparation and code

Type : Suspension Concentrate [Code : SC]

IIIA 1.6 Function

Insecticide

IIIA 1.7 Other/special studies

This is not an EC data requirement/ not required by Regulation 1107/2009.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and Physical state (IIIA 2.1)	Visual and Olfactory Inspection	11.2 wt% Sulfoxaflo TSN032891-0003	Tan liquid at 25.0 °C with a mild odor	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level
Explosive properties (IIIA 2.2.1 / 1)	EEC A14	11.2 wt% Sulfoxaflo TSN032891-0003	Not explosive No significant exotherm by DSC.	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level
Explosive properties (IIIA 2.2.1 / 2)	EEC A14	N/A	None of the components have functional groups of known explosive potential.	N/A	Madsen, S. 2011, Report No. NAFST-11-176	Evaluated and agreed at EU level
Oxidizing properties (IIIA 2.2.2)	EEC A17	N/A	None of the components have functional groups of known oxidising potential.	N/A	Madsen, S. 2011, Report No. NAFST-11-176	Evaluated and agreed at EU level
Flash point (IIIA 2.3.1)	EEC A9	11.2 wt% Sulfoxaflo TSN032891-0003	Flashpoint > 100 °C	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Flammability (IIIA 2.3.2)	EEC A10, A11, or A12	N/A	Not applicable. Not required for an SC formulation.	N/A	N/A	-
Auto-flammability (IIIA 2.3.3)	EEC A15, A16 or UN Test	11.2 wt% Sulfoxaflor TSN032891-0003	self-ignition temperature 380 °C	Y	Turner, B., 2011, Report No. NAFST-11-2	Evaluated and agreed at EU level
Acidity or alkalinity and pH (IIIA 2.4.1)	CIPAC MT 31 and 75	N/A	Not required since the pH during stability testing was >4 and <10 and was stable after storage	N/A	N/A	-
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2 / 1)	CIPAC MT 75.3	11.2 wt% Sulfoxaflor TSN032891-0003	3.81 @ 24.8°C (1% aqueous suspension)	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	11.2 wt% Sulfoxaflor TSN032891-0003	4.21 (1% aqueous suspension)	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.4.2 / 2)						
Kinematic viscosity (IIIA 2.5.1)	OECD 114	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Dynamic viscosity (IIIA 2.5.2)	OECD 114	11.2 wt% Sulfoxaflor TSN032891-0003	units = mPas <u>20.1°C</u> <u>RPM</u> 287.7 10 456.3 5.0 534.8 4.0 725.4 2.5 842.3 2.0 1266 1.0 <u>40.0°C</u> <u>RPM</u> 142.5 20 214.1 10 321.6 5.0 372.8 4.0 546.8 2.0 787.5 1.0 non-Newtonian liquid	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (IIIA 2.5.3)	EEC A5	11.2 wt% Sulfoxaflor TSN032891-0003	59.0 mN/m @ 0.01% 43.5 mN/m @ 0.2% percent v/v dilution in water @ 20 °C	Y	Turner, B., 2011, Report No. NAFST-11-2	Evaluated and agreed at EU level
Relative density (IIIA 2.6.1)	EEC A3	11.2 wt% Sulfoxaflor TSN032891-0003	1.0572 g/mL @ 20.0 °C	Y	Frank, Ashleigh, 2011, Report No. FAPC-G-11-27	Evaluated and agreed at EU level
Bulk or tap density (IIIA 2.6.2)	CIPAC MT 169	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Storage Stability after 14 days at 54 °C (IIIA 2.7.1)	CIPAC MT 46 (accelerated storage)	11.2 wt% Sulfoxaflor TSN032891-0003	<u>Glass Container</u> Sulfoxaflor a.i. before storage = 11.27% Sulfoxaflor a.i. after storage = 11.23% No significant physical changes observed and all properties were within acceptable limits before and after storage.	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	CIPAC MT 46 (accelerated storage)	11.2 wt% Sulfoxaflor TSN032891-0003	<u>Conditions: 8 weeks at 40 °C</u> <u>HDPE Container</u> Sulfoxaflor a.s. before storage = 11.27% Sulfoxaflor a.s. after storage = 11.13% <u>PET Container</u> Sulfoxaflor a.i. before storage = 11.27% Sulfoxaflor a.i. after storage = 11.09% No significant physical changes observed and all properties were within acceptable limits before and after storage for both HDPE	Y	Rao, T.V., 2011, Report No. NAFST-11-65	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			and PET containers.			
Minimum content after heat stability testing (IIIA 2.7.3)	CIPAC MT46 (accelerated storage)	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39, 48, 51 or 54	11.2 wt% Sulfoxaflor TSN032891-0003	Product was stable following 7 days at 0 °C. No separation was observed.	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level
Ambient temperature shelf life (IIIA 2.7.5)	GIFAP Monograph No. 17	11.8 wt% Sulfoxaflor TSN301891	<u>Conditions: 1 year Ambient HDPE Container</u> Sulfoxaflor a.s. before storage = 11.9% Sulfoxaflor a.s. after storage = 11.7%	Y	Rao, T.V., 2014, Report No. NAFST-12-315 (1 year Interim Report)	Provisional stability after 1 year storage is acceptable. The two years study is therefore missing and is required.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			<p><u>PET Container</u></p> <p>Sulfoxaflor a.i. before storage = 11.9%</p> <p>Sulfoxaflor a.i. after storage = 11.7%</p> <p>No significant physical changes observed and all properties were within acceptable limits before and after storage for both HDPE and PET containers.</p> <p>The final 24 month report is expected in April, 2015</p>			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	GIFAP Monograph No. 17	not applicable	HDPE and PET bottles are expected to be compatible with GF-2626 after 24 months storage at ambient based on storage data of similar formulations and the results for both accelerated and 1 year ambient testing. Final data will be reported following the completion of the 24 month study.	N/A	Rao, T.V., 2014, Report No. NAFST-12-315 (1 year Interim Report)	Provisional stability after 1 year storage is acceptable. The two years study is therefore missing and is required.
Wettability (IIIA 2.8.1)	CIPAC MT 53.3	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.1 CIPAC MT 47.2	11.2 wt% Sulfoxaflor TSN032891-0003	Only traces (<0.1 mL) of foam were observed after 10 seconds. Rate: 0.5% v/v	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level
Suspensibility (IIIA 2.8.3.1)	CIPAC MT 184	11.2 wt% Sulfoxaflor TSN032891-0003	Max use rate (0.5% w/v): 100.32% Min use rate (0.1% w/v): 101.39%	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (IIIA 2.8.3.2)	CIPAC MT 174	11.2 wt% Sulfoxaflor TSN032891-0003	100.51%	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level
Dilution stability (IIIA 2.8.4)	CIPAC MT 41	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Dry sieve test (IIIA 2.8.5.1)	Not Relevant	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Wet sieve test (IIIA 2.8.5.2)	CIPAC MT 185	11.2 wt% Sulfoxaflor TSN032891-0003	0.102% retained on 75 µm sieve	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution (IIIA 2.8.6.1)	OECD 110	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Nominal size range of granules (IIIA 2.8.6.2)	CIPAC MT 170	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Dust content (IIIA 2.8.6.3)	CIPAC MT 171 gravimetric	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Particle size of dust (IIIA 2.8.6.4)	OECD 110	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Friability and attrition (IIIA 2.8.6.5)	CIPAC MT 178	not applicable	not applicable not required for an SC	N/A	N/A	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			formulation			
Emulsifiability (IIIA 2.8.7.1)	-	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Emulsion stability (IIIA 2.8.7.2)	-	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Re-emulsifiability (IIIA 2.8.7.3)	-	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Stability of dilute emulsions (IIIA 2.8.7.4)	-	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Stability of emulsions	-	not applicable	not applicable	N/A	N/A	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.8.7.5)			not required for an SC formulation			
Flowability (IIIA 2.8.8.1)	-	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Pourability (including rinsed residue) (IIIA 2.8.8.2)	CIPAC MT 148	11.2 wt% Sulfoxaflor TSN032891-0003	2.55% residue 0.22% rinsed residue	Y	Rao, T.V., 2011, Report No. NAFST-11-64	Evaluated and agreed at EU level
Dustability following accelerated storage (IIIA 2.8.8.3)	CIPAC MT 34	not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Physical compatibility of tank mixes	-	not applicable	This material is not labelled to be mixed with other products	N/A	N/A	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.9.1)						
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	not applicable	This material is not labelled to be mixed with other products	N/A	N/A	-
Adhesion to seeds (IIIA 2.10.1)	-	not applicable	not used for seed treatment	N/A	N/A	-
Distribution to seed (IIIA 2.10.2)		not applicable	not applicable not required for an SC formulation	N/A	N/A	-
Miscibility (IIIA 2.11)	Not required by Regulation 1107/2009.	-	-	-	-	-
Dielectric breakdown (IIIA 2.12)	Not required by Regulation 1107/2009.	-	-	-	-	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Corrosion characteristics (IIIA 2.13)	Not required by Regulation 1107/2009	-	-	-	-	-
Container material (IIIA 2.14)	Not required by Regulation 1107/2009	-	-	-	-	-
Other/special studies (IIIA 2.15)	no other special studies	-	-	-	-	-

IIIA 2.16 Summary and evaluation of data presented under Points 2.1 to 2.15

GF-2626 SC is a tan liquid. It does not possess any explosive or oxidizing properties. The material demonstrated stability and performance acceptable to the intended use of this product based on the completed studies to date. Accelerated stability data after 2 weeks at 54 °C and 8 weeks 40 °C of storage and ambient stability after 1 year of storage indicated stability and performance properties are preserved.

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IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of use

GF-2626 is a 120 g/L Suspension Concentrate formulation of sulfoxaflor intended for use as an insecticide in agriculture. For full details of all uses please refer to Appendix 2 of this document (table of intended uses).

IIIA 3.2 Nature of effects on harmful organisms

GF-2626 contains the active substance sulfoxaflor, a sulfoximine insecticide, which acts as an agonist at the nicotinic acetyl-cholin receptor; death follows ingestion and/or absorption by the target insect pests.

IIIA 3.3 Details of intended use

IIIA 3.3.1 Details of existing uses

For full details of all uses please refer to Appendix 2 of this document (table of intended uses). The list of target crops and pests grouped by regulatory zones can be found below in IIIA 3.3.2 point.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

GF-2626 controls the following pests in the target protected (greenhouse) crops.

CROP	TARGET 1	PESTS CONTROLLED	TARGET 2	PESTS CONTROLLED
Fruiting vegetables - Tomato, Cherry Tomato, Pepper (Bell and non Bell), Eggplant , etc.	Aphids	<i>Aphis gossypii</i> , <i>Myzus persicae</i> , <i>Aphis fabae</i> , <i>Macrosiphum euphorbiae</i> ,	Whiteflies	<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>
Cucurbits - Cucumber, Melon, Water Melon, Zucchini (Courgette), etc.	Aphids	<i>Aphis gossypii</i> , <i>Myzus persicae</i> , <i>Aphis fabae</i> , <i>Aphis nasturtii</i> , <i>Macrosiphum euphorbiae</i> ,	Whiteflies	<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>
Ornamentals (Bulbs, Ornamentals, Flowers)	Aphids	<i>Aphis gossypii</i> , <i>Myzus persicae</i> , <i>Aphis fabae</i> , <i>Macrosiphum euphorbiae</i> , <i>Macrosiphum rosae</i>	Whiteflies	<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>

IIIA 3.3.3 Effects achieved

GF-2626 is intended to provide effective control of the pests listed above. Sulfoxaflor exhibits a high degree of efficacy against a wide range of sap-feeding insects, including those resistant to neonicotinoids and other insecticides.

IIIA 3.4 Proposed application rates (active substance and preparation)

For full details of all uses please refer to Appendix 2 of this document (table of intended uses).

IIIA 3.5 Concentration of active substance in the material used

For full details of all uses please refer to Appendix 2 of this document (table of intended uses).

IIIA 3.6 Methods of application, type of equipments used and volume of diluent

GF-2626 can be applied through all conventional sprayers including tractor mounted or self propelled hydraulic sprayers or mistblowers if they are in good working order and have been calibrated to manufacturer instructions.

For full details of all uses please refer to Appendix 2 of this document (table of intended uses).

IIIA 3.7 Number and timings of applications, timing, growth stages (of crop and harmful organism) and duration of protection

IIIA 3.7.1 Maximum number of applications and their timings

Maximum number of applications and their timings are detailed in Appendix 2 of this document (table of intended uses).

IIIA 3.7.2 Growth stages of crops or plants to be protected

Growth stages of crops or plants to be protected are detailed in Appendix 2 of this document (table of intended uses).

IIIA 3.7.3 Development stages of the harmful organism concerned

GF-2626 is applied to the target insects when they are likely in mixed growth stages of eggs, larvae, nymphs and adults. In any situation there is likely to be a number of life stages present so it is not possible to define a single development stage.

IIIA 3.7.4 Duration of protection afforded by each application

Duration of protection is dependent on many variables such as pest pressure, weather conditions, temperature, etc. For aphids knockdown of insects present and typically 14 - 21 days protection is expected from a single application of GF-2626.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Maximum 2 applications are allowed in a season. Duration of protection is dependent on many variables such as pest pressure, weather conditions, temperature, etc. After a fast

knockdown of insects typically 14 - 21 days protection is expected from a single application of GF-2626. In situations where multiple applications of insecticides are made against the target pest, it is expected that GF-2626 will be used in programmes with other insecticides with different modes of action which will ensure season long periods of protection where required. In these instances the duration of protection from GF-2626 will be sufficient, when used with other products, to ensure full crop protection. These programmes will be dependent on the portfolio of insecticides approved for the pest/crop in the Member State.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Minimum waiting period or other precaution between last application and sowing or planting succeeding crops is not required as GF-2626 applied at the registered rate is safe to any following crop.

IIIA 3.8.2 Limitations on choice of succeeding crops

Limitations on choice of succeeding crops do not exist as GF-2626 has no limitations on succeeding crops.

IIIA 3.8.3 Description of damage to rotational crops

GF-2626 does not damage succeeding crops (Zonal Biological Assessment Dossier, Active approval II 6.2.6).

IIIA 3.9 Proposed instructions for use as printed on labels

Proposed instructions for use are specified on country labels, located in Document A.

IIIA 3.10 Other/Special studies

There are no other special studies required for this formulation.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Nature and characteristics of the packaging:

Specific Requirement:	
Material:	<ol style="list-style-type: none"> PET Bottle HDPE bottle
Capacity:	<p>1. PET Bottles 0.25 litre, 0.5 litre, 1 litre, 2 litre, 3 litre, 5 litre, 10 litre, 20 litre.</p> <p>0.25 litre bottles may or may not be, packed 12 x 0.25 litre or 24 x 0.25 litre to an outer corrugated fibreboard case.</p> <p>0.5 litre bottles, may or may not be, packed 10 x 0.5 litre to an outer corrugated fibreboard case.</p> <p>1 litre bottles, may or may not be, packed 10 x 1 litre to an outer corrugated fibreboard case.</p> <p>2 litre bottles, may or may not be, packed 8 x 2 litre to an outer corrugated fibreboard case.</p> <p>3 litre bottles, may or may not be, packed 6 x 3 litre to an outer corrugated fibreboard case.</p> <p>5 litre bottles, may or may not be, packed 2 x 5 litre, 3 x 5 litre or 4 x 5 litre to an outer corrugated fibreboard case.</p> <p>10 litre bottles may or may not be, packed 2 x 10 litre to an outer corrugated fibreboard case.</p> <p>20 litre bottle may or may not be packed to an outer corrugated fibreboard case.</p> <p>2. HDPE bottle, 0.25 litre, 0.5 litre, 1 litre, 2 litre, 3 litre,</p>

	<p>5 litre, 10 litre, 20 litre.</p> <p>0.25 litre bottles may or may not be, packed 12 x 0.25 litre or 24 x 0.25 litre to an outer corrugated fibreboard case.</p> <p>0.5 litre bottles, may or may not be, packed 10 x 0.5 litre to an outer corrugated fibreboard case.</p> <p>1 litre bottles, may or may not be, packed 10 x 1 litre, 12 x 1 litre to an outer corrugated fibreboard case.</p> <p>2 litre bottles, may or may not be, packed 8 x 2 litre to an outer corrugated fibreboard case.</p> <p>3 litre bottles, may or may not be, packed 6 x 3 litre to an outer corrugated fibreboard case.</p> <p>5 litre bottles, may or may not be, packed 2 x 5 litre, 3 x 5 litre or 4 x 5 litre to an outer corrugated fibreboard case</p> <p>10 litre bottles may or may not be, packed 2 x 10 litre to an outer corrugated fibreboard case.</p> <p>20 litre bottle may or may not be packed to an outer corrugated fibreboard case.</p>
Type of closure and size of opening:	<p>PET and HDPE: Induction Seal, Bore seal, compression seal or valve seal.</p> <p>Screw cap 28, 45, 50, 61 and 63 mm (with induction, compression, bore seal or valve seal)</p>

IIIA 4.1.2 Suitability of the packaging and closures

Statement of compliance:

The packaging complies with ADR regulations having been tested using the ADR test methods appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued.

IIIA 4.1.3 Resistance of the packaging material to its contents

Containers tested as part of the accelerated stability study indicated that GF-2626 is compatible with HDPE and PET bottles. Containers tested as part of the 2 year ambient study are in progress and will be reported when completed. However, based on similar formulations (e.g. 240 g/L SC of sulfoxaflor) it is expected that GF-2626 will be compatible with HDPE and PET bottles.

Storage Conditions:

Stability of the container has been tested for 8 weeks at 40°C and for 1 year at ambient conditions (interim report). The ambient testing continues to evaluate the container and its contents for 2 years at ambient temperature. Based on similar composition formulations (e.g. 240 g/L SC of sulfoxaflor), it is expected to perform acceptably.

Methodology:

Method DAS-AM-G-09-19 has been used to determine formulation stability in container. Visual observations used to study the effect of the formulation on the container and closure material.

Summary:

The active ingredient content of sulfoxaflor in GF-2626 after 2 weeks at 54 °C of storage was 99.65% of the initial analysis after storage in glass. Additionally, the active ingredient content of sulfoxaflor in GF-2626 after 8 weeks at 40 °C of storage was 99% of the initial analysis after storage in HDPE, 98% of the initial analysis after storage in PET; and after 1 year ambient storage, the active ingredient content was 98.9% and 98.2% of the initial analysis after storage in HDPE and PET, respectively. Studies with GF-2626 following 24 months at ambient temperature are in progress and stored in HDPE and PET containers. Based on similar composition formulations (e.g. 240 g/L SC of sulfoxaflor) and the accelerated and 1 year data, HDPE and PET bottles are expected to show no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product.

HDPE and PET bottles are proposed primary sales packages for GF-2626 and are reported in this document.

The sulfoxaflor active concentrations after 14 days at 54 °C in glass, 8 weeks at 40 °C in HDPE and PET, and 1 year ambient in HDPE and PET were greater than 95% of the initial value and met the Food and Agriculture Organisation (FAO) and World Health Organization (WHO) Specifications for stability of pesticides. The accelerated stability conditions tested can be extrapolated to predict a shelf-life of at least 2 years ambient storage.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

All equipment which has been used with GF-2626 should be rinsed thoroughly with clean water immediately after use until all visible residues have been removed. Water used for rinsing should be applied to the crop if possible in accordance with normal agricultural practice. Alternatively rinsing water containing low levels of sulfoxaflor may be offered to a licensed waste contractor for disposal. A safety data sheet should be provided to any prospective waste contractor so that the disposal requirements of GF-2626 may be evaluated prior to acceptance of the transaction.

No additional protective clothing to that used during the application is recommended for cleaning application equipment.

IIIA 4.2.2 Effectiveness of the cleaning procedures

The biological properties of GF-2626 are such that there are no special requirements needed for effective cleaning of equipment other than rinsing with clean water as described above.

IIIA 4.3 Re-entry periods to protect man, livestock, and the environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

For full details of all uses please refer to Appendix 2 of this document (table of intended uses).

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

Re-entry period for livestock is not relevant, since sulfoxaflor is not used on crops intended for animal grazing.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

Under practical conditions of use, there is no reason for workers to enter the crop shortly after treatment. The general approach of avoiding re-entry until the spray solution has dried is recommended.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

The pre-harvest intervals indicated in the GAP for the crops supported in this submission (Appendix 2) define withholding periods (PHI's). No additional withholding periods are required.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

Good agricultural practice dictates avoid handling until the spray solution has dried is recommended.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

No waiting period is defined as sulfoxaflor has been shown to be safe to following crops (Zonal Biological Assessment Dossier, Active approval II 6.2.6). For management of crop residues a waiting period of 30 days is proposed for succeeding crops.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

Not applicable, there are no known conditions under which the product cannot be used

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

IIIA 4.4.1 Warehouse storage

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.2 User level storage

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.3 Transport

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.4 Fire

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.5 Nature of protective clothing proposed

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.6 Characteristics of protective clothing proposed

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C).

IIIA 4.4.8 Procedures to minimise the generation of waste

In general use, employ good practice to minimise waste when using the preparation. Only purchase and store quantities of product that is required in the short term. Do not open larger containers than is necessary for immediate requirements. Do not mix a volume of spray solution greater than is required for immediate use.

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.5.4 Protection of emergency workers and bystanders

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.5.5 First aid measures

Refer to the safety data sheet for GF-2626 provided in Registration Report (dRR Part C)

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

GF-2626 does not require specific neutralisation. Any spilled material should be contained and swept up into labelled containers for disposal

IIIA 4.6.1 Details of proposed procedures for small quantities

Not applicable, no neutralization procedures are proposed

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Not applicable, no neutralization procedures are proposed

IIIA 4.6.3 Procedures for disposal of small quantities of neutralised waste

Not applicable, no neutralization procedures are proposed

IIIA 4.6.4 Procedures for disposal of large quantities

Not applicable, no neutralization procedures are proposed

IIIA 4.6.5 Evaluation of products of neutralisation (large quantities)

Not applicable, no neutralization procedures are proposed

IIIA 4.6.6 Procedures for disposal of large quantities of neutralised waste

Not applicable, no neutralization procedures are proposed

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

As the halogen content of sulfoxaflor is less than 60%, there is no need for a pyrolysis study.

IIIA 4.8 Disposal procedures for the plant protection product

IIIA 4.8.1 Detailed instruction for safe disposal of product and its packaging

If destruction is necessary then incineration is recommended, however contact with the supplier should be made to evaluate the return of excess material before destruction is undertaken. Incineration (minimum 1220°C for 2 seconds) must take place in a facility approved to handle chemical waste. As the halogen content is <60% there is no need for a pyrolysis study.

Container and washings must be disposed of safely and in accordance with applicable regulations. The preferred options are to send to a licensed reclaimer or to permitted incinerators. Do not re-use the container for any purpose. No other data is available to assess the safety and effectiveness of these procedures.

IIIA 4.8.2 Methods other than controlled incineration for disposal

No additional disposal methods are recommended

IIIA 4.9 Other/special studies

There are no other/special studies available.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

GF-2626 (Sulfoxaflor 120 g/L SC) is currently not authorised for use within the European Union.

An Emergency Use derogation has been granted, in accordance with Article 53 of Regulation 1107/2009, for the use of GF-2626 to control cotton mealybug (*Phenacoccus solenopsis*) in ornamental plants in Cyprus (period of use 1st July – 1st November 2014).

IIIA 11.2 Information on established maximum residue levels (MRLs) in other countries

EU MRLs have not yet been officially established (October 2014), but the table below lists the MRLs proposed by EFSA (EFSA Journal 2014;12(5):3692) following review of the MRL submission during the active substance approval process:


Code	Commodity	MRL (mg/kg)	Comments/Observations
Plant products			
Representative uses – European GAP			
0231010	Tomatoes (outdoor & indoor)	0.06	A higher MRL is proposed on the basis of the MRL application for an import tolerance.
0231030	Aubergines (outdoor & indoor)	0.06	Extrapolated from tomatoes.
0231020	Peppers (outdoor & indoor)	0.15	A higher MRL is proposed on the basis of the MRL application for an import tolerance.
0232010	Cucumbers (outdoor & indoor)	0.03	
0232030	Courgettes (outdoor & indoor)	0.03	Extrapolated from cucumber.
0233010	Melons (outdoor & indoor)	0.02	
0233030	Watermelons (outdoor & indoor)	0.02	Extrapolated from melon
0500090	Wheat (Spelt /Triticale) grain	0.015	A higher MRL is proposed on the basis of the MRL application for an import tolerance
0500070	Rye grain	0.15	Extrapolated from wheat grain
0500010	Barley grain	0.04	
0500050	Oats	0.04	Extrapolated from barley grain
0401090	Cotton seed	0.01*	SEU only.
MRL application			
0120010	Almonds	0.01*	
0120080	Pecans	0.01*	
0130010	Apple	0.4	
0130020	Pear	0.4	
0140010	Apricots	0.5	
0140030	Peaches (Nectarines and similar hybrids)	0.5	

0151010	Table grapes	2.0	
0151020	Wine grapes	0.01*	
0152000	Strawberries	0.5	
0211000	Potatoes	0.01*	
0231010	Tomatoes	0.3	
0231020	Peppers	0.4	
0241010	Broccoli	0.7	
0243010	Mustard greens	2.0	
0251020	Lettuce	4.0	
0252010	Spinach (leaf)	6.0	
0256030	Celery (leaf)	1.5	
0401060	Rape seed	0.1	
0401070	Soya bean (seeds)	0.2	
0500090	Wheat grain	0.09	
0500010	Barley grain	0.01*	A higher MRL is proposed on the basis of the representative uses in the peer review.
Animal products – representative uses – European GAP			
1030000	Eggs	0.01*	Poultry
1016030	Liver	0.01*	
1016010	Muscle	0.01*	
1016020	Fat	0.01*	
1020000	Milk	0.01*	Ruminant (bovine, sheep, goat, horse and other farm animals) There are different commodity code numbers depending on whether the commodity is from bovine, sheep, goat or horse.
	Liver	0.02	
	Muscle	0.01*	
	Fat	0.01*	
	Kidney	0.015	
Animal products – MRL application			
1030000	Eggs	0.01*	Poultry
1016030	Liver	0.01*	
1016010	Muscle	0.01*	
1016020	Fat	0.01*	
1020000	Milk	0.03	Ruminant (bovine, sheep, goat, horse) There are different commodity code numbers depending on whether the commodity is from bovine, sheep, goat or horse.
	Liver	0.2	
	Muscle	0.07	
	Fat	0.04	
	Kidney	0.1	
1011020	Swine fat	0.01*	Pig
1011010	Swine meat	0.01*	
1011030	Swine liver	0.015	
1011040	Swine kidney	0.01	

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

IIIA 11.3 Justified Proposals for Classification and Labelling

Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards		
Health hazards		
Environmental hazards	Aquatic Chronic 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

IIIA 11.5 Proposed label

Proposed labels are provided in the relevant Part A.

IIIA 11.6 Specimens of proposed packaging

Specimens of packaging will be provided on request.

Appendix 1 List of data submitted in support of the application

Data owner: DAS = Dow AgroSciences

Data protection statement

Dow AgroSciences is the first applicant for approval of this active substance. Data protection for the studies and tests indicated in the following reference list is claimed for a period of 10 years from the first authorisation of the formulation in each Member State in accordance with Article 59 of Regulation (EC) No 1107/2009.

These tests and studies are submitted to a Member State for the first time and as such, all are considered necessary for the authorisation. Relevant studies (as listed in SanCo Guidance Document 7109/VI/1995) have been conducted in compliance with the principles of GLP or GEP.

NOTE: Studies in bold were not evaluated at EU active approval

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.1	Frank, A.	2011	<p>Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflor</p> <p>Source: Dow AgroSciences LLC, Indianapolis, IN; USA</p> <p>Report No.: FAPC-G-11-27</p> <p>GLP/GEP (Y/N): Y</p> <p>Published (Y/N): N</p>	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.2.1/1 (see IIIA1 2.1)	Frank, A.	2011	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflor Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-11-27 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 2.2.1/2	Madsen, S.	2011	Oxidising and Explosive Properties Waiver for GF-2626 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-11-176 GLP/GEP (Y/N): N Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.2.2 (see IIIA1 2.2.1/2)	Madsen, S.	2011	Oxidising and Explosive Properties Waiver for GF-2626 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-11-176 GLP/GEP (Y/N): N Published (Y/N): N	Y	DAS
KIIIA1 2.3.1 (see IIIA1 2.1)	Frank, A.	2011	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflo Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-11-27 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.3.3	Turner, B.	2011	<p>Determination of Surface Tension and Auto-Ignition Temperature for GF-2626</p> <p>Source: Dow AgroSciences LLC, Indianapolis, IN; USA</p> <p>Source: Huntingdon Life Sciences Ltd</p> <p>Report No.: NAFST-11-2</p> <p>GLP/GEP (Y/N): Y</p> <p>Published (Y/N): N</p>	Y	DAS
<p>KIIIA1 2.4.2/1</p> <p>(see IIIA1 2.1)</p>	Frank, A.	2011	<p>Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflor</p> <p>Source: Dow AgroSciences LLC, Indianapolis, IN; USA</p> <p>Report No.: FAPC-G-11-27</p> <p>GLP/GEP (Y/N): Y</p> <p>Published (Y/N): N</p>	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.4.2/2	Rao, T.V.	2011	GF-2626: Laboratory Study of Accelerated Storage Stability at 54 °C and Stability at 0 °C Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-11-64 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 2.5.2 (see IIIA1 2.1)	Frank, A.	2011	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflor Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-11-27 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.5.5 (see IIIA1 2.3.3)	Turner, B.	2011	Determination of Surface Tension and Auto-Ignition Temperature for GF-2626 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Source: Huntingdon Life Sciences Ltd Report No.: NAFST-11-2 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 2.6.1 (see IIIA1 2.1)	Frank, A.	2011	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2626, an End-Use Product Containing Sulfoxaflor Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-11-27 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.7.1 (see IIIA1 2.4.2/2)	Rao, T.V.	2011	GF-2626: Laboratory Study of Accelerated Storage Stability at 54 °C and Stability at 0 °C Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-11-64 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 2.7.2	Rao, T.V.	2011	GF-2626: Laboratory Study of Accelerated Storage Stability at 40 °C in PET and HDPE Containers Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-11-65 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.7.4 (see IIIA1 2.4.2/2)	Rao, T.V.	2011	GF-2626: Laboratory Study of Accelerated Storage Stability at 54 °C and Stability at 0 °C Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-11-64 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 2.7.5, 2.7.6	Rao, T.V.	2014	GF-2626: Three Year Laboratory Study of Storage and Corrosion Characteristics at Ambient Temperatures in PET and HDPE Bottles Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-12-315 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
KIIIA1 2.8.2; 2.8.3.1; 2.8.3.2; 2.8.5.2; 2.8.8.2; (see IIIA1 2.4.2/2)	Rao, T.V.	2011	GF-2626: Laboratory Study of Accelerated Storage Stability at 54 °C and Stability at 0 °C Source: International Institute of Biotechnology and Toxicology, Tamil Nadu, India Report No.: NAFST-11-64 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KIIIA1 4.1.2	Waid, C.	2010	Analytical Method and Validation for the Determination of XDE-208 in GF-2372 and GF-2032 End Use Products and in XDE-208 Technical Grade Active Ingredient Dow AgroSciences LLC Report No.: DAS-AM-G-09-19 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS

Appendix 2: Table of intended uses, GAP and justification for the risk envelope

Country	Crop
Austria	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Belgium	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Bulgaria	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Croatia	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Cyprus	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
France	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon)
Germany	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Greece	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Ireland	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Italy	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Malta	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Netherlands	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Portugal	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
Poland	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Romania	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Spain	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers
UK	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zucchini, Melon), Bulbs, Ornamentals, Flowers

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Aubergines (incl. Pepinos)	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interval)	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	<u>Aphids</u> : One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies</u> : Either two applications of 0.024 kg a.s./ha with a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Bulbs, Ornamentals, Flowers	All zones (AT, BE, BG, FR, DE, EL, IE, IT, NL, PT, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 12-59 All year	1-2 (7 days min interval)	0.0012-0.024	200 - 2000	0.024-0.048 (see Remarks)	1	<u>Aphids</u> : One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies</u> : Either two applications of 0.024 kg a.s./ha with a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Cucurbits (edible peel – cucumbers,	All zones (AT, BE,	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar	BBCH 20-87 All year	1-2 (7 days	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	<u>Aphids</u> : One or two applications of 0.024 g a.s./ha. Two applications would be

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	kg as/hl min max	Water (l/ha) min max	kg as/ha min max		
courgettes, gherkins; inedible peel – melons, pumpkins/squash, Zucchini, watermelons)	BG, FR, DE, EL, IE, IT, NL, PT, RO, ES, UK, PL)						spray, broadcast		min interval)					minimum 7 days interval. <u>Whiteflies</u> : Either two applications of 0.024 kg a.s./ha with a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Pepper (incl. Chilli pepper)	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interval)	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	<u>Aphids</u> : One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies</u> : Either two applications of 0.024 kg a.s./ha with a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Tomatoes	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA,	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interval)	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	<u>Aphids</u> : One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies</u> : Either two applications of 0.024 kg

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
	NL, PT, RO, ES, UK, PL)													a.s./ha with a minimum 7 days interval or only one application of 0.048 g a.s./ha.

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

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

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at 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

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions