

REGISTRATION REPORT

Part B

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

Detailed summary of the risk assessment

TRANSFORM (GF-2372)

500 g/Kg Sulfoxaflor

Southern Zone

Zonal Rapporteur Member State: France

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

The applicant has proposed

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III A 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

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.

The Draft Assessment Report (DAR) on sulfoxaflor was finalised and distributed by Ireland in November 2012, with a recommendation for approval of the active substance according to Regulation (EC) 1107/2009. The EFSA peer review process was conducted and the EFSA conclusion was published in May 2014.

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. EU MRLs have been established (Reg (EU) 396/2005).

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-2372. 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 and the Commission Review Report are provided in Table #-1.

Table #-1: Details for the active substance

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

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 :

- (a) the risk to bees and other non-target arthropods;
- (b) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards:

- (a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;
- (b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;
- (c) the risk to pollinators other than honey bees;
- (d) the risk to bee brood.

The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.'

NOTE

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

III A 1.1 Applicant

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

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.

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.

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.

There are no formed toxicologically, ecotoxicologically or environmentally relevant impurities.

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

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

The code number for the preparation is GF-2372. Refer to Registration Report Part A for trade names.

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

Content of active substances and formulants

Active (including variant)	Pure			Technical (at the minimum purity of 950 g/kg)		
	g/kg	g/kg	g/kg	g/kg	g/kg	g/kg
	Nominal	Lower limit*	Upper limit*	Nominal	Lower limit**	Upper Limit**
Sulfoxaflor	500	475	525	526.3	501.3	551.3

* FAO tolerance limits for nominal declared content of above 250 up to 500 g/kg is $\pm 5\%$

* *FAO tolerance limits for nominal declared content of above 500 g/kg is ± 25 g/kg

Certified limits of each component

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

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
	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

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

This is not an EC data requirement.

IIIA 1.4.1.2 Discussion of the formation of impurities of toxicological concern

There is no impurity of toxicological concern.

IIIA 1.5 Type of preparation and code

Type : Water dispersible granule [Code : WG]

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

The formulation GF-2372 was one of the representative formulations for the EU active approval submission of the active substance sulfoxaflor.

No FAO specification is available for Sulfoxaflor yet.

There is no relevant impurity in the technical material so no relevant impurity needs to be monitored in the formulation.

The preparation does not contain any co-formulants H304 >10%.

Commercial Packagings: HDPE bottle, PET bottle and foil bag (BoPA/LDPE/foil/LLDPE).

Use concentration:

0.0048 – 0.048% w/v (South zone)

0.008 – 0.048% w/v (Fr)

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	49.9 wt% Sulfoxaflo ^r TSN031070-0004	White Granular at 24 °C with a mild odor	Y	Frank, Ashleigh, 2009, Report No. FAPC-G-09-17	Acceptable Evaluated and agreed at EU level
Explosive properties (IIIA 2.2.1 / 1)	EEC A14	49.9 wt% Sulfoxaflo ^r TSN031070-0004	Not explosive Not impact sensitive Thermal sensitivity: an exothermic event was observed at 206°C with a heat energy of 385 J/g Impact sensitivity: not impact sensitive	Y	Frank, Ashleigh, 2009, Report No. FAPC-G-09-17	Acceptable Evaluated and agreed at EU level
Explosive properties (IIIA 2.2.1 / 2)	EEC A14	Not applicable	Based on the integral composition, as no co formulant neither active substance have explosive properties, the formulation should be considered as a product without explosive properties.	Y	Madsen, S. 2011, Report No. NAFST-11-177	Acceptable Evaluated and agreed at EU level
Oxidizing properties (IIIA 2.2.2)	EEC A17	Not applicable	Based on the integral composition, as no co formulant neither active substance have oxidizing properties, the formulation should be considered as a product without oxidizing properties.	Y	Madsen, S. 2011, Report No. NAFST-11-177	Acceptable Evaluated and agreed at EU level
Flash point (IIIA 2.3.1)	EEC A9	not applicable	Not required on a WG formulation	Y	N/A	-

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	49.9 wt% Sulfoxaflor TSN031070-0004	not highly flammable GF-2372 ignited but failed to sustain a flame after 19 mm.	Y	Turner, B., 2009, Report No. NAFST-09-86	Acceptable Evaluated and agreed at EU level
Auto-flammability (IIIA 2.3.3)	EEC A15, A16 or UN Test	49.9 wt% Sulfoxaflor TSN031070-0004	No self-ignition temperature under the condition of the test A small exothermic energy was observed at approximately 190°C possibly due to decomposition of one of the components in the test substance. No further exothermic reactions were observed indicating that formulation does not self ignite under the conditions of the test	Y	Turner, B., 2009, Report No. NAFST-09-86	Acceptable Evaluated and agreed at EU level
Acidity or alkalinity and pH (IIIA 2.4.1)	CIPAC MT 31 and 75	not applicable	not required since the pH was not less than 4 or greater than 10.	N/A	N/A	-
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2 / 1)	CIPAC MT 75.3	49.9 wt% Sulfoxaflor TSN031070-0004	7.05 at 24.8°C (1% aqueous dilution)	Y	Frank, Ashleigh, 2009, Report No. FAPC-G-09-17	Acceptable Evaluated and agreed at EU level
Kinematic viscosity (IIIA 2.5.1)	OECD 114	not applicable	Not required on a WG formulation	-	-	-
Dynamic viscosity (IIIA 2.5.2)	OECD 114	not applicable	Not required on a WG formulation	-	-	-

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	not applicable	Not required on a WG formulation	-	-	-		
Relative density (IIIA 2.6.1)	EEC A3	not applicable	Not required on a WG formulation	-	-	-		
Bulk or tap density (IIIA 2.6.2)	CIPAC MT 169	49.9 wt% Sulfoxaflor TSN031070-0004	0.42 g/mL at 24.1°C	Y	Frank, Ashleigh, 2009, Report No. FAPC-G-09-17	Acceptable Evaluated and agreed at EU level		
Storage Stability after 14 days at 54 °C (IIIA 2.7.1)	CIPAC MT 46 (accelerated storage) Analytical method DAS-AM-G-09-19 CIPAC MT 75.3 (pH) CIPAC MT 47.2 (foam) CIPAC MT 53.3 (wettability) CIPAC MT 185 (wet sieve test) CIPAC MT 178 (attrition) CIPAC MT 171 (dust) CIPAC MT 58.2 (particle size) CIPAC MT 174 (degree of dispersion) CIPAC MT 184	49.1 wt% Sulfoxaflor TSN031070-0009	Glass Container			Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level The preparation is stable during 14 days at 54°C as physical properties are not significantly modified. Persistent foam is not modified after storage nevertheless is still out of the acceptable limits. Before and after storage, the formulation is nearly
				T ₀	After 14 days at 54°C			
			Sulfoxaflor content % w/w (analytical method DAS-AM-G-09-19 fully validated in the DAR)	49.4	49.3			
			pH (1% dilution) at ambient temperature	7.25	7.20			
			Persistent foam after 1 min (mL)					
			0.4 % w/v	70	65			
			2.0 % w/v	102	100			
			Wettability at 5% w/v (sec)	5.75	4.08			
			Wet sieve test (75 µm) (%)	0.10	0			
			Attrition (%)	99.9	99.9			
			Dust content (mg)	3.2	4.3			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings			GLP Y/N	Reference	Acceptability / comments
	(suspensibility)		Particle size 710 µm	71.5 % remain ed	59.7 % remain ed			dust free.
			Degree of dispersion (%)	96	92.8			
			Suspensibility 0.001 % 2.0 %	99.2 % 89.0 %	99.7 % 86.2 %			
			No significant physical changes observed and all properties were within acceptable limits before and after storage. Persistent foam slightly exceeded the recommended maximum at a concentration 10X higher than the highest application rate. A separate persistent foam study conducted at the highest application rate provided acceptable results (see IIIA 2.8.2)					
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	CIPAC MT 46 (accelerated storage) Analytical method DAS-AM-G09-19 CIPAC MT 75.3 (pH) CIPAC MT 47.2 (foam) CIPAC MT 53.3	49.1 wt% Sulfoxaflor TSN031070-0009	8 weeks at 40°C Storage was performed in PET for one test item, in HDPE for the second and in foil laminate for the third. <u>Sulfoxaflor content:</u> Initially: 49.4 % w/w After storage in HDPE: 49.4 % w/w After storage in PET: 49.5 % w/w After storage in Sachets: 49.24 %			Y	Stock, M., 2010, Report No. FOR-10-8	Acceptable Evaluated and agreed at EU level The persistent foam is found out of the acceptable limits before and after

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	(wettability) CIPAC MT 185 (wet sieve) CIPAC MT 178 (attrition) CIPAC MT 171 (dust) CIPAC MT 58.2 (particle size) CIPAC MT 174 (dispersion) CIPAC MT 184 (suspensibility)		w/w <u>Packages:</u> No relevant loss of weight was observed after storage in HDPE, PET and sachets. <u>pH of 1 % dilution:</u> Initially: 7.25 After storage in HDPE: 7.47 After storage in PET: 7.47 After storage in Sachets: 7.36 <u>Persistent foaming for 0.4 % w/v after 1 min:</u> Initially: 70 mL After storage in HDPE: 68 mL After storage in PET: 60 mL After storage in Sachets: 59 mL <u>Persistent foaming for 2.0 % w/v after 1 min:</u> Initially: 102 mL After storage in HDPE: 102 mL After storage in PET: 102 mL After storage in Sachets: 102 mL <u>Wettability:</u> Initially: 5.75 sec After storage in HDPE: 1.99 sec After storage in PET: 1.38 sec After storage in Sachets: 1.77 sec <u>Wet sieve test:</u> Initially: 0.10 % After storage in HDPE: 0 % After storage in PET: 0.20 %			storage. The proposed packages (HDPE, PET and sachet based on foil laminate) were found compatible with the formulation. The persistent foams are not in the acceptable limits at the concentration 0.4% and 2%. As mentioned in the DAR, the allowed maximum concentration of use is 0.04% w/v.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability comments /
			<p>After storage in Sachets: 0 %</p> <p><u>Attrition resistance:</u></p> <p>Initially: 99.9 %</p> <p>After storage in HDPE: 99.9 %</p> <p>After storage in PET: 100 %</p> <p>After storage in Sachets: 100 %</p> <p><u>Dust content:</u></p> <p>Initially: 0.0032 g</p> <p>After storage in HDPE: 0.0054 g</p> <p>After storage in PET: 0.0047 g</p> <p>After storage in Sachets: 0.0056 g</p> <p>(nearly dust free in all tested cases)</p> <p><u>Degree of dispersion:</u></p> <p>Initially: 96.0 %</p> <p>After storage in HDPE: 98.3 %</p> <p>After storage in PET: 96.4 %</p> <p>After storage in Sachets: 96.2 %</p> <p><u>Suspensibility at 2 % w/v:</u></p> <p>Initially: 89.0 %</p> <p>After storage in HDPE: 85.6 %</p> <p>After storage in PET: 86.1 %</p> <p>After storage in Sachets: 84.5 %</p> <p><u>Suspensibility at 0.001 % w/v:</u></p> <p>Initially: 99.2 %</p> <p>After storage in HDPE: 99.7 %</p> <p>After storage in PET: 100.4 %</p> <p>After storage in Sachets: 99.9 %</p> <p>No significant physical changes observed and all properties were within acceptable limits before</p>			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			and after storage. Persistent foam slightly exceeded the recommended maximum at a concentration 10X higher than the highest application rate. A separate persistent foam study conducted at the highest application rate provided acceptable results (see IIIA 2.8.2)			
Minimum content after heat stability testing (IIIA 2.7.3)	CIPAC MT46 (accelerated storage)	not applicable	Not required on a WG formulation	-	-	-
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39, 48, 51 or 54	not applicable	Not required on a WG formulation	-	-	-
Ambient temperature shelf life (IIIA 2.7.5)	GIFAP Monograph No. 17 Analytical method DAS-AM-G09-19 CIPAC MT 75.3 (pH) CIPAC MT 47.2 (foam) CIPAC MT 53.3 (wettability) CIPAC MT 185 (wet sieve) CIPAC MT 178	49.1 wt% Sulfoxaflor TSN031070-0009	3 years at ambient temperature Storage was performed in PET (1 L) for one test item, in HDPE (1 L) for the second and in foil laminate for the third one at ambient temperature for three years <u>Sulfoxaflor content:</u> Initially: 49.4 % w/w After storage in HDPE: 49.6 % w/w After storage in PET: 48.8 % w/w	Y	Stock, M., 2013, Report No. FOR-10-10	Acceptable Evaluated and agreed at EU level The preparation is stable during 3 years at room temperature.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	(attrition) CIPAC MT 171 (dust) CIPAC MT 58.2 (particle size) CIPAC MT 174 (dispersion) CIPAC MT 184 (suspensibility)		<p>After storage in Sachets: 49.4 % w/w</p> <p><u>Packages:</u> No relevant loss of weight was observed after storage in HDPE, PET and sachets (highest weight change: 1.4 %).</p> <p><u>pH of 1 % dilution at 22°C</u> Initially: 7.25 After storage in HDPE: 7.00 After storage in PET: 7.25 After storage in Sachets: 7.12</p> <p><u>Persistent foaming for 0.4 % w/v after 1 min:</u> Initially: 70 mL After storage in HDPE: 64 mL After storage in PET: 59 mL After storage in Sachets: 60 mL</p> <p><u>Persistent foaming for 0.04 % w/v after 1 min:</u> Initially: not determined After storage in HDPE: 42 mL After storage in PET: 43 mL After storage in Sachets: 39 mL</p> <p><u>Wettability:</u> Initially: 5.75 sec After storage in HDPE: 2.58 sec After storage in PET: 2.41 sec After storage in Sachets: 2.15 sec</p> <p><u>Wet sieve test:</u> Initially: 0.10 % After storage in HDPE: 0 %</p>			<p>The proposed packages (HDPE, PET and sachet based on foil laminate) were found compatible with the formulation.</p> <p>Comparable results were found after storage at ambient temperature for two years.</p> <p>The persistent foams are not in the acceptable limits at the concentration 0.4% and 2%. As mentioned in the DAR, the allowed maximum concentration of use is 0.04% w/v.</p>

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability comments /
			<p>After storage in PET: 0 % After storage in Sachets: 0 % <u>Attrition resistance:</u> Initially: 99.9 % After storage in HDPE: 99.9 % After storage in PET: 99.8 % After storage in Sachets: 100 % <u>Dust content:</u> Initially: 0.0032 g After storage in HDPE: 0.0002 g After storage in PET: 0.0002 g After storage in Sachets: 0.0001 g (nearly dust free in all tested cases) <u>Particle size distribution:</u> no relevant modification of the distribution was observed after three years storage <u>Degree of dispersion:</u> Initially: 96.0 % After storage in HDPE: 97 % After storage in PET: 95.8 % After storage in Sachets: 96.8 % <u>Suspensibility at 2 % w/v:</u> Initially: 89.0 % After storage in HDPE: 88.1 % After storage in PET: 81.0 % After storage in Sachets: 86.8 % <u>Suspensibility at 0.001 % w/v:</u> Initially: 99.2 % After storage in HDPE: 104 % After storage in PET: 104 % After storage in Sachets: 102 %</p>			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			No significant physical changes observed and all properties were within acceptable limits before and after storage. Persistent foam slightly exceeded the recommended maximum at a concentration 10X higher than the highest application rate. A separate persistent foam study conducted at the highest application rate provided acceptable results (see IIIA 2.8.2)			
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	GIFAP Monograph No. 17	N/A	HDPE bottles, PET bottles, and foil-lined bags have been shown to be compatible with GF-2372 after 36 months storage at ambient temperature.	-	Stock, M., 2013, Report No. FOR-10-10	Acceptable Evaluated and agreed at EU level
Wettability (IIIA 2.8.1)	CIPAC MT 53.3	49.1 wt% Sulfoxaflor TSN031070-0009	5.75 seconds	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.1 CIPAC MT 47.2	49.1 wt% Sulfoxaflor TSN031070-0009	Persistent foam 47 mL (after 1 min) 43 mL (after 12 min) at maximum application rate of 0.04% w/v	Y	Stock, M., 2011, Report No. NAFST-11-175	Acceptable Evaluated and agreed at EU level. The max allowed use rate is 0.04%

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
						w/v
Suspensibility (IIIA 2.8.3.1)	CIPAC MT 184	49.1 wt% Sulfoxaflor TSN031070-0009	Max use rate (2.0% w/v): 89.0% Min use rate (0.001% w/v): 99.2%	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Spontaneity of dispersion (IIIA 2.8.3.2)	CIPAC MT 174	49.1 wt% Sulfoxaflor TSN031070-0009	96.0%	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Dilution stability (IIIA 2.8.4)	CIPAC MT 41	not applicable	Not required on a WG formulation	-	-	-
Dry sieve test (IIIA 2.8.5.1)	Not Relevant	not applicable	Not required on a WG formulation	-	-	-
Wet sieve test (IIIA 2.8.5.2)	CIPAC MT 185	49.1 wt% Sulfoxaflor TSN031070-0009	0.1% remained on the 75 µm sieve.	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Particle size distribution (IIIA 2.8.6.1)	OECD 110	not applicable	Not required on a WG formulation	-	-	-
Nominal size range of granules (IIIA 2.8.6.2)	CIPAC MT 170	49.1 wt% Sulfoxaflor TSN031070-0009	Size, µm % 850 0.1 710 71.5 500 25.7 425 1.56 355 0.4	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable 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
			250 0.3 150 0.1 receiver pan 0.3			
Dust content (IIIA 2.8.6.3)	CIPAC MT 171 gravimetric	49.1 wt% Sulfoxaflor TSN031070-0009	3.2 mg of dust were found indicated that the formulation is nearly dust free	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Particle size of dust (IIIA 2.8.6.4)	OECD 110	not applicable	Not required on a WG formulation	-	-	-
Friability and attrition (IIIA 2.8.6.5)	CIPAC MT 178	49.1 wt% XDE-208 TSN031070-0009	The attrition resistance was measured equal to 99.9%	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Emulsifiability (IIIA 2.8.7.1)	-	not applicable	Not required on a WG formulation	-	-	-
Emulsion stability (IIIA 2.8.7.2)	-	not applicable	Not required on a WG formulation	-	-	-
Re-emulsifiability (IIIA 2.8.7.3)	-	not applicable	Not required on a WG formulation	-	-	-
Stability of dilute emulsions (IIIA 2.8.7.4)	-	not applicable	Not required on a WG formulation	-	-	-
Stability of emulsions (IIIA 2.8.7.5)	-	not applicable	Not required on a WG formulation	-	-	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Flowability (IIIA 2.8.8.1)	CIPAC MT 172	49.1 wt% sulfoxaflor TSN031070-0009	Following two weeks storage at 54 °C, the formulation did not flow spontaneously though a 4.75 mm sieve, but was completely through the sieve following 5 liftings.	Y	Stock, M., 2010, Report No. FOR-10-7	Acceptable Evaluated and agreed at EU level
Pourability (including rinsed residue) (IIIA 2.8.8.2)	CIPAC MT 148	not applicable	Not required on a WG formulation	-	-	-
Dustability following accelerated storage (IIIA 2.8.8.3)	CIPAC MT 34	not applicable	Not required on a WG formulation	-	-	-
Physical compatibility of tank mixes (IIIA 2.9.1)	-	not applicable	This material is not labelled to be mixed with other products	-	-	-
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	not applicable	This material is not labelled to be mixed with other products	-	-	-
Adhesion to seeds (IIIA 2.10.1)	-	not applicable	Not used for seed treatment	-	-	-
Distribution to seed (IIIA 2.10.2)	-	not applicable	Not used for seed treatment	-	-	-

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Miscibility (IIIA 2.11)	Not required by Regulation 1107/2009.	-	-	-	-	-
Dielectric breakdown (IIIA 2.12)	Not required by Regulation 1107/2009.	-	-	-	-	-
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

The formulation GF-2372 is a water dispersible granules formulation (WG). 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 white granular solid with mild odour, containing 500 g/kg of sulfoxaflor. This formulation does not present explosive and oxidising properties. It is not highly flammable, and is not auto-flammable up to 400°C. In aqueous solution (1% dilution), it has a pH value 7.05 at 25°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C/8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The maximum allowed use rate is 0.04% w/v. The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE, PET and foil laminate. Its technical characteristics are acceptable for a WG formulation. The formulation is not classified for the physical-chemical part.

III A 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

III A 3.1 Field of use

GF-2372 is a 500 g/Kg Water Dispersible Granule 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).

III A 3.2 Nature of effects on harmful organisms

GF-2372 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.

III A 3.3 Details of intended use

III A 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 III A 3.3.2 point.

III A 3.3.2 Details of harmful organisms against which protection is afforded

GF-2372 controls the following pests in the target crops:

CROP	PESTS CONTROLLED
Cereals (wheat, barley, oats, rye, spelt, triticale-spring and winter planted)	Sitobium avenae, Rhopalosiphum padi, Metopolophium dirhodum, Schizaphis graminum
Cotton	Aphis gossypii
Oil seed rape	Brevicoryne brassicae, Myzus persicae

III A 3.3.3 Effects achieved

GF-2372 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.

III A 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).

III A 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).

III A 3.6 Methods of application, type of equipments used and volume of diluent

GF-2372 can be applied through all conventional sprayers including tractor mounted or self propelled hydraulic sprayers 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

For full details of all uses please refer to 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-2372 is applied to aphid eggs, apterous nymphs and alate 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-2372

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-2372. In situations where multiple applications of insecticides are made against the target pest, it is expected that GF-2372 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-2372 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-2372 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-2372 has no limitations on succeeding crops.

IIIA 3.8.3 Description of damage to rotational crops

GF-2372 does not damage succeeding crops (Zonal Biological Assessment Dossier, Annex III 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:

Description and specification of the packaging

Specific Requirement:	
Material:	1. PET Bottle 2. HDPE Bottle 3. Foil Bag (BoPA/LDPE/foil/LLDPE)
Capacity:	1. 0.25 to 5 Litres (represent 0.125 to 2.5 kg) 2. 0.25 to 10 litres (represent 0.125 to 5 kg) 3. 0.025 to 1kg The bottles or bags may or may not be packed in a fibreboard carton. The bottles or bags may or may not be additionally packed in multiples in a corrugated fibreboard case.
Type of closure and size of opening:	1 and 2. Induction Seal, compression seal or valve seal. Screw cap 45, 50, 61 and 63 mm (with induction, compression, or valve seal) 3. Bag may be closed by sealing (hot jaws, HF). Bags are equipped with or without plastic zipper for reclosure.

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.

Resistance of the packaging material to its contents

Containers tested as part of the accelerated and 3 year ambient stability studies indicated that GF-2372 is compatible with HDPE and PET bottles and foil-laminate sachets.

Stability of the container has been tested for 8 weeks at 40°C and for 3 years at ambient conditions.

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-2372 after 2 weeks at 54 °C of storage was 99.8% of the initial analysis prior to storage in glass. Additionally, the active ingredient content of sulfoxaflor in GF-2372 after 8 weeks at 40 °C of storage was 100% of the initial analysis after storage in HDPE, 100.2% of the initial analysis after storage in PET, and 99.6% of the initial analysis after storage in foil-lined bags. The stored product showed no significant physical changes after accelerated stability testing. Likewise, the active ingredient content of sulfoxaflor in GF-2372 after 3 years of ambient storage was 100% of the initial analysis after storage in HDPE, 99% of the initial analysis after storage in PET, and 100% of the initial analysis after storage in foil-lined bags. The HDPE and PET bottles and foil-lined bags showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product.

Based on the chemical and physical results obtained from these studies, it can be concluded that GF-2372 is chemically and physically compatible with HDPE and PET bottles and foil-lined bags.

HDPE and PET bottles and foil-lined bags are proposed primary sales packages for GF-2372 and are reported in this document.

The sulfoxaflor active concentrations after 14 days at 54 °C in glass, 8 weeks at 40 °C and 3 years ambient in HDPE and PET bottles and foil-lined bags 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 3 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-2372 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-2372 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-2372 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).

The proposed PHI for the crops being supported in this dossier (GF-2372):

Crop	Zone	PHI
------	------	-----

Cereals (wheat, barley, oats, rye, spelt and triticale)	South	21 days
Oilseed rape	South	28 days
Cotton	South	14 days

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, Annex III 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

Warehouse storage

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

User level storage

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

Transport

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

Fire

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

Nature of protective clothing proposed

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

Characteristics of protective clothing proposed

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

Suitability and effectiveness of protective clothing and equipment

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C).

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.

Combustion products likely to be generated in the event of fire

Refer to the safety data sheet for GF-2372 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

Containment of spillages

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C)

Decontamination of areas, vehicles and buildings

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C)

Disposal of damaged packaging, adsorbents and other materials

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C)

Protection of emergency workers and bystanders

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C)

First aid measures

Refer to the safety data sheet for GF-2372 provided in Registration Report (dRR Part C)

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

GF-2372 does not require specific neutralisation. Any spilled material should be contained and swept up into labelled containers for disposal

Details of proposed procedures for small quantities

Not applicable, no neutralization procedures are proposed

Evaluation of products of neutralization (small quantities)

Not applicable, no neutralization procedures are proposed

Procedures for disposal of small quantities of neutralised waste

Not applicable, no neutralization procedures are proposed

Procedures for disposal of large quantities

Not applicable, no neutralization procedures are proposed

Evaluation of products of neutralisation (large quantities)

Not applicable, no neutralization procedures are proposed

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

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.

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-2372 (Sulfoxaflor 500 g/kg WG) is currently not authorised for use within the European Union.

IIIA 4.10 IIIA 11.2 Information on established maximum residue levels (MRLs) in other countries

EU MRLs have been established (Reg (EU) 396/2005)

IIIA 11.3 Justified Proposals for Classification and Labelling

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

Physical hazards		
Health hazards	Specific target organ toxicity – Repeated exposure category 2	
Environmental hazards	Aquatic Chronic 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H373	H373 May cause damage to organs
	H410	Very 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 4.11 IIIA 11.5 Proposed label

Proposed labels are provided in the relevant Part A.

IIIA 4.12 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)	Relied on	Owner
KIIIA1 2.1	Frank, A.	2009	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Bulk Density, Explodability, and pH of GF- 2372, an End-Use Product Containing XDE-208 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-09-17 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.2.1/1 (see KIIIA1 2.1)	Frank, A.	2009	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Bulk Density, Explodability, and pH of GF- 2372, an End-Use Product Containing XDE-208 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-09-17 GLP/GEP (Y/N): Y Published (Y/N): N	Y	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)	Relied on	Owner
KIIIA1 2.2.1/2	Madsen, S.	2011	Oxidising and Explosive Properties Waiver for GF-2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-11-177 GLP/GEP (Y/N): N Published (Y/N): N	Y	Y	DAS
KIIIA1 2.2.2 (See IIIA1 2.2.1/2)	Madsen, S.	2011	Oxidising and Explosive Properties Waiver for GF-2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-11-177 GLP/GEP (Y/N): N Published (Y/N): N	Y	Y	DAS
KIIIA1 2.3.2	Turner, B.	2009	Determination of Flammability (solids) and Relative Self- Ignition Temperature for GF-2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-09-86 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.3.3 (See KIIIA1 2.3.2)	Turner, B.	2009	Determination of Flammability (solids) and Relative Self- Ignition Temperature for GF-2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-09-86 GLP/GEP (Y/N): Y Published (Y/N): N	Y	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)	Relied on	Owner
KIIIA1 2.4.2 (See KIIIA1 2.1)	Frank, A.	2009	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Bulk Density, Explodability, and pH of GF- 2372, an End-Use Product Containing XDE-208 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-09-17 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.6.2 (See KIIIA1 2.1)	Frank, A.	2009	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Bulk Density, Explodability, and pH of GF- 2372, an End-Use Product Containing XDE-208 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FAPC-G-09-17 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.7.1	Stock, M.	2010	Two-Week Accelerated Storage Stability and Flowability of GF- 2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FOR-10-7 GLP/GEP (Y/N): Y Published (Y/N): N	Y	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)	Relied on	Owner
KIIIA1 2.7.2	Stock, M.	2010	Storage Stability and Package Corrosion Characteristics of GF-2372; Eight-Week Accelerated Study Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FOR-10-8 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.7.5, 2.7.6	Stock, M.	2013	Storage Stability and Package Corrosion Characteristics of GF-2372; Three-Year Ambient Study Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FOR-10-10 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.8.1	Stock, M.	2010	Two-Week Accelerated Storage Stability and Flowability of GF- 2372 Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: FOR-10-7 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Y	DAS
KIIIA1 2.8.2	Stock, M.	2011	Persistent Foaming of GF-2372 End-Use Product Source: Dow AgroSciences LLC, Indianapolis, IN; USA Report No.: NAFST-11-175 GLP/GEP (Y/N): N Published (Y/N): N	Y	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)	Relied on	Owner
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	Y	DAS

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

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Interval between applications (min)	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/ha min max	Water (l/ha) min max	kg as./ha min max		
Cotton	South (EL)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 20-87	1-2	7	0.004-0.0016	300 - 1000	0.024	14	Two applications would be minimum 7 days interval.
Oilseed Rape	South (FR)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 10 - 29 Sep-Dec BBCH 30 – 87 Apr-Jun	1-2	21	0.004-0.016	100-600	0.024	28	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the April-June period. If no autumn application, 2 spring applications are possible.
Cereal (Wheat, Barley,	South (FR, IT)	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray,	BBCH 12-29 Sep-Dec	1-2	21	0.004-0.016	100-600	0.024	21	Two applications would be minimum 21 days interval.

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Interval between applications (min)	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		
Oats, Rye, Spelt, Triticale) [W, S]							broadcast	BBCH 30 – 87 Mar-Jul							Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the March-July period. If no autumn application, 2 spring applications are possible.

- (a) For crops, the EU and Codex classifications (both) should be used; where individual plant, between the plant - type of 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 Stages of Plants, 1997, Blackwell,
- (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) information on season at time of application
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 possible under practical conditions of use
- (f) All abbreviations used must be explained

- (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth ISBN 3-8263-3152-4), including where relevant,
- (k) Indicate the minimum and maximum number of application
- (l) PHI - minimum pre-harvest interval

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

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