

REGISTRATION REPORT

Part B

Section 2: Methods of analysis

Detailed summary of the risk assessment

CLOSER (GF-2626)

120 g/L Sulfoxaflor

All Zones

Zonal Rapporteur Member State: France

(Greenhouse G)

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

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IIIA 5 METHODS OF ANALYSIS

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 5.1 Analytical standards and samples

IIIA 5.1.1 Samples of the preparation

Samples will be provided upon request.

IIIA 5.1.2 Analytical standards for the pure active substance

Samples will be provided upon request.

IIIA 5.1.3 Analytical standards for the active substance as manufactured

Samples will be provided upon request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other compounds included in the residue definition

Samples will be provided upon request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

Samples will be provided upon request.

IIIA 5.2 Methods of analysis of the plant protection product

Analytical methods for determination of sulfoxaflor and relevance of CIPAC methods in GF-2626 were evaluated as part of the EU review of sulfoxaflor active substance.

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

The following analytical method for the determination of the active substance in the plant protection product performed on GF-2626 **was assessed in the EU review**. The study was deemed acceptable but since this is a new substance a full summary of this report is also provided below.

| | |
|--------------|---|
| Report: | DAS-AM-G-11-1 |
| Title: | Analytical Method and Validation for the Determination of Sulfoxaflor in GF-2650 and GF-2626 End Use Products |
| Document No: | NA |
| Guidelines: | SANCO 3030/99 |
| GLP | yes |

| | |
|---|--|
| Description of the method | This method is an internal standard reverse phase HPLC method using a Zorbax SB-Phenyl column and a UV detector (260 nm). Isocratic conditions using 65% water with 0.5% phosphoric acid and 35% methanol with 0.5% phosphoric acid mobile phase. |
| Specificity | The method is specific to Sulfoxaflor as there were no interferences >3% from any of the reagents, internal standard or formulation blanks on the specific retention window for the Sulfoxaflor analytes. |
| Interference by other substances | There are no interferences >3% from any of the components present in either of the formulation blanks or technical Sulfoxaflor. This was confirmed by analysing an aliquot of the respective formulation blanks. |
| Explanation of interferences contributing more than $\pm 3\%$ | Not relevant as no interferences were observed contributing at more than $\pm 3\%$ |
| Linearity | The linearity of the method has been determined from 0.467 – 2.30 mg/mL Sulfoxaflor and 0.509 – 2.04 mg/mL 4-ethylphenol internal standard, and is demonstrated by r^2 values of 0.9996 and 0.9992, respectively. The mg/mL concentration range for sulfoxaflor is equivalent to 4.68 – 23.2 weight percent of formulated product. |
| Accuracy | The accuracy of the method was tested through the preparation of synthetic samples at approximately 50 – 200% of the nominal concentration. Recovery data was obtained over the range of 4.68 – 23.2% Sulfoxaflor by weight. The recovery for Sulfoxaflor ranged from 98.6% to 101.8%, with an average recovery of 100.2%. |

| | |
|---|---|
| Repeatability | <p>Method precision was determined by replicate analyses of a sample of GF-2626. The precision for Sulfoxaflor was calculated as $\pm 0.08\%$ (standard deviation) at an average concentration of 11.1 % w/w Sulfoxaflor in GF-2626. System precision was determined by replicate injection of a method precision sample solution of GF-2626. The system precision was calculated for Sulfoxaflor as $\pm 0.02\%$ (relative standard deviation) and $\pm 0.71\%$ (relative standard deviation) for the internal standard.</p> <p>The data was acceptable as confirmed by the Horwitz equation. No outliers were discarded during the calculations of precisions.</p> |
| Applicability of existing CIPAC methods | No CIPAC method is available |

IIIA 5.2.2 For preparations containing more than one active substance. Description of the method for determining each in the presence of the other

Not applicable; no other active substances are contained in this formulation. See IIIA 5.2.1 above.

IIIA 5.2.3 Applicability of existing CIPAC methods

See IIIA 5.2.1 above.

IIIA 5.2.4 Description of analytical methods for determination of relevant impurities

There are no relevant impurities in this formulation.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

No methods are required as none of the co-formulants are defined as relevant for toxicity (environment, health).

IIIA 5.3 Description of analytical methods for the determination of residues

Analytical methods are active substance data and were provided in the EU review of sulfoxaflor and were considered adequate (EFSA Scientific Report (2014); 12(5):3692).

IIIA 5.3.1 Description of analytical methods for the determination of residues in crops**Crop and Animal Matrices**

Analytical methods are active substance data and were provided in the EU review of sulfoxaflor and were considered adequate (EFSA Scientific Report (2014); 12(5):3692). Details of the EU agreed methods for sulfoxaflor are provided below in Table 5.3.1-01.

Table 5.3.1-01: EU Conclusions: Analytical methods for residues of sulfoxaflor in crop/animal matrices

| Crop/ Matrix | Study | EU Agreed Method ¹ | | |
|--|--------|-------------------------------|---------------------------------------|----------------|
| | | Method | Analyte | LOQ (mg/kg) |
| Wet Crops Dry Crops Oily Crops Acidic Crops | Method | 091031 | Sulfoxaflor X11719474 X11721061 | 0.01 |
| Wet Crops Dry Crops | ILV | 101097 | Sulfoxaflor X11719474 X11721061 | 0.01 |
| Wet Crops Dry Crops Oily Crops Acidic Crops | Method | CEMS-4295 | Sulfoxaflor X11719474 X11721061 | 0.01 |
| Muscle bovine poultry | Method | 091188 (Amended) | Sulfoxaflor X11719474 X11721061 | 0.01 |

| Crop/ Matrix | Study | EU Agreed Method ¹ | | |
|---|--------|-------------------------------|--------------------------------------|----------------|
| | | Method | Analyte | LOQ (mg/kg) |
| Kidney bovine Liver bovine poultry Fat bovine poultry Milk, whole Cream Egg | | | | |
| Liver bovine Milk, whole Egg | ILV | 101098 | Sulfoxaflo X11719474 X11721061 | 0.01 |
| Muscle bovine Kidney bovine Liver bovine Fat bovine | Method | CEMS-4567 | Sulfoxaflo X11719474 X11721061 | 0.01 |

| Crop/ Matrix | Study | EU Agreed Method ¹ | | |
|---|--------|-------------------------------|---------------------------------------|----------------|
| | | Method | Analyte | LOQ (mg/kg) |
| Milk, whole Milk, skim Cream | | | | |
| Muscle poultry Liver poultry Fat poultry Eggs | Method | CEMS-4568 | Sulfoxaflor X11719474 X11721061 | 0.01 |

¹ EFSA Scientific Report (2014); 12(5):3692

IIIA 5.3.2 Storage stability of working solutions in analytical methodology

The storage stability of working solutions was provided in the EU review of sulfoxaflor and was considered adequate.

IIIA 5.4 Description of methods for the analysis of soil

Analytical methods are active substance data and were provided in the EU review of sulfoxaflor and were considered adequate (EFSA Scientific Report (2014); 12(5):3692). Details of the EU agreed methods are provided below in Table 5.4-01.

Table 5.4-01 EU Conclusions: Analytical methods for residues of sulfoxaflor in soil

| Matrix | Study | EU agreed method ¹ | | |
|--------|--------|-------------------------------|--|-------------|
| | | Method | Analyte | LOQ (mg/kg) |
| Soil | Method | 091185 | Sulfoxaflor X11719474 X11519540 X11579457 | 0.001 |
| Soil | ILV | 101100 | Sulfoxaflor X11719474 X11519540 X11579457 | 0.001 |

¹ EFSA Scientific Report (2014); 12(5):3692

IIIA 5.5 Description of methods for the analysis of sediment

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

IIIA 5.6 Description of methods for the analysis of water

Analytical methods are active substance data and were provided in the EU review of sulfoxaflor and were considered adequate (EFSA Scientific Report (2014); 12(5):3692. Details of the EU agreed methods are provided below in Table 5.6-01.

Table 5.6-01: EU Conclusions: Analytical methods for residues of sulfoxaflor in water

| Matrix | Study | EU agreed method ¹ | | |
|-------------|------------------|-------------------------------|-------------|---------------------|
| | | Method | Analyte | LOQ (µg/L) |
| Water (all) | Method (and ILV) | 091186 (Amended) | Sulfoxaflor | |
| | | | X11719474 | 0.050 (with SPE) |
| | | | X11579457 | 0.250 (without SPE) |
| | | | X11519540 | |

¹ EFSA Scientific Report (2014); 12(5):3692

IIIA 5.7 Description of methods for the analysis of air

Analytical methods are active substance data and were provided in the EU review of sulfoxaflor and were considered adequate (EFSA Scientific Report (2014); 12(5):3692. Details of the EU agreed methods are given below in Table 5.7-01.

Table 5.7-01 EU Conclusions: Analytical methods for residues of sulfoxaflor in air

| Matrix | Study | EU agreed method1 | | |
|--------|--------|-------------------|-------------|-------------|
| | | Method | Analyte | LOQ (µg/m3) |
| Air | Method | 091133 | Sulfoxaflor | 0.30 |

¹ EFSA Scientific Report (2014); 12(5):3692.

IIIA 5.8 Description of methods for the analysis of body fluids and tissues

Sulfoxaflor is not classified as toxic or very toxic and therefore a method for body fluids or tissues is not required.

IIIA 5.9 Other/special studies

There are no additional European requirements for formulated products.

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.

| Annex Point | Author | Year | Title Source (where different from company) Company Report No. GLP or GEP status Published or unpublished | Data protection claimed (Y/N) | Owner |
|-------------|----------|------|--|--|-------|
| 5.2.1 | 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 | 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 | | |
| Aubergines (incl. Pepinos) | All zones (AT, BE, BG, HR, | GF-2626 | G | Aphids, Whiteflies | SC | 120 g/L | Ground applied foliar spray, | 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 minimum 7 days |

| 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 | | |
| | CY, FR, DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL) | | | | | | broadcast | | min interval) | | | | | 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, courgettes, gherkins; inedible peel – melons, pumpkins/ squash, Zucchini, watermelons) | All zones (AT, BE, BG, FR, DE, EL, IE, IT, 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. |
| Pepper (incl. | All zones (AT, BE, BG, HR, | GF-2626 | G | Aphids, Whiteflies | SC | 120 g/L | Ground | BBCH 20-87 All year | 1-2 | 0.0016- | 500 - 1500 | 0.024-0.048 (see | 1 | <u>Aphids</u> : One or two |

| 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 | | |
| Chilli pepper) | CY, FR, DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL) | | | | | | applied foliar spray, broadcast | | (7 days min interval) | 0.0096 | | Remarks) | | 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, 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. |

- (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

- (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

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

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