



Environmental
Protection Authority
Te Mana Rauhi Taiao

EPA STAFF EVALUATION AND REVIEW REPORT

Application for approval to import and manufacture GF-2032 for
release



Executive Summary

Background information

1. Dow Agro Sciences (Australia) Limited has applied for approval to import or manufacture GF-2032 containing sulfoxaflor as the active ingredient. GF-2032 is intended for use as a pesticide to control sucking insects on a variety of crops.
2. GF-2032 is in the form of a suspension concentrate and contains 240 g/l sulfoxaflor. Sulfoxaflor is very ecotoxic to bees when they come in contact with spray. There is evidence to suggest that the residues of GF-2032 though, are not toxic to bees after a matter of hours.
3. GF-2032 will be mixed with water and sprayed with conventional ground boom spraying equipment as a foliar spray.

Classification

4. The staff of the Environmental Protection Authority (“the staff”) have classified GF-2032 based on its compositions and the effects of its components:

Hazard Endpoint	HSNO classification
Target organ systemic toxicity	6.9A
Aquatic ecotoxicity	9.1B
Soil ecotoxicity	9.2A
Terrestrial invertebrate ecotoxicity	9.4A

Submissions

5. In response to public notification of the application, a submission was received from the National Beekeepers’ Association (NBA). The NBA was concerned about the toxicity of the substance to bees due to the presence of sulfoxaflor. The NBA requested that the applicant presents more data to demonstrate that this product is safe to beneficial pollinators.
6. The NBA have requested to be heard at a public hearing, though may reconsider that position once they have read this document. If they do reconsider, then agree that they no longer wish to be heard, then there will not be a public hearing for this application.

Controls

Default controls

7. A number of default controls are prescribed by regulations under the Hazardous Substances and New Organisms Act 1996 (the Act) as a consequence of the toxicity and ecotoxicity classifications of this substance. These controls form the basis of the controls that are listed in Appendix D.

8. The staff consider that it is appropriate for certain variations to be made to the default controls. These variations are discussed in Section 7 of this Evaluation and Review (E&R) Report and listed in Appendix E.

Additional controls

9. The staff propose the addition of a number of use and labelling controls for the substance under section 77A of the Act.
10. The label must contain the following statement:
- “Highly toxic to bees. Will kill foraging bees directly exposed through contact during spraying and while spray droplets are still wet. For treatments made to crops in flower or upwind of adjacent plants in flower that are likely to be visited by bees at the time of application, spraying should not occur during the daytime if temperatures within an hour after the completion of spraying are expected to exceed 12 °C. It is recommended that flowering plants on orchard floors be mown just prior to spraying. In top fruit crops the risk to bees from spraying during flowering applies from pink/white bud until after petal fall.”*
11. The use of GF-2032 should be restricted so that:
- The substance shall not be applied into, onto or over water.¹*

Risk and benefits assessment

12. The staff risk assessment has identified that the acute risks to bees is high and requires ensuring application occurs only when bees are not present within the application area. The label statement identified above is one that the applicant has proposed to manage that risk. The staff consider that this label statement will mitigate the acute risks to bees.
13. The staff consider that with controls in place, the risks to end-users, bystanders and the environment are negligible.
14. Benefits of GF-2032 will include:
- Reducing production losses through direct feeding damage caused by sucking insects;
 - Reducing the incidence of plant viruses which are transmitted via sucking insects;
 - Replacing more harmful current pest control methods (organophosphates, carbamates and synthetic pyrethroids).

Conclusion

15. The staff’s risk assessment indicates that with controls in place, there is a negligible level of risk to human health or to the environment using GF-2032.
16. With the proposed controls in place, the overall level of benefit provided by the availability of GF-2032 is greater than the level of adverse effects.

¹ Where ‘water’ means water in all its physical forms, whether flowing or not, but does not include water in any form while in a pipe, tank or cistern or water used in the dilution of the substance prior to application

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1. Summary

Application Code	ERMA200886
Application Type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application Sub-Type	Notified - Category C
Applicant	Dow Agro Sciences (Australia) Limited
Purpose of the application	To import or manufacture GF-2032, an insecticide containing sulfoxaflor, to be used on commercial crops for the control of aphids, dimpling bug, greenhouse whitefly and other key pests
Date Application Received	4 October 2011
Submission Period	7 October 2011 – 21 November 2011
Submissions received	A submission was received from the National Beekeepers' Association (NBA)
Information request	The consideration of the application was postponed to allow further data to be presented by the applicant f

2. Background

- 2.1. GF-2032 is an insecticide containing 240 g/l of sulfoxaflor. It is in the form of a suspension concentrate. GF-2032 is intended for use as an insecticide for the control of aphids, mealy bug, greenhouse whitefly and other key pests on commercial crops.
- 2.2. The applicant has described the lifecycle of the substance as follows.
- 2.3. GF-2032 will either be imported in bulk, imported in finished packaging or made and packed in New Zealand.

Importation

- 2.4. When imported, the manufactured product will be imported by sea freight into New Zealand in bulk or in finished packaging, in compliance with the UNRTG requirements for dangerous goods for marine transport. Upon customs clearance it will be transported to the Dow AgroSciences Limited warehouse designed for the secure storage of agricultural compounds. Bulk transportation is by way of designated trucks and rail wagons designed solely for the transportation of hazardous goods.

Manufacture

- 2.5. When manufactured in New Zealand, GF-2032 would be packaged according to the requirements of the Hazardous Substances (Packaging) Regulations 2001 or if made for export in packages that comply with the importing country requirements, and stored at the New Plymouth facility until transport by road using specialised chemical transport companies to retail farm supply distributors or the point of export.

Transport

- 2.6. If GF-2032 is imported into New Zealand as finished goods or made locally, it will be distributed mainly in 5 litre plastic jerrycans and possibly in similar containers of 1, 10 and 20 litres. Larger containers may be imported for re-packaging. Transportation of large quantities of GF-2032 would be expected to be by an approved third party transport operator.

Storage

- 2.7. The substance may be stored by distributors until sold to farmers, who will transport the substance to their property for secure storage until used according to uses approved by the ACVM Group of the NZFSA.

Use

- 2.8. The substance is to be used by mixing with water and sprayed with conventional ground boom spraying equipment. The substance mixed with water is applied directly to the foliage of the target crops as listed on the label. The applications are to be made according to the Management of Agrichemicals (NZS 8409).

3. Process, consultation and notification

- 3.1. The application was lodged pursuant to section 28 of the Act.
- 3.2. The Labour Group of the Ministry of Business, Innovation and Employment (MBIE)², the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the Ministry of Primary Industries, the Ministry of Health and the Department of Conservation (DOC) were advised of the application. No comments were received.
- 3.3. The application was publicly notified as it was considered that there is likely to be significant public interest in the application because it contains an active ingredient which has not previously been approved in New Zealand. A submission was received from the NBA opposing the approval of GF-2032 on the basis that there was not enough data on the risks to bees provided in the application.
- 3.4. Initially, the application did not contain sufficient information for the staff of the EPA ("the staff") to undertake a full assessment of the substance from a scientific and technical perspective. The staff requested the following additional information under section 58 of the Act to provide data to fill gaps to allow assessment of these substances to be completed satisfactorily.
- Information on the intended uses in New Zealand (a GAP table);
 - Ecotoxicity data on GF-2032 (avian and aquatic studies);
 - Further information on non-target arthropods;
 - Information on residues in pollen and nectar and, bee brood; and
 - Information on larval toxicity.

² Formerly the Department of Labour.

- 3.5. In response to this information request, the applicant has provided the above information to the EPA. The staff consider that this now means that we have sufficient information to make an assessment of the substance.
- 3.6. In preparing this report, the staff took into account:
- The application form;
 - The submission received;
 - Additional information received from the applicant;
 - The response to the submissions from the applicant;
 - The content presented by the applicant at meetings with the EPA and the submitter; and
 - Existing approvals for other pesticides.

4. Hazardous properties

- 4.1. The staff determined the hazard profile of GF-2032 based on the information provided by the applicant and other available information as documented in Appendix A.

Table 1 Hazard classification of GF-2032

Hazard Endpoint	Applicant	Staff
Target organ / systemic toxicity	-	6.9A
Aquatic toxicity	No	9.1B
Soil toxicity	9.2B	9.2A
Terrestrial vertebrate toxicity	9.3B	No
Terrestrial invertebrate toxicity	9.4A	9.4A

5. Submissions

- 5.1. This application was open for submissions from 7 October 2011 to 21 November 2011 and one submission was received. The submission is attached as Appendix B.
- 5.2. A significant number of the submitter's concerns were around information provided in the application which was incorrect. These factual errors have since been amended, and so staff consider that there is no need to address them here.
- 5.3. Instead, given the significant interactions that have occurred between staff, the applicant and the submitter, we have identified the concerns that the staff understand are still held by the submitter.

Fluorine atoms on the sulfoxaflor molecule

- 5.4. In addition to their submission the NBA made the following comments. The three fluorine atoms are part of the trifluoromethyl moiety which was added by Zhu et al (2011) who noted;
- "An investigation of the pyridyl ring SAR revealed that the better aphidicidal activity was afforded by the small lipophilic, electron-withdrawing substituents at the 6-position, with 6-trifluoromethyl being one of the best substituents in terms of aphid control" (p. 2951).
- 5.5. Nowhere in any of Dr Kramer's presentations did he discuss the degradates of this 6-position moiety. It was assumed to remain stable despite its being a lipophilic electron-withdrawing substituent.
- 5.6. Dr Kramer did not address the impact of this lipophilic substituent on the fatty acid esters that are so important in the pheromone ecology of the larvae/forager bee interaction.
- 5.7. In other pesticide studies, the trifluoromethyl moiety has indeed broken down into fluorocitrate or fluoroacetate degradates that are metabolic poisons, i.e. they block the Krebs cycle in the mitochondria.

Staff response

- 5.8. Staff are not concerned by the fluorine atoms in the case of sulfoxaflor. Staff have checked which metabolites were formed in the different studies with sulfoxaflor and found that there is no cleavage of the trifluoromethyl moiety. The link with the pyridin ring is preserved so the concerns are not relevant for this substance.

Persistence of sulfoxaflor

- 5.9. The submitter holds some concerns over the persistence of sulfoxaflor based on the data they have seen.

Staff response

- 5.10. Staff have assessed GF-2032 and do not consider that its persistence is of concern.

6. Risk, cost and benefit assessment

- 6.1. The staff's identification and assessment of risks and costs (adverse effects) and benefits (positive effects) is set out in this section and supported by information in Appendix C.

Risks and costs

Human health

- 6.2. The staff have evaluated the potential of sulfoxaflor and GF-2032 to cause adverse effects to the health and safety of humans during all stages of the substance's lifecycle using a qualitative risk assessment methodology.
- 6.3. The staff have classified GF-2032 as a target organ toxicant (6.9A).

- 6.4. In the staff's opinion, chronic hazards normally require repeated exposure to the substance for the adverse effects to occur and are therefore most relevant to the end-users.
- 6.5. The risks of GF-2032 to human health and safety at various stages of its lifecycle are summarised in Table 2.

Environmental

- 6.6. The staff have evaluated the potential of GF-2032 to cause adverse effects to the environment during all stages of the substance's lifecycle using a qualitative risk assessment methodology.
- 6.7. The staff have classified GF-2032 as being toxic to the aquatic environment (9.1B) and very toxic soil organisms (9.2A) and terrestrial invertebrates (9.4A).
- 6.8. The risks of GF-2032 to the environment at various stages of its lifecycle are summarised in Table 3.

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Table 2: Qualitative assessment of risks to human health for GF-2032

Lifecycle	Description	Likelihood	Magnitude	Matrix	Comment	Level of risk
Manufacture and packaging	Target organ toxicity	Highly improbable	Major	Low	<p>Manufacturing and packaging facilities in New Zealand will be required to meet the HSNO requirements for equipment, emergency management and Personal Protective Equipment (PPE). Compliance with HSNO information provisions (e.g. labels, advertising, Safety Data Sheets (SDS), and MBIE Health and Safety requirements will also apply.</p> <p>While the qualitative descriptors indicate a low level of risk driven by the major chronic effects, the staff consider that these requirements will make the likelihood of exposure that would lead to a chronic effect so highly improbable that the level of risk for the chronic toxic adverse effects is negligible.</p>	Negligible
Importation, transport, storage	Target organ toxicity	Highly improbable	Major	Low	<p>Workers and bystanders will only be exposed to the substance during this part of the lifecycle in isolated incidents where spillage occurs. HSNO controls (e.g. labels, SDS and packaging) and adherence to the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994 (as applicable) will apply.</p> <p>Chronic toxic adverse health effects from exposure to GF-2032 require repeated exposure, the likelihood of which is so highly remote in this stage of the substance's lifecycle as to not occur.</p>	Negligible
Use	Target organ toxicity	Highly improbable	Major	Low	<p>It is considered that, whilst the chronic toxic properties of this substance could cause major adverse effects to the user, the voluntary risk will be sufficiently managed by users involved in the application of this substance to reduce the effect level from low to negligible.</p>	Negligible

Lifecycle	Description	Likelihood	Magnitude	Matrix	Comment	Level of risk
					It is also considered that the use pattern of this substance is similar to a number of existing substances and therefore does not present a greater risk to users than other substances currently available for similar end-use.	
Disposal	Target organ toxicity	Highly improbable	Major	Low	<p>The applicant indicates that the rinse water is to be discharged onto a designated disposal area or onto wasteland away from desirable plants and sources of water. Label instructions also advise on disposal of empty containers and unused product. The triple-rinsed empty containers or unused product would also be suitable for the collection by the Agrecovery container and chemical recycling programme.</p> <p>In all cases of disposal, the substance will be disposed of in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991.</p>	Negligible

Table 3: Qualitative assessment of risks to the environment for GF-2032

Lifecycle	Description	Likelihood	Magnitude	Matrix	Comment	Level of risk
Manufacture, importation, transport and storage	Death or adverse effects to aquatic organisms or non-target terrestrial vertebrates.	Highly improbable	Moderate	Negligible	Provided there is adherence to the HSNO controls (and the Land Transport Rule 45001, the Civil Aviation Act 1990 and the Maritime Transport Act 1994 (as applicable)) the staff consider a spill to be highly improbable. Furthermore, provided importers, manufacturers and those handling the substances adhere to the HSNO controls relating to storage and bunding requirements, a spill is only likely to lead to localised effects.	Negligible
Use	Death or adverse effects to aquatic organisms or non-target terrestrial vertebrates.	Highly improbable	Moderate	Negligible	The use of labelling and safety data sheets prohibiting application of the substance onto, over, or into water and compliance with approved handler requirements will adequately manage most of the risks to the aquatic and terrestrial environments. The additional labelling statement will mitigate the risks to bees.	Negligible
Disposal	Death or adverse effects to aquatic organisms or non-target terrestrial vertebrates.	Highly improbable	Moderate	Negligible	The applicant indicates that the rinse water is to be discharged onto a designated disposal area or onto wasteland away from desirable plants and sources of water. Label instructions also advise on disposal of empty containers and unused product. The triple-rinsed empty containers or unused product would also be suitable for the collection by the Agrecovery container and chemical recycling programme. In all cases of disposal, the substance will be disposed of in accordance with the requirements of the Hazardous Substances (Disposal) Regulations 2001 and the Resource Management Act 1991.	Negligible

Relationship of Māori to the Environment

- 6.9. The potential effects on the relationship of Māori to the environment have been assessed in accordance with sections 6(d) and 8 of the HSNO Act. Under these sections all persons exercising functions, powers, and duties under this Act shall take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (te Tiriti o Waitangi).
- 6.10. As outlined in Table 1, the hazards of GF-2032 have the potential to inhibit Māori in fulfilling their role of kaitiaki particularly in regards to the deterioration of aquatic environments; negative health affect to taonga flora and fauna; and the negative affect to the general health and well-being of individuals and the community.
- 6.11. Based on the assessment of human health and environmental risks of GF-2032 outlined in Tables 2 and 3 above, and when considering information provided relating to the proposed use pattern, the staff consider that the risks to the relationship of Māori to the environment are likely to be negligible.
- 6.12. In addition, GF-2032 may enhance the ability of Māori to fulfil their role as kaitiaki by providing benefits such as reducing the incidence of plant viruses and replacing more harmful pest control substances.
- 6.13. Based on the assessment for GF-2032 outlined in Tables 2 and 3 above, and when considering information provided relating to the proposed use pattern, the staff consider that the risks to the relationship of Māori to the environment are likely to be negligible.
- 6.14. Given this assessment, there is no evidence to suggest that the use of GF-2032 in accordance with controls, will breach the principles of the Treaty of Waitangi.

Assessment of risks to society and the community and the market economy

- 6.15. There are not expected to be any significant adverse impacts on the social environment with the controlled use of GF-2032, apart from the health effects and environmental effects already discussed. Consequently, the staff suggest that this aspect of potential risk need not be considered further.

New Zealand's international obligations

- 6.16. The staff did not identify international obligations that affect the approval of ESN or the bait.

Overall assessment of risks

- 6.17. With controls in place (as detailed in Section 7), the staff consider that the risks to human health and the environment associated with GF-2032 are mitigated. The overall level of risk is therefore negligible.

Identification of benefits

6.18. The applicant has stated that the use of Gf-2032 may provide the following benefits:

- Reducing production losses through direct feeding damage caused by sucking insects;
- Reducing the incidence of plant viruses which are transmitted via sucking insects;
- Replacing more harmful current pest control methods (organophosphates, carbamates and synthetic pyrethroids).

The effects of the substances being unavailable

6.19. If GF-2032 were unavailable, the benefits associated with the availability of the substance would not be realised.

Overall assessment of benefits

6.20. The staff are satisfied that the availability of GF-2032 will provide beneficial effects for some businesses and users of the substance.

7. Controls

7.1. Based on the hazard classification determined for GF-2032, a set of associated default controls specified by regulations under the Act has been identified by the staff as being applicable. The default controls form the basis of the controls set out in Appendix D. Based on its risk assessment, the staff consider that the additions, variations and deletions set out below are applicable to GF-2032.

The setting of exposure limits

7.2. Tolerable Exposure Limits (TELS) can be set to control hazardous substances entering the environment in quantities sufficient to present a risk to people. No TELs have been set for any component of GF-2032 at this time as the level of risk to bystanders is considered negligible. The EPA is however, required to set ADE and PDE values for new active ingredients that may become present in food, to allow the setting of Maximum Residue Levels (MRLs) by MPI.

7.3. The EPA typically adopts Workplace Exposure Standard (WES) values listed in the Ministry of Business, Innovation and Employment's WES Document³ to control exposure in places of work. MBIE has set WES values for Components C, D⁴, F¹, J², but due to the low concentrations at which they are present in the formulation, these have not been applied to GF-2032.

7.4. The default controls allow the EPA to set Environmental Exposure Limits (EELs) to control hazardous substances entering the environment, and application rates for class 9 substances that are to be applied to an area of land (or air or water) and for which an EEL has been set. No

³ <http://www.business.govt.nz/healthandsafetygroup/information-guidance/all-guidance-items/workplace-exposure-standards-and-biological-exposure-indices/workplace-exposure-standards-and-biological-indices-2013.pdf>

EELs are set for any component of GF-2032 at this time as the level of risk to the environment is considered negligible. The default EEL values have been deleted.

- 7.5. As no EELs have been set for GF-2032, no maximum application rates are required to be set. However, the staff note that the environmental exposure modelling indicates there may be a risk where the substance is used outside the specific parameters of the risk assessment. It is therefore considered appropriate to set the following maximum application rates under section 77A.

100 g sulfoxaflor/ha per application; two applications per year with a minimum interval of 14 days between applications for ground-based applications

24 g sulfoxaflor/ha per application; two applications per year with a minimum interval of 14 days between applications for aerial applications.

Variation and deletion of controls

- 7.6. The default controls include requirements for ecotoxic substances to be under the control of an approved handler. However, it is considered that, for GF-2032, this control should only apply during use of the substance, as the risks to the environment during the other phases of the lifecycle will be adequately managed by other controls on the substance. Accordingly, the following control has been substituted for Regulation 9(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001:

(1) The substance must be under the personal control of an approved handler when the substance is:

(a) applied in a wide dispersive⁴ manner; or

(b) used by a commercial contractor.

- 7.7. The staff note that the specified controls do not address the risks associated with storage or use of the substances within stationary container systems (e.g. tanks). These risks include the failure of primary containment resulting in a large spill of the substance into the environment. In addition, the default controls do not allow for dispensation where it is unnecessary for any pipework associated with the stationary container systems to have secondary containment. Accordingly, the application of controls addressing these risks are considered more effective than the specified default controls in terms of their effect on the management, use and risks of the substance. The revised controls are shown in Appendix D.
- 7.8. The default controls include requirements for secondary containment of pooling substances. It is considered that the risks associated with the containment of substances which are not class 1 to 5 substances (i.e. do not ignite or explode) are different to those associated with class 1 to

⁴ 'Wide dispersive' use refers to activities which deliver uncontrolled exposure — also refer to: <http://www.epa.govt.nz/Publications/ER-IS-33-2.pdf>

5 substances. Consequently the secondary containment requirements can be reduced. It is considered that these reduced secondary containment measures are adequate to manage the risks of a spillage of GF-2032 as this substance does not ignite or explode. Therefore, the proposed variation is more cost-effective in terms of managing the risks of the substance. The revised controls are shown in Appendix D.

Additional controls

7.9. The staff note that the environmental risk assessment indicates that restrictions on use are necessary to mitigate the risks GF-2032 presents to the aquatic environment. Accordingly, it is considered that the application of controls addressing these risks will be more effective than the default controls in terms of their effects on the management, use and risks of the substance. Consequently, the following additional control is applied to GF-2032 to restrict the level of risk to the environment:

- GF-2032 shall not be applied onto or into water.

7.10. Due to the high acute toxicity of this substance to bees, it is important that bees are not exposed to the spray. To help prevent harm to bees, the staff consider that the following statement must appear on the label:

Highly toxic to bees. Will kill foraging bees directly exposed through contact during spraying and while spray droplets are still wet. For treatments made to crops in flower or upwind of adjacent plants in flower that are likely to be visited by bees at the time of application, spraying should not occur during the daytime if temperatures within an hour after the completion of spraying are expected to exceed 12 °C. It is recommended that flowering plants on orchard floors be mown just prior to spraying. In top fruit crops the risk to bees from spraying during flowering applies from pink/white bud until after petal fall.

7.11. The staff consider that the application of these controls will be more effective than the specified (default) controls in terms of their effect on the management, use and risks of GF-2032 (section 77A(4)(a)).

Environmental user charges

7.12. The staff consider that use of controls on GF-2032 are an effective means of managing risks associated with this substance. Therefore, it is not considered necessary to apply environmental user charges to this substance as an alternative or additional means of achieving effective risk management. Accordingly, no report has been made to the Minister for the Environment.

Review of controls for cost-effectiveness

7.13. The staff consider that the proposed controls are the most cost-effective means of managing the identified potential risks and costs associated with this application.

8. Overall evaluation and recommendation

- 8.1. The staff's risk assessment indicates that there is a negligible level of risk to human health or to the environment using GF-2032 with controls in place.
- 8.2. The staff also consider that, with the proposed controls in place (Appendix D), the overall level of benefit provided by the availability of this substance is sufficiently great to allow the application to be approved in accordance with clause 26.

Appendix A: Staff classification of GF-2032

The applicant submitted formulation test data for some endpoints of GF-2032. For endpoints where no formulation data was provided, the staff have classified GF-2032 using mixture rules as described in the User Guide to Thresholds and Classifications⁵.

Table 1: Classifications of GF-2032

Hazard Endpoint	Applicant	Staff
Target organ / systemic toxicity	-	6.9A
Aquatic toxicity	No	9.1B
Soil toxicity	9.2B	9.2A
Terrestrial vertebrate toxicity	9.3B	No
Terrestrial invertebrate toxicity	9.4A	9.4A

Data quality – overall evaluation

The data used by staff to classify sodium nitrite are the classifications which have been officially gazetted during the transfer process and are publicly available through the HSNO Chemical Classification Information Database (CCID)⁶. Where additional data have been considered for the risk assessment of the bait, the EPA has adopted the Klimisch *et al* (1997)⁷ data reliability scoring system for evaluating data used in the hazard classification and risk assessment of chemicals.

The staff have assigned Klimisch data reliability scores to submitted studies.

The staff acknowledge that there are frequently data gaps in the hazard classification for chemicals which have been in use internationally for a long time. International programmes such as the OECD High Production Volume programme⁸, REACH⁹, and European Regulation 1107/2009/EC¹⁰ are progressively working towards filling these data gaps. As new information becomes available, staff will update the Hazardous Substances and New Organisms (HSNO) classifications for those substances.

Physico-chemical properties of GF-2032

Table 2: Physico-chemical properties of GF-2032

⁵ <http://www.epa.govt.nz/Publications/ER-UG-03-2.pdf>

⁶ <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>

⁷ Klimisch, H-J., Andrear, M., & U. Tillmann, 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Reg. Toxicol. Pharmacol.* 25, 1–5 (1997)

⁸ <http://www.icca-chem.org/Home/ICCA-initiatives/High-production-volume-chemicals-initiative-HPV/>

⁹ http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

¹⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF>

Property	Results	Test method	Klimisch Score (1-4)	Reference
Colour	Tan	visual	4	Dow – Document M-III (Tier 2)
Physical state	Liquid	visual		
Odour	Mild	Olfactory		
Oxidizing properties	Nil	830.6314		
pH	4.67 at 23.9°C (1% w/w dilution in water)	CIPAC MT 75.1		
Explosive properties	Nil	EEC A14		
Relative Density	1.1066 g/mL at 20°C	EEC A3		
Viscosity (mPas)	<u>20 °C</u> <u>40 °C</u> <u>RPM</u>	830.7100		
	- 242.3 12			
	275.1 10			
	463.8 379.0 6.0			
	525.9 - 5.0			
	615.0 500.3 4.0			
	744.0 598.0 3.0			
	848.4 - 2.5			
	1209 951.0 1.5			
	Non-newtonian fluid: viscosity decreasing with increasing shear rate			
Surface Tension	0.05 g ai/L: 47.0 mN/m 0.75 g ai/L: 42.0 mNm	EEC A5		

Mammalian toxicology - Robust study summaries for the formulation

Acute toxicity [6.1]

Type of Study	Acute oral toxicity in the rat
Flag	Key study
Test Substance	GF-2032
Endpoint	LD ₅₀
Value	>5000 mg/kg
Reference	Durando, J., GF-2032 Acute oral toxicity study in rats: Acute toxic class method, Dow Project ID: 080049, eurofins Product Safety Laboratories, USA, 2009
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None of any significance

GLP	Yes
Test Guideline/s	USEPA OPPTS 870.1100, OECD 423, EEC Part B.B1
Species	Rat
Strain	F344/DuCrI
No/Sex/Group	4
Dose Levels	5000 mg/kg
Exposure Type	Oral gavage
Study Summary	Treatment-related effects were confined to ano-genital staining in 1 female and 3 males on Days 1 and/or 2. There were no other findings
Additional Comments	
Conclusion	LD ₅₀ is >5000 mg/kg

Acute Dermal Toxicity [6.1 (dermal)]

Type of study	Acute dermal toxicity in the rat
Flag	Key study
Test Substance	GF-2032
Endpoint	LD ₅₀
Value	>5000 mg/kg
Reference	Dana Oley, S.D., GF-2032: Acute dermal toxicity study in rats, Dow Project ID: 080050, eurofins Product Safety Laboratories, USA, 2009
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None of any significance
GLP	Yes
Test Guideline/s	USEPA OPPTS 870.1200, OECD 402, EEC Part B.3
Species	Rat
Strain	F344/DuCrI
No/Sex/Group	5
Dose Levels	5000 mg/kg
Exposure Type	Dermal, 24 hours occluded
Study Summary	There were no adverse treatment-related signs or any indications of dermal irritation in any animal.
Conclusion	LD ₅₀ is >5000 mg/kg

Acute Inhalation Toxicity [6.1 (inhalation)]

Type of study	Acute inhalation toxicity in the rat
Flag	Key study
Test Substance	GF-2032
Endpoint	LC ₅₀

Value	Not achieved
Reference	Kreiger, S.M., Garlinghouse, C.R., GF-2032: Acute liquid aerosol inhalation toxicity study in F344/DuCrI rats, Dow Project ID: 081191, The Dow Chemical Company, USA, 2009
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None
GLP	Yes
Test Guideline/s	USEPA OPPTS 870.1300 (1998), OECD 403, (1981), EEC ISSN 0378-6978 (1992)
Species	Rat
Strain	F344/DuCrI
Study summary	Various aerosol generation systems were investigated in an attempt to produce a stable respirable atmosphere of GF-2032. The highest concentration attainable during the preliminary work was 16.41 mg/l with a mass median aerodynamic diameter (MMAD) particle size of over 44 microns. A particle size of 3.61 microns MMAD with a geometric standard deviation of 1.59 microns was obtained at a concentration of 0.32 mg/l GF-2032 per liter of air however the generation apparatus clogged after 60 minutes. Repeated attempts to improve on methodology consistently resulted in plugged generation equipment, large, non-respirable particle size and very low exposure concentrations.
Conclusion	The regulations (e.g. Directive 94/79/EC, 1994) require formulations to be tested in their native form, therefore dilution with water was not conducted. Therefore, due to the inability to generate a sustainable respirable aerosol (i.e. 1-4 µm MMAD as defined by USEPA, 1998) at any concentration an inhalation study in rats was not conducted.

Skin Irritation [6.3/8.2]

Type of study	Skin irritation in the rabbit
Flag	Key study
Test Substance	GF-2032
Endpoint	Skin irritation
Value	Non irritant
Reference	Dana Oley, S., GF-2032: Primary skin irritation study in rabbits, DOW Project ID: 080051, eurofins Product Safety Laboratories, USA, 2009
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None
GLP	Yes
Test Guideline/s	USEPA OPPTS 870.2500, OECD 404, EEC Part B.4

Species	Rabbit
Main Draize Score	Erythema and oedema - 0
Strain	New Zealand White
No/Sex/Group	3 – females only
Dose Levels	0.5 ml, dermal, semi occluded for 4 hours
Study Summary	Within 1 hour of dressing removal a single rabbit showed very slight erythema however no irritation was evident 24 hours later. There were no other findings.
Conclusion	Non irritant to skin

Eye Irritation [6.4/8.3]

Flag	Key study
Test Substance	GF-2032
Endpoint	Eye irritancy
Value	Non irritant to eye
Reference	Dana Oley, S., GF-2032: Primary eye irritation study in rabbits, Dow Project ID: 080052, eurofins Product Safety Laboratories, USA, 2009
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None
GLP	Yes
Test Guideline/s	USEPA OPPTS 870.2400, OECD 405, EEC Part B.5
Species	Rabbit
Mean Draize Score	Ocular opacity 0, Iritis 0.1, Conjunctivitis 0.4, Chemosis 0
Strain	New Zealand white
No/Sex/Group	3 – females only
Dose Levels	0.1 ml ocular instillation
Study Summary	One hour after dosing iritis was evident in 2 animals and conjunctivitis in all 3 animals however these signs declined with time and resolved by 72 hours
Conclusion	Non irritant

Contact Sensitisation [6.5]

Flag	Key study
Test Substance	GF-2032, positive control: α -hexylcinnamaldehyde (HCA)
Endpoint	Sensitisation
Value	Non sensitiser
Reference	Wiescinski, C.M., Sosinski, L.K., GF-2032: Local lymph node assay in CBA/J mice, Dow Project ID: 081180, The Dow Chemical Company,

	USA, 2008
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None
GLP	Yes
Test Guideline/s	USEPA OPPTS 870.2600 (2003), OECD 429 (2002, EEC Part B.42 (2004)
Species	Mouse
Strain	CBA/J
No/Sex/Group	females only, preliminary study 1, main study 6
Exposure Type	Topical to the ear
	Preliminary study - 1%, 5%, 25%, 50%, 75%, 100%
	Main study – 5%, 25%, 100%
Study Summary	There was no erythema at the site of application or any other signs. The proliferative responses were 0.6, 0.5, 0.7 at 5%, 25%, 100% respectively, thus Gf-2032 did not demonstrate dermal sensitisation potential as defined by a 3-fold increase over concurrent controls.
Conclusion	Non sensitiser

General conclusion about acute toxicity

GF-2032 has low acute toxicity and is not a skin or eye irritant or a contact sensitiser.

Other studies: Dermal Absorption

Type of Study	Dermal Absorption
Flag	Key study
Test Substance	GF-2032 containing ¹⁴ C-XDE-208
Endpoint	rat and human dermal absorption comparability
Value	The test substance was poorly absorbed through human and rat skin although absorption was consistently higher in rat skin than human.
Reference	Roper, C.S., XDE-208: The <i>in vitro</i> percutaneous absorption of radiolabelled XDE-208 in formulation (GF-2032) and two in-use spray dilutions through rat and human skin, Dow ID: Not specified, Charles River, UK, 2010
Klimisch Score	1 (reliable without restriction)
Amendments/Deviations	None
GLP	Yes
Test Guideline/s	OECD 428
Species Tissue	Rat and human skin

Dose Levels	Concentrate 240 g/l GF-2032, In-use dilutions 0.48 g/l GF-2032 (highest), 0.024 g/l GF-2032 (lowest)
Exposure Type	10 µl/cm ² on to the surface of the stratum corneum
Study Summary	<p>Dermal delivery of ¹⁴C-XDE-208 240 g/l essentially ceased after 8 to 12 hours. Results showed the dislodgeable and unabsorbed dose and the stratum corneum profiles for rat and human to be similar. The comparative absorbed dose was 0.26% and 1.3% for human and rat skin respectively. The absorbed dose for rat skin was 5-fold greater than for human skin. A similar difference in this ratio was evident for the dermal delivery and potentially absorbable dose.</p> <p>The dermal delivery of ¹⁴C-XDE-208 at 0.48 g/l for rat and human skin based on absorption profiles had a degree of similarity. However there was a wash-in effect observed in the rat after 10 hours that was not evident in human skin. The absorption rate also reduced more evidently after washing in the rat than in human skin. Absorption at 24 hours was continuing although at a decreased rate. The dermal delivery was 1.93% and 7.63% for human and rat skin respectively. [EPA staff note the study reports the percentage of applied dose absorbed in humans was 1.54%.] The dermal delivery for rat was four-fold greater than for human skin. A similar difference was noted when the potentially absorbable doses were compared but only a 2.5-fold ratio was observed for the absorbed dose.</p> <p>The dermal delivery of ¹⁴C-XDE-208 at 0.024 g/l absorption profiles were also similar for rat and human skin. However, the rate of absorption fell more evidently in human skin ~4 hours after dosing and the reduction in the rat was increased after washing ~10 hours post dose. Absorption at 24 hours was continuing although at a significantly decreased rate. The dermal delivery was 1.94% and 7.21% for human and rat skin respectively indicating absorption through rat skin was 3.7-fold higher than through human skin. [EPA staff note the study reports the percentage of applied dose absorbed in humans was 1.15%.] A similar difference in this ratio was observed for the potentially absorbable dose and absorbed dose.</p>
Conclusion	At the three concentrations examined absorption through rat skin was consistently greater than through human skin although the test substance was not readily absorbed through either tissue. The total percentage of absorbed dose was 0.26, 1.54 and 1.15% through human skin and 1.30, 3.94 and 4.34 through rat skin at 240, 0.48 and 0.24 g/l respectively.

Ecotoxicity - Robust study summaries for the formulation

Aquatic toxicity

Fish acute toxicity (Freshwater species)

Flag: Key study

Test substance: GF-2032

Species: Rainbow trout, *Onchorynchus mykiss*

Type of exposure: 96 hour, static

Endpoint: LC₅₀

Value: >1000 mg GF-2032/L

Reference: DAS0800074

Klimisch score: 1

Amendments/Deviations: none

GLP: yes

Test guidelines: OECD 203

Dose levels:

nominal: 65, 130 250 500 1000 mg GF-2032/L

measured: 62.1, 122, 243, 467, and 939 mg GF-2032/L or 93 to 97% of the nominal concentrations.

Study summary: The control and test substance solutions <500 mg GF-2032/L were clear and colorless with no visible precipitate, surface film, or undissolved test substance throughout the test. The 500 and 1,000 mg GF-2032/L test treatment solutions were cloudy at initiation and throughout the test. Based on nominal concentrations, the 96-hour LC₅₀ was >1,000 mg GF-2032/L (95% confidence limits could not be calculated). Based on mean calculated concentrations, the 96-hour LC₅₀ was >939 mg GF-2032/L (95% confidence limits could not be calculated). The 96-hour NOEC was 500 mg GF-2032/L (nominal concentration) or 467 mg GF-2032/L (mean measured concentration) based upon the lack of mortality at this and all lower test substance treatments.

Conclusion: Rainbow trout 96 hour LC₅₀ >1000 mg GF-2032/L

Invertebrates acute toxicity (Freshwater species)

Flag: Key study

Test substance: GF-2032

Species: *Daphnia magna*

Type of exposure: 48 hour, static, limit test

Endpoint: EC₅₀

Value: >880 mg GF-2032/L (nominal)

Reference: DAS 080075

Klimisch score: 2

Amendments/Deviations:

GLP: yes

Test guidelines: OECD 202

Dose levels:

nominal: 0, 1000 mg GF-2032/L

mean measured: 880 mg GF-2032

Study summary: Analytical confirmation of sulfoxaflor, the active ingredient in the test substance GF-2032, in test solutions was performed at 0 and 48 hours. The measured concentration in the test substance treatment sample collected at 0 hour was 923 mg GF-2032/L or 92% of the nominal concentration, indicating the treatment was appropriately dosed at test initiation. The measured concentration in the test substance treatment sample collected at 48 hours was 836 mg GF-2032/L or 84% of the nominal concentration. The mean measured concentration in the test solution was 880 mg GF-2032/L or 88% of the nominal concentrations.. Recoveries from QC samples ranged from 85 to 98% of the nominal concentrations. The biological response results were reported based on the mean calculated concentration.

After 48 hours of exposure, immobility was 0% in the 0 (control) and 1,000 mg GF-2032/L treatments. The estimated 24- and 48-hour EC₅₀, based on mean measured concentrations, was >880 mg GF-2032/L, the highest concentration tested. There were no sub-lethal effects noted in the control or treatments during the definitive test. The 48-hour NOEC, based on mean measured concentrations, was 880 mg GF-2032/L, the highest test substance treatment.

Conclusion: *Daphnia magna* 48 hour EC₅₀ >1000 mg GF-2032/L (nominal)

Algae acute toxicity (Freshwater species)

Flag: Key study

Test substance: GF-2032

Species: freshwater diatom, *Navicula pelliculosa*

Type of exposure: 72 hour static

Endpoint: E_rC₅₀

Value: >100 mg GF-2032/L (nominal)

Reference: DS101301

Klimisch score: 2

Amendments/Deviations: None

GLP: yes

Test guidelines: OECD 201

Dose levels:

Nominal: 1.2, 3.7, 11, 33 and 100 mg GF-2032/L

mean measured: 1.06, 3.41, 9.94, 29.9, and 94.7 mg GF-2032/L

Study summary: Calculated concentrations of GF-2032 (based on analysis of sulfoxaflor) in the test substance treatment solutions at test initiation were 1.01, 3.25, 9.57, 28.8, and 93.1 mg GF-2032/L, which represented recoveries of 84 to 93% of the nominal concentrations. The calculated concentrations for the 1.2, 3.7, 11, 33, and 100 mg GF-2032/L nominal treatments at 72 hours were 1.11, 3.56, 10.3, 30.9, and 96.2 mg GF-2032/L, respectively, which represented recoveries of 93 to 96% of the nominal concentrations. The biological response results were reported based upon the nominal GF-2032 concentrations.

After 72 hours of exposure, mean cell density in the control was 36.8×10^4 cells/mL, or 37 times the initial nominal cell density. The mean cell density in the GF-2032 treatments at 72 hours ranged from a low of 26.0×10^4 cells/mL at the concentration of 100 mg GF-2032/L to a high of 36.9×10^4 cells/mL at the concentration of 11 mg GF-2032/L. Percent inhibition in algal growth at 72 hours, as compared to the control, ranged from 29% at the concentration of 100 mg GF-2032/L to 0% at the concentration of 11 mg GF-2032/L. Percent inhibition in growth rate from time zero to 72 hours, as compared to the control, ranged from 10% at the concentration of 100 mg GF-2032/L to 0% at the concentration of 11 mg GF-2032/L. Based on nominal concentrations, the NOEC at 72 hours was 11 mg GF-2032/L, based on the lack of a statistically significant reduction in growth rate from time zero at this and lower test substance treatments. Based on growth rate, the estimated 72-hour E_rC_{50} was >100 mg GF-2032/L, the highest concentration tested. The coefficient of variation of average specific growth rates during the whole test period in control replicates was 1%. The mean coefficient of variation in growth rate between adjacent time periods was 23% for the control replicates.

Conclusion: 72-hour E_rC_{50} was >100 mg GF-2032/L

General conclusion about aquatic ecotoxicity for GF-2032

On the basis of the limited acute data on the formulation (ie rainbow trout, daphnia and freshwater diatom), GF-2032 does not trigger the HSNO thresholds for aquatic toxicity.

It is unclear why the toxicity of the formulation was not tested against the species shown to be more sensitive in the studies on the active ingredient, sulfoxaflor. Those data indicate that GF-2032 is highly toxic to other aquatic invertebrates, ie mysid shrimp and chironomid midges,

Soil macro-invertebrates chronic toxicity

Flag: key study

Test substance: GF-2032 (22% w/w sulfoxaflor)

Species: earthworm, *Eisenia fetida*

Type of exposure: 56-day natural soil

Endpoint: NOEC

Value: 0.64 mg ai/kg dry soil

Reference: OECD 2011 (e)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 207

Study summary: The chronic toxicity of GF-2032 (suspension concentrate, 22% sulfoxaflor) to the earthworm (*Eisenia fetida*) was determined in four different natural soils (from Spain, France, Italy and Germany). Adults with a visible clitellum were exposed over a period of 28 days to nominal concentrations of 0.08, 0.16, 0.32, 0.64 and 1.28 mg a.i./kg dry soil. In addition, a purified water control was tested. Adult mortality and growth effects (fresh weight) were assessed after 28 days, adults were removed, and the number of offspring present in the treated soil was determined after a further 28 days. Mean adult mortality ranged 1.3-5.0% in all four control soils; significant mortality was observed at the highest treatment level in the soil from France (18% mortality). There was no effect on fresh weight of surviving adult worms in any soil at any treatment level. At the end of the 56-day test, a significant decrease in number of juveniles was observed at the highest treatment level in the soil from Germany (47% decrease relative to controls).

Conclusion: The 28d LC₅₀ was >1.28 mg a.i./kg dry soil and the 56d NOEC was 0.64 mg a.i./kg dry soil (number of juveniles).

Non-target plants acute toxicity

Flag: Key study

Test substance: GF-2032

Species: 11 crop species – 4 monocot (oats, ryegrass, maize, onion) and 7 dicot (oilseed rape, cabbage, soybean, carrot, cucumber, tomato, lettuce)

Type of exposure: foliar, vegetative vigour, Tier 1 (limit) and Tier 2

Endpoint: 21 day ER₂₅

Value: >200 g ai/ha

Reference: OECD 2011 (f)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 227

Study summary: The effects of GF-2032 (suspension concentrate, 240 g/L sulfoxaflor) on the vegetative vigour of 11 terrestrial non-target plants were determined in a Tier 1 (limit) test. Young plants (2 to 4 true leaves) of four monocotyledon species (oats, ryegrass, maize, onion) and seven dicotyledon species (oilseed rape, cabbage, soybean, carrot, cucumber, tomato, lettuce) were sprayed at nominal rates of 100 and 200 g a.i./ha plus 0.05% Silwet L-77 (a non-ionic organosilicone wetting agent). Onion response was further examined in a Tier 2 test at nominal rates of 12.5, 25, 50, 100 and 200 g a.i./ha plus 0.05% Silwet L-77. Deionised water controls and Silwet L-77 controls were also tested for all bioassays. Phytotoxicity was assessed 7, 14, and 21 days after treatment. Foliar biomass (fresh weight) and shoot length were assessed at the end of the 21-day observation period. In the Tier1 onion test, phytotoxic symptoms in the controls confounded interpretation of the growth response in the treatment groups. For the remaining species in the Tier1 test and the onions in the Tier2 test, control plants were of acceptable health and less than 25% effect was observed for all endpoints at any test rate. The 21d ER₂₅ and ER₅₀ values were >200 g a.i./ha.

Conclusion: The 21d ER₂₅ and ER₅₀ values were >200 g a.i./ha.

Flag : Key study

Test substance: GF-2032

Species: Four monocotyledon species (oats, ryegrass, maize, onion) seven dicotyledon species (oilseed rape, cabbage, soybean, carrot, cucumber, tomato, lettuce)

Type of exposure: sprayed soil, seedling emergence Tier 2

Endpoint: 21 day ER₂₅

Value: >400 g ai/ha

Reference: OECD 2011 (f)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 208

Study summary: The effects of GF-2032 (suspension concentrate, 240 g/L sulfoxaflor) on the seedling emergence and growth of 11 terrestrial non-target plants were determined in a Tier 2 test. Four monocotyledon species (oats, ryegrass, maize, onion) and seven dicotyledon species (oilseed rape,

cabbage, soybean, carrot, cucumber, tomato, lettuce) were sprayed pre-emergence at nominal rates of 3.13, 6.25, 12.5, 25, 50, 100, 200 and 400 g a.i./ha plus 0.05% Silwet L-77 (a non-ionic organosilicone wetting agent). Deionised water controls and Silwet L-77 controls were also tested. Percent emergence was determined followed by phytotoxicity and survival assessments 7, 14, and 21 days after application. Foliar biomass (fresh weight) and shoot length were assessed at the end of the 21-day observation period. No rate-response effect was observed for any parameter for any species. The 21d ER₂₅ and ER₅₀ values were >400 g a.i./ha.

Conclusion: The 21d ER₂₅ and ER₅₀ values were >400 g a.i./ha.

Nitrogen transformation test

Flag: Key study

Test substance: GF2032

Species: soil micro-organisms

Type of exposure: 28d nitrogen transformation test

Endpoint: EC₂₅

Value: >0.161 mg ai/ha

Reference: OECD 2011 (g)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 216

Study summary: The effects of GF-2032 (suspension concentrate, 22% sulfoxaflor) on soil microflora were assessed in a test that measured nitrogen turnover (mineralization). Silty sand soil was treated with nominal concentrations of 0.065 and 0.161 mg a.i./kg dry soil, and the nitrate content was measured over a 28-day period. In addition, an untreated control soil was tested. The rate of nitrogen formation was considerably inhibited during the first 7 days at 0.161 mg a.i./kg dry soil (28% inhibition relative to control); however, adverse effects were not apparent after 14 or 28 days. The differences relative to control were less than 25% after 28 days indicating the product is not expected to have long-term influence on nitrogen transformation in soils.

Conclusion: After 28 days at 0.161 mg a.i./kg dry soil (= 0.733 mg formulation/kg dry soil) , the change in nitrogen transformation was <25% relative to control.

The test concentrations were based on a rate (24 g a.i./ha) that was only a fraction of the proposed maximum single application rates of 96 g a.i./ha (Australia, Canada), 150 g a.i./ha (United States) and 192 g ai/ha (New Zealand).

Carbon transformation test

Flag: key study

Test substance: GF2032

Species: soil micro-organisms

Type of exposure: soil, 28-day carbon transformation

Endpoint: EC₂₅

Value: >0.161 mg a.i./kg dry soil

Reference: OECD 2011 (g)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 217

Study summary: The effects of GF-2032 (suspension concentrate, 22% sulfoxaflor) on soil microflora were assessed in a test that measured carbon transformation (short-term substrate-induced respiration). Silty sand soil was treated with nominal concentrations of 0.065 and 0.161 mg a.i./kg dry soil, and the carbon dioxide released was measured over a 28-day period. In addition, an untreated control soil was tested. After 28 days, no significant differences from control in short-term respiration were observed for both concentrations (7.4% inhibition at 0.065 mg a.i./kg dry soil; 5.0% stimulation at 0.161 mg a.i./kg dry soil). The differences relative to control were less than 25% at any sampling time indicating the product is not expected to have long-term influence on carbon transformation in soils.

Conclusion: After 28 days at 0.161 mg ai/kg dry soil, the change in carbon mineralization was <25% relative to control. The test concentrations were based on a rate (24 g ai/ha) that was only a fraction of the proposed maximum single application rates of 96 g a.i./ha (Australia, Canada), 150 g ai/ha (United States) and 192 g ai/ha (New Zealand).

General conclusion about soil ecotoxicity

GF-2032 exhibits chronic toxicity to earthworms, but does not trigger the HSNO thresholds for toxicity to plants or soil microbial function at the rates tested.

Terrestrial vertebrate toxicity

For effects on terrestrial vertebrates other than birds, refer to the mammalian toxicity section.

Oral toxicity

Flag: Key study

Test substance: GF-2032

Species: Northern bobwhite quail, *Colinus virginianus*

Type of exposure: acute oral

Endpoint: LD₅₀

Value: >2250 mg formulation/kg bw

Reference: DAS 080073

Klimisch score: 2

Amendments/Deviations: -

GLP: yes

Test guidelines: OPPTS 850.2100

Dose levels:

Nominal: 0, 292, 486, 810, 1350, and 2250 mg formulation/kg body weight

Study summary: There were no mortalities in the control group. In addition, there were no mortalities in the 292, 486, 810, and 1350 mg/kg treatment groups. However, there was 10% (1 of 10) mortality at the 2250 mg/kg dosage level. All birds in the control group and the 292 and 486 mg/kg treatment groups were normal in appearance and behaviour throughout the test.

At the 810 mg/kg dosage level, no signs of toxicity were observed.

At the 1350 mg/kg dosage level, signs of toxicity were first noted on the morning of Day 3, when one male was noted with a ruffled appearance and one female was noted with a ruffled appearance and lethargy. By the morning of Day 5, both birds had recovered and were normal in appearance and behaviour for the remainder of the test. All other birds at the 1350 mg/kg dosage group were normal in appearance and behaviour for the duration of the test.

At the 2250 mg/kg dosage level, signs of toxicity were first noted on the morning of Day 3, when four birds displayed a ruffled appearance, two also displaying lethargy. One of the males was also noted with a slight bruising on the head, an incidental finding first observed on Day 2. The only mortality was noted on the morning of Day 4, when a male was found dead. All but one bird displayed clinical signs during the course of the study. Signs of toxicity observed at the 2250 mg/kg dosage level were ruffled appearance, reduced reaction to external stimuli (sound and movement), loss of coordination, depression and lethargy. By the morning of Day 8, all surviving birds that had displayed signs of toxicity had recovered and were normal in appearance and behaviour for the remainder of the test.

Body Weight and Feed Consumption

When compared to the control group, from Day 0 to Day 3 there was a statistically significant ($p < 0.01$), treatment-related, loss of mean body weight among females at the 1350 mg/kg dosage level and among males and females at the 2250 mg/kg dosage level. A statistically significant difference ($p < 0.01$) in mean

body weight on Day 3 was noted for female in the 1350 and 2250 mg/kg dosage groups. Statistically significant weight gains were noted among males at the 1350 mg/kg dosage group ($p < 0.05$) and among females at the 1350 and 2250 mg/kg dosage groups ($p < 0.01$) between Day 3 and Day 7. Statistically significant ($p < 0.01$) weight gains were again noted among females at the 2250 mg/kg dosage group between Day 7 and Day 14. All other changes in body weights were not statistically significant when compared to the control.

There was no apparent treatment related effect upon feed consumption at the 292 or 486 mg/kg dosage levels or among males in the 810 mg/kg treatment group. The slight reduction in feed consumption noted among females at the 810 mg/kg dosage level from Day 0 to Day 3 was attributed to the pen mate aggression observed, and was not considered to be treatment related. Given the effects seen upon body weight change from Day 0 to Day 3, the slight reductions in feed consumption among females from the 1350 mg/kg treatment group and males and females from the 2250 mg/kg treatment group may have been related to treatment (Table 3). Mean feed consumption by treatment groups from Day 4 to Day 7 and from Day 8 to Day 14 were comparable to the control group.

A gross necropsy was performed on the single mortality, a male from the 2250 mg/kg dosage group. The bird's spleen was pale and there was petechial hemorrhaging in the breast muscles, findings that were considered to be treatment related.

The acute oral LD_{50} value for northern bobwhite exposed to GF-2032 as a single oral dose was determined to be greater than 2250 mg/kg, the highest dosage tested. The no-mortality level was 1350 mg/kg. The no-observed effect level was 810 mg/kg, based upon signs of toxicity and a body weight effect at the 1350 mg/kg dosage level.

Conclusion: The acute oral LD_{50} value for northern bobwhite exposed to GF-2032 as a single oral dose was determined to be greater than 2250 mg formulation/kg.

Ecotoxicity to bees

Laboratory tests (acute oral and contact)

Flag: Key study

Test substance: GF-2032

Species: adult honeybee, *Apis mellifera*

Type of exposure: 48 hour acute oral

Endpoint: LD_{50}

Value: 0.0515 μg a.i./bee

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 213

Study summary: The acute toxicity of GF-2032 (suspension concentrate, 22.0% w/w sulfoxaflor) to the honeybee (*Apis mellifera*) was determined after oral exposure. Adult worker bees were exposed to nominal doses of 0.0063, 0.0125, 0.025, 0.05, 0.1 and 0.2 µg a.i./bee dispersed in sucrose solution and observed for 48 hours. In addition, a sucrose solution control was tested. A slight effect on diet consumption beginning at 0.1 µg a.i./bee was observed indicating sulfoxaflor was not palatable to the bees. After 48 hours, there was no mortality in the control group and dose-response mortality was observed in the treatment groups ranging 2-96%. One bee (3%) in the 0.05 µg a.i./bee treatment exhibited sub-lethal effects (such as uncoordinated attempts to move, increased amounts of grooming, lethargy or diarrhoea) at the end of the test.

Conclusion: The 48-hour oral LD₅₀ is 0.0515 µg a.i./bee.

Flag: Key study

Test substance: GF-2032

Species: adult bumblebee, *Bombus terrestris*

Type of exposure: 72 hour acute oral

Endpoint: LD₅₀

Value: 72-hour LD₅₀ 0.027 µg a.i./bee.

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: Steen et al. (1996) in Proceedings 6th International Symposium on the hazard of pesticides for bumblebees, Appendix 28

Study summary: The acute toxicity of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) to the bumblebee (*Bombus terrestris*) was determined after oral exposure. Adult worker bees were exposed to nominal doses of 0.010, 0.019, 0.035, 0.065 and 0.120 µg a.i./bee dispersed in sucrose solution and observed for 72 hours. In addition, a sucrose solution control was tested. After 72 hours, there was 6.7% mortality in the control group and dose-response mortality was observed in the treatment groups ranging 10.0-96.7%. No sub-lethal effects were observed throughout the duration of the test.

Conclusion: The 72-hour oral LD₅₀ is 0.027 µg a.i./bee.

Flag : Key study

Test substance: GF-2032

Species: adult honeybee *Apis mellifera*

Type of exposure: 48 hour acute contact

Endpoint: LD₅₀

Value: 0.130 µg a.i./bee

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: OECD 214

Study summary: The acute toxicity of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) to the honeybee (*Apis mellifera*) was determined after contact exposure. Adult worker bees were topically exposed to nominal doses of 0.021, 0.047, 0.103, 0.227 and 0.5 µg a.i./bee and observed for 48 hours. In addition, a wetting agent control and a water control were tested. There was 6% mortality in both controls, and dose-response mortality was observed in the treatment groups ranging 8-98% in the treatment groups. No sub-lethal effects were noted at the end of the test.

Conclusion: The 48-hour contact LD₅₀ is 0.130 µg a.i./bee.

Flag : Key study

Test substance: GF-2032

Species: adult bumblebee *Bombus terrestris*

Type of exposure: 72 hour acute contact

Endpoint: LD₅₀

Value: 72-hour LD₅₀ was 7.554 µg a.i./bee

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: Steen et al. (1996) in Proceedings 6th International Symposium on the hazard of pesticides for bumblebees, Appendix 28

Study summary: The acute toxicity of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) to the bumblebee (*Bombus terrestris*) was determined after contact exposure. Adult worker bees were topically exposed to nominal doses of 0.01, 0.1, 1, 10 and 100 µg a.i./bee and observed for 72 hours. In addition, a wetting agent control and a water control were tested. There was 6.7% mortality in the water control, 3.3% mortality in the wetting agent control, and dose-response mortality was observed in the treatment groups ranging 3.3-100.0% in the treatment groups. No sub-lethal effects in surviving bees were noted

Conclusion: The 72-hour contact LD₅₀ is 7.554 µg a.i./bee.

Cage tests

Flag: key study

Test substance: GF-2032

Species: honeybee, *Apis mellifera*

Type of exposure: 24h acute contact to aged foliar residues

Endpoint: %mortality

Value: In the 200 g a.i./ha treatments weathered for 3, 6 and 24 hours, the corrected mean mortalities were 4.0, 1.3 and 0.7% respectively

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: OPPTS 850.3030

Study summary: The effects of foliar residues of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on the honeybee (*Apis mellifera*) were determined after 24 hours of contact exposure. Alfalfa foliage was sprayed at a nominal rate of 200 g a.i./ha. Residues were allowed to weather in the field for 3, 6 and 24 hours of application. In addition, untreated alfalfa foliage was maintained for the controls. The alfalfa was harvested and placed into cages containing the bees.

Conclusion: After 24 hours, mean mortality in the controls was 0.7%. In the 200 g a.i./ha treatments weathered for 3, 6 and 24 hours, the corrected mean mortalities were 4.0, 1.3 and 0.7%, respectively. Sub-lethal symptoms in the surviving bees included bees lying on their back and lethargy.

Flag: key study

Test substance: GF-2372 [sulfoxaflor 50% WDG]

Species: honeybee, *Apis mellifera*

Type of exposure: 24h acute contact to aged foliar residues

Endpoint: %mortality

Value: 3-, 6-, and 24-hour weathered treatments, the corrected mean mortalities were 0.7, 2.8 and 14% at 100 g a.i./ha and 9.9, 11 and 15% at 200 g a.i./ha

Reference: OECD 2011 (i)

Klimisch score: 2

GLP: yes

Test guidelines: OPPTS 850.3030

Study summary: Alfalfa foliage was sprayed at nominal rates of 100 and 200 g a.i./ha. Residues were allowed to weather in the field for 3, 6 and 24 hours of application. In addition, untreated alfalfa foliage was maintained for the controls. Applications were made using a staggered schedule so that all weathering periods could be harvested at the same time. Once harvested, the alfalfa foliage was chopped into 1- to 3-inch long segments and 15 g subsamples were placed into plastic screened bee cages containing *Apis mellifera*. Each cage (14 x 19 x 10 cm) served as one replicate. Twenty-five bees were used per replicate with six replicates per treatment. Mortality and signs of toxicity were assessed after 24 hours.

After 24 hours, mean mortality in the controls was 5%. In the 3-, 6-, and 24-hour weathered treatments, the corrected mean mortalities were 0.7, 2.8 and 14% at 100 g a.i./ha and 9.9, 11 and 15% at 200 g a.i./ha. Sublethal symptoms were not observed in the surviving bees.

Conclusion: In the 3-, 6-, and 24-hour weathered treatments, the corrected mean mortalities were 0.7, 2.8 and 14% at 100 g a.i./ha and 9.9, 11 and 15% at 200 g a.i./ha.

Note that this is a different formulation to GF-2032 but the results have been included for completeness. There is some uncertainty as to the effects of the other ingredients [other than the active] on the observed mortality which was higher in this study than in the previous study using GF-2032. The difference in test results between the studies may reflect the variability inherent in this type of study.

Semi field studies (tunnel)

Flag: supporting

Test substance: GF-2032

Species: Honeybee *Apis mellifera*

Type of exposure: semi-field [tunnel]

Endpoints: Mortality, behaviour, flight intensity, condition of the colonies and the development of the bee brood

Reference: Hecht-Rost S. (2009) GF-2032 A semi-field study to evaluate effects on the honeybee *Apis mellifera carnica* L (Hymenoptera, Apidae) in *Phacelia tanacetifolia* in France in 2008, Study ID 080349, December 21, 2009

Amendments/Deviations: *varroa* mite infections were detected in controls

Klimisch score: 2

GLP: yes

Test guidelines: CEB draft guideline no 230: methode d'évaluation des effets de toxicité aigue et a court terme des préparations phytopharmaceutiques sur l'abeille domestique (*Apis mellifera*)

OEPP/EPPO (2001): Guideline for the efficacy evaluation of plant protection products - Side effects on honeybees. OEPP/EPPO, PP 1/170(3) 2001.

Dose levels: 6.25, 12.5, 24.0, 48.0, 96.0 g ai/ha nominal

Study summary: This semi-field tunnel study was conducted to determine the effects of GF-2032 (nominally 240 g a.i./L SC formulation containing sulfoxaflor) on the honeybee, *Apis mellifera carnica* L. This study included seven treatment groups of the test item GF-2032 applied at calculated rates of 99, 50, 24, 13.6 and 6.5 g a.i./ha in separated tunnels. A sixth group (tunnel) treated with tap water served as control. As reference item "Perfekthion" BAS 152 11 I (dimethoate) was applied at a rate of 400 g ai/ha (nominal). All applications were conducted when bees were actively foraging (> 5 bees/m²) during daily bee-flight and with a spray volume of 300 L water/ha. The effect of the test item was examined on small bee colonies in tunnels (approx. 100 m²) placed on plots with *Phacelia tanacetifolia*.

Mortality, behaviour, flight intensity, condition of the colonies and the development of the bee brood (% comb area with eggs, larvae, capped brood) was assessed prior to application and up to 7 days after the application. In order to evaluate the magnitude of residues of the test item GF-2032 pollen samples from inside the hives and flowers of *P. tanacetifolia* were taken for analysis. The influence of the test item was evaluated by comparing the results in the test item treatments to the water treated control and the data recorded in the reference item treatment.

Results

Mortality

Application of sulfoxaflor up to 99 g ai/ha appeared to increase bee mortality by up to 7X compared to controls during the first 3 days after application. After this time, bee mortality returned to levels observed in the controls.

Flight intensity

An approximate dose-dependent decline in flight intensity was also observed from 0DAA through 3DAA in the sulfoxaflor treatments. Flight intensity was reduced in sulfoxaflor treatments relative to controls from 4DAA through 7DAA, although dose-dependency was not observed. Some light intoxication symptoms within the first hour after the application with 13.6 g ai/ha was observed and some cramped bees within the first hour after application with 50 and 99 g ai/ha.

Behaviour

No further effects on behaviour were observed.

Colony strength

The effect of sulfoxaflor on colony strength is difficult to interpret due to the large difference among control and treated hives prior to pesticide application (# bees/hive in controls was 2X that of treated hives on - 2DAA). On 7DAA, no obvious dose-dependent trend in colony strength was apparent among hives from plots treated with 6.5 to 99 g ai/ha sulfoxaflor.

Brood

The effects of sulfoxaflor on bee brood are considered inconclusive due to the presence of *Varroa* mites in control hives and the short observation period (7 days).

Residues

Residues of sulfoxaflor up to 1 ppm were detected in *Phacelia* pollen 7 days after application and showed a general decline with decreased application rates. Residues in flowers were detected only in the treatment with 24 g ai/ha. Residues in flowers (max of 1.7 ppm on 0DAA) declined steadily to about 0.1 ppm by 7DAA. Based on this decline, one can infer higher residues in pollen on 0DAA.

Mortality in the reference toxicant (dimethoate) treatment was elevated by up to 10X of controls from 0DAA to 3DAA, indicating that the application procedures resulted in significant exposure to bees. Similarly, flight intensity was extremely impacted (reduced) in the dimethoate treatment.

Although this study had several strengths (multiple dosing levels, measurement of residues, documented exposure and effects with reference toxicant (dimethoate), it also had several limitations that either confounded the interpretation of results and/or limits their use in pollinator risk assessment. Specifically, the maximum application rate tested (99 g ai/ha) was 3X below the proposed seasonal maximum on the US label (300 g ai/ha). The presence of *Varroa* mites in control hives may have compromised control brood performance measures (no *Varroa* were reported in other treatments). Furthermore, the post treatment observation was only 7 days which may be insufficient to detect effects on developing brood. For brood development, OECD Guideline 75 suggests 7 d exposure + 19 d observation period.

Conclusion: The worker bee mortality increases after exposure to GF-2032 which is short lived (3 DAA). Effects on foraging activity were observed and were short term effects. The effects on brood development inconclusive. Long term effects on brood were not evaluated. The maximum tested dose is lower than the proposed NZ rate.

Flag: supporting

Test substance: GF-2032

Species: Honeybee *Apis mellifera*

Type of exposure: semi-field [tunnel]

Endpoints: Mortality, behaviour, flight intensity, condition of the colonies and the development of the bee brood

Reference: Schmitzer S. (2010) Testing of GF-2032 on honey bees (*Apis mellifera* L.) under semi-field conditions-tunnel test. DAS study no 080083, May 25,2010

Klimisch score: 2

GLP: yes

Test guidelines: OEPP/EPPO (2001): Guideline for the efficacy evaluation of plant protection products - Side effects on honeybees. OEPP/EPPO, PP 1/170(3) update 2000, 19 - 23 .

Dose levels: 24 and 48 g ai/ha

Study summary: A tunnel test was conducted, in order to assess the effect of GF-2032 on honey bees workers and brood) under semi-field conditions. Tunnels (14 m length x 5.5 m width x 2.5 m height) were set up on a ca. 40 m² plot of *Phacelia tanacetifolia* (4m x 10m) and small bee colonies were introduced eight days before the daytime application. A water control and a toxic reference and Perfection EC (400 g/L dimethoate) were included in the study.

Three application scenarios were conducted: Scenario 1: 48 g a.i./ha of GF-2032 was applied to the crop in the evening after bee flight to evaluate the impact of dried residues on foliage. The day after following this application, the bees were introduced to the tunnels and were exposed to the residues of the test item for 9 days.

Scenario 2: 24 g a.i./ha of GF-2032 was applied during the day with bees actively foraging.

Scenario 3: 48 g a.i./ha of GF-2032 was applied in the middle of the day with bees actively foraging.

The water-treated control and reference item (600 g dimethoate/ha) were applied to the whole plot in two operations, in the middle of the day with foraging bees present (daytime applications). The trial was carried out using three tunnels (i.e. replicates) for each treatment group, with one bee hive per tunnel. Mortality, foraging activity and behaviour of adult bees were recorded daily over the course of the study. Brood condition was assessed 4 days prior to application and 9 days following application.

Results

Mortality

Adult foraging bees exposed to GF-2032 at rates of 24 and 48 g a.i./ha (during flight) exhibited a statistically-significant increases in mortality of up to 20X the rate observed in controls on the day of application. This increase in mean daily worker bee mortality was short lived, however, having returned to a factor of 1.5X of controls by 1DAA (for the 24 g a.i./ha during flight; 48 g a.i./ha after flight treatments) and 3DAA(for the 48 g a.i./ha during flight treatment). No statistically significant effects on daily mortality rates were detected after 0DAA or when data were combined from 0DAA and 7DAA. The lack of statistical significance should be interpreted with caution because of the apparent low statistical power of the test for this endpoint caused by the variability in this endpoint.

Flight intensity

Application of GF-2032 led to a reduction of foraging activity of bees on the day of application. Relative to control bees, mean foraging intensity on 0DAA was reduced by 25% in the 24 g a.i./ha (during flight) and 48 g a.i./ha (after flight) treatments and was reduced by 50% in the 48 g a.i./ha treatment. No statistical analysis was conducted on the 0DAA results. For the remainder of the test, mean forage intensity of bees was comparable between the controls and GF-2032 treatments, indicating the reduction in foraging intensity was a short-term effect. When forage intensity was evaluated from 0DAA through 7DAA, no statistically significant differences were detected according to the study author. Foraging activity in the dimethoate-treated tunnels (reference item) was severely reduced from 0DAA through 7DAA, which indicates the methods used to quantify foraging activity were appropriately sensitive.

Behaviour

As seen with bee mortality and flight intensity results, the behavioural abnormalities reported for adult worker bees were short lived, having occurred only on 0DAA for the 48 g a.i./ha (after flight) and 24 g a.i./ha (during flight) treatments and 0DAA through 1DAA for the 48 g a.i./ha (during flight) treatment. Behavioural abnormalities included uncoordinated movement, cramps, intensive cleaning and aggressiveness.

Brood

The condition of brood among the hives was similar 4 days prior to pesticide application, which indicates differences in brood condition among hives would not likely confound interpretation of the study results. Nine days following the applications, all brood stages could be found at the end of the test in each of the colonies. The presence nectar and pollen in the combs on 9DAA indicates that bees were able to forage successfully on the crop. The mean % comb area with nectar, pollen, eggs and larvae were comparable among treatments and controls, although no statistical analysis was conducted of these data. The only noticeable difference among brood condition was a slight increase in the percent capped brood in treatments (20-40%) compared to controls (20-25%). Given the small magnitude of increase and the high variability within treatments, this difference is not expected to be statistically significant and its biological significance is uncertain.

Conclusion: The worker bee mortality increases after exposure to GF-2032 which is short lived. Effects on foraging activity and abnormal behaviour were observed and were short term effects. No effects on brood

development were observed up to 9 days after treatment. Long term effects on brood were not evaluated. The maximum tested dose is lower than the proposed NZ rate.

Flag: supporting

Test substance: GF-2626 [sulfoxaflor 12%]

Species: Honeybee *Apis mellifera*

Type of exposure: semi-field [tunnel]

Endpoints: Mortality, behaviour, flight intensity, condition of the colonies and the development of the bee brood

Reference: DAS study no 80755 [additional study 2.7]

Klimisch score: 2

GLP: yes

Test guidelines: OEPP/EPPO (2001): Guideline for the efficacy evaluation of plant protection products - Side effects on honeybees. OEPP/EPPO, PP 1/170(3) update 2000, 19 - 23 .

OECD No. 75, "Guidance Document on the Honey Bee (*Apis mellifera* L.) Brood Test under Semi-Field Conditions", No. 75, ENV/JM/MONO(2007)22

Study summary: The aims of the study were to determine the effects on honey bee colonies including brood development, when bee colonies enclosed within tunnels were exposed to different rates and application timing of GF-2626.

Small bee colonies (*Apis mellifera camica* L.), maintained according to normal beekeeping practice, containing 4 honeycombs with honey, pollen and all brood stages present were used for the test. The preliminary brood check indicated healthy colonies with all brood stages present and a sufficient supply with nectar and pollen. The mean number of bees per colony in the test groups one day before daytime application was very similar.

A tunnel test was conducted, in order to assess the effect of GF-2626 on honey bee brood under semi-field conditions. Tunnels (14 m length x 5.5 m width x 2.5 m height) were set up on a ca. 50 m² plot of *Phacelia tanacetifolia* (2 x 24 m²) and small bee colonies were introduced four days before daytime applications. A water control and a toxic reference (Insegar [250 g/kg fenoxycarb]) were included in the study.

Three application scenarios were conducted:

Scenario 1: 48 g ai/ha of GF-2626 was applied to the crop before flowering. Nine days following this application, the bees were introduced to the tunnels when the *Phacelia* was now in full flower and were exposed to the residues of the test item. This application was conducted 13 days before the daytime applications.

Scenario 2: In the evening before the daytime application two test item rates of 24 and 48 g a.i./ha were applied after the bees were active in order to expose the bees to dried residues of the test item the next day.

Scenario 3: 24 g ai/ha of GF-2626 was applied in the middle of the day with foraging bees present (daytime applications).

The water-treated control and the reference item (300 g fenoxycarb/ha) were applied also during daytime with foraging bees present.

The trial was carried out using three tunnels (*i.e.* replicates) for each treatment group, with one bee hive per tunnel. Following the daytime applications, ontogenesis of a defined number of honey bee eggs was observed for each treatment group and colony. Mortality of adult bees and pupae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial.

The exposure period of the bees to the water, test item and reference item treated crops in the tunnels was 7 days (10 days for the pre-flower treatment). Afterwards the bee hives were removed from the tunnels to an area with no main flowering, bee attractive crops. Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days. This was done by marking 120 eggs at the first brood area fixing day BFDO (BFD = Brood Area Fixing Day) and investigating the further progress of their development in regular intervals until day 21 following the daytime application (BFD 22 following BFDO).

Natural field conditions. Weather conditions were good during all applications and the whole experimental period. It was warm with no precipitations during the entire experimental time (day 27 following daytime application). High foraging activities during the entire time of the exposure phase indicated that the bees were well exposed to the dried residues of the test item.

Results

Behavioural Abnormalities

Following all test item applications no behavioural abnormalities could be observed at any time. In one tunnel of the 48 g a.i./ha evening treatment, on the day following the evening application, a few bees (up to 8) were found behaving abnormally (uncoordinated movement or intensive cleaning). Since this number of bees was very low and this was the only occurrence of behavioural abnormalities during the entire trial, it was not fully clear if this was test item related. No behavioural abnormalities were observed in the control group and in the reference item group treated with Insegar (300 g fenoxycarb/ ha).

Condition of the Colonies

The brood check one day before the application indicated all colonies were healthy with all brood stages present and a sufficient supply with nectar and pollen. After application of GF-2626, no indication of a test item related effect on the condition of the colonies was observed. All test item treated colonies survived the trial and were comparable to the control colonies. In one colony of the 48 g a.i./ha pre-flowering treatment level, no eggs and larvae were found during 2-3 assessments following the application. The explanation for

this is that the queen was lost due to the extensive handling work on the colonies. At the end of the trial, eggs and a new queen were found again in this colony (the colony re-queened itself). Since, this was the only irregularity and could not be seen also at the other test item colonies, this must be seen as incidental rather than a treatment effect. There was no indication of any hazard of the test item on the condition of the bee colonies. After treatment with the reference item Insegar (300 g fenoxacarb /ha) a decrease of maggots and closed brood was observed over the course of the experiment.

Colony Strength

The mean number of bees per colony in the six treatment groups one day before application was very similar (2610 to 3660 mean bees per colony). Colony sizes among all treatment groups differed over the course of the study. There was a similar pattern of development in the control and the test item treatment groups 24 and 48 g a.i./ha after bee flight and 24 g a.i./ha during bee flight. Colony sizes remain on a comparable level until day 27 ranging around 57 to 129 % compared to the initial values. Colony sizes in the 48 g a.i./ha pre-flowering treatment group was little lower compared to the other colonies.

Colonies in the reference item treatment group developed normally until day 15, but thereafter decreased down to <50 % at the last assessment, compared to the initial value.

Brood Compensation Index:

Looking at the brood compensation index, which shows the development of the brood at each assessment, a continuous brood development was observed in all GF-2626 treated groups as well as in the control group. The brood compensation indices following the labelling of the egg stage were very similar (or even higher) to the control values during all assessments up to day 21 following the daytime application (BFD +22). The compensation indices for the GF-2626 treatments followed pattern similar to the control, however indices in the 24 g a.i./ha after bee flight group were slightly retarded at BFD+5, +9 and +16. At the end of the trial (BFD+22) the brood compensation indices in all test item treated groups were the same or higher compared to the control group. There was no statistical significant difference to the control group at any assessment.

There was a strong break down in brood compensation in the Insegar reference item treated group over the entire trial. No real recovery could be observed in the reference item group.

Accordingly, no effect on the overall brood development was identifiable following the labelling of the egg stage in the GF-2626 treatment groups.

The high termination rate of the marked cells after treatment with the reference item Insegar (fenoxycarb) was also reflected by the brood compensation indices.

Conclusion:

For honey bees and colonies exposed to pre-flower treatment with 48 g a.i./ha, to dried residues applied at 24 and 48 g a.i./ha after bee flight and to direct exposure to 24 g a.i./ha, no effects on mortality, flight intensity and behaviour were observed.

No effects on colony development, colony strength or bee brood were observed after exposure of the bees to pre-flower treatment with 48 g a.i./ha, to dried residues applied at 48 g a.i./ha after bee flight and to direct exposure to 24 g a.i./ha. Following the application of 24 g a.i./ha after the bee flight, brood termination rate of the bee colonies was higher compared to the control. Since this was not obvious in the higher rate with 48 g a.i./ha and after direct application to the bees to 24 g a.i./ha, this must be seen as not a test item related effect.

Clear adverse effects were observed in the reference item treated colonies (Insegar (300 g fenoxycarb/ha)).

No adverse effect on the overall survival of the colonies could be observed after application of GF-2626 at all rates and treatment scenarios.

Note that this is a different formulation to GF-2032 and that the tested dose rate is lower than the proposed rate in NZ.

Flag: supporting

Test substance: GF-2626 [sulfoxaflor 12%]

Species: Honeybee *Apis mellifera*

Type of exposure: semi- field [tunnel]

Endpoint: Mortality, behaviour, flight intensity, condition of the colonies and the development of the bee brood

Reference: DAS study no 101599 [additional study 2.8]

Klimisch score: 2

GLP: yes

Test guidelines: OEPP/EPPO (2001): Guideline for the efficacy evaluation of plant protection products - Side effects on honeybees. OEPP/EPPO, PP 1/170(3) update 2000, 19 - 23 .

OECD No. 75, "Guidance Document on the Honey Bee (*Apis mellifera* L.) Brood Test under Semi-Field Conditions", No. 75, ENV/JM/MONO(2007)22

Study summary: The aims of the study were to determine the effects on honey bee colonies including brood development, when bee colonies enclosed within tunnels were exposed to different rates and application timing of GF-2626.

Small bee colonies (*Apis mellifera camica* L.) maintained according to normal beekeeping practice, containing 4 honeycombs with honey, pollen and all brood stages present were used in the test. The preliminary brood check indicated healthy colonies with all brood stages present and a sufficient supply with nectar and pollen. The mean number of bees per colony in the test groups one day before daytime application was very similar.

A tunnel test was conducted, in order to assess the effect of GF-2626 on honey bee brood under semi-field conditions. Tunnels (14 m length x 5.5 m width x 2.5 m height) were set up on a ca. 50 m² plot of *Phacelia tanacetifolia* (2 x 24 m²) and small bee colonies were introduced four days before daytime applications. A water control and a toxic reference (Insegar [250 g/kg fenoxycarb]) were included in the study.

Three application scenarios were conducted:

- Scenario 1: 48 g ai/ha of GF-2626 was applied to the crop before flowering. Five days following this application, the bees were introduced to the tunnels when the *Phacelia* was now in full flower and were exposed to the residues of the test item. This application was conducted 15 days before the daytime applications.
- Scenario 2: In the evening before the daytime application two test item rates of 24 g a.i./ha were applied after the bees were active in order to expose the bees to dried residues of the test item the next day.
- Scenario 3: 24 g ai/lha of GF-2626 was applied in the middle of the day with foraging bees present (daytime applications).

The water-treated control and the reference items (300 g fenoxycarb/ha and 600 g dimethoate/ha) were applied also during daytime with foraging bees present.

The trial was carried out using three tunnels (*i.e.* replicates) for each treatment group, with one bee hive per tunnel. Following the daytime applications, ontogenesis of a defined number of honey bee eggs was observed for each treatment group and colony. Mortality of adult bees and pupae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial.

The exposure period of the bees to the water, test item and reference item treated crops in the tunnels was 7 days (17 days for the pre-flower treatment).

Afterwards the bee hives were removed from the tunnels to an area with no main flowering, bee attractive crops. Ontogenesis of the bees from egg to adult workers was observed for a period of 21 days. This was done by marking 120 eggs at the first brood area fixing day BFDO (BFD = Brood Area Fixing Day) and investigating the further progress of their development in regular intervals until day 20 following the daytime application (BFD 21 following BFDO).

Natural field conditions. Following a very hot and dry summer period, the weather changed and it was getting colder and frequently rain occurred. Weather conditions during all applications were good. It was windless, sunny and warm. First rain following the pre-flower application occurred 10 days following the application. Following the evening and daytime applications the first precipitation occurred 34 and 19 hours, respectively. High foraging activities on the day of the daytime applications indicated that the bees were well exposed to the fresh and dried residues of the test item. The days following the daytime applications the weather was variable and frequently some rain occurred.

Results

Behavioural Abnormalities

Following all test item applications no behavioural abnormalities could be observed at any time. No behavioural abnormalities were observed in the control group and in the reference item group treated with Insegar (300 g/ha fenoxycarb). Treatment with the 2nd reference substance Perfekthion EC (600 g/ha dimethoate) led to discoordinated movements and/or cramps, at least on the day of the application.

Condition of the Colonies

The brood check two days before the daytime application indicated all colonies were healthy with all queens and brood stages present and a sufficient supply with nectar. Pollen could not visually be detected in all colonies before and after the applications. After application of GF-2626, no indication of a test item related effect on the condition of the colonies was observed. All test item treated colonies survived the trial and were comparable to the control colonies. At any assessments, all brood stages could be found in the test item treated colonies and all queens (or a sufficient amount of eggs) were present. There was no indication of any hazard of the test item on the condition of the bee colonies.

After treatment with the reference item Insegar (300 g/ha fenoxycarb) a decrease of maggots and closed brood was observed over the course of the experiment. The other reference item Perfekthion EC (600 g/ha dimethoate) caused a general decrease of brood stages and the colonies at test end were obviously weaker compared to the other colonies.

Colony Strength

The mean number of bees per colony in the six treatment groups one day before application was very similar (2460 to 3300 mean bees per colony). Colony sizes among all treatment groups did not differ very much in size over the course of the study.

Only at the last assessment on day 60, there was a clear decrease due to the progressed season. There was a very similar pattern of development in the control and all test item treatment groups. Colony sizes remain on a comparable level until day +27 ranging around 81 to 131 % compared to the initial values. At the last assessment all test item and control colonies ranged from 69 % to 81 % compared to their initial values.

Colonies in the reference item treatment group with Insegar showed a progress until day 16 and thereafter decreased. Reference item Perfekthion EC led to a continuous decrease of number of bees in the treated colonies until test end on day 60.

Brood Compensation Index:

Looking at the brood compensation index, which shows the development of the brood at each assessment, a continuous brood development was observed in all GF-2626 treated groups as well as in the control group. The brood compensation indices following the labelling of the egg stage in both 24 g ai/ha treatment groups were similar but slightly higher compared to the control values during all assessments up to day 21 following the application (BFD +21). The compensation indices in the 48 g a.i/ha pre-flower treatment group was

similar at BFD +5 and BFD +10, but thereafter very slightly retarded on BFD 17 and 21. There was no statistical significant difference of the test item treatments to the control group at any assessment.

There was a strong break down in brood compensation in both reference item treatments (Insegar and Perfekthion EC). The decrease was stronger after treatment with Perfekthion EC. No real recovery could be observed for both reference item groups.

Accordingly, no effect on the overall brood development was identifiable following the labelling of the egg stage in the GF-2626 treatment groups.

The high termination rate of the marked cells after treatment with both reference items Insegar (fenoxycarb) and Perfekthion EC (Dimethoate) was also reflected by the brood compensation indices. There was as strong break down in brood compensation in the both reference item treated groups over the entire time. No real recovery could be observed.

Conclusion:

For honey bees and colonies exposed to pre-flower treatment with 48 g a.i./ha, to dried residues applied at 24 g a.i./ha after bee flight and to direct exposure to 24 g a.i./ha, no effects on mortality, flight intensity and behaviour were observed.

No effects on colony development, colony strength or bee brood were observed after exposure of the bees to pre-flower treatment with 48 g a.i./ha, to dried residues applied at 24 g a.i./ha after bee flight and to direct exposure to 24 g a.i./ha.

Clear adverse effects were observed in both reference item treatment groups, after treatment with Insegar (300 g fenoxycarb/ha) or Perfekthion EC (600 g dimethoate/ha).

No adverse effect on the overall survival of the colonies could be observed 60 days after application of GF-2626 at all rates and treatment scenarios.

Note that this is a different formulation to GF-2032 and that the tested dose rate is lower than the proposed rate in NZ.

Flag: supporting

Test substance: GF-2372 [sulfoxaflor 50%]

Species: Honeybee *Apis mellifera*

Type of exposure: semi- field [tunnel]

Endpoint: condition of the colonies and the development of the bee brood

Reference: Ythier E. (2012) Sulfoxaflor: a semi field study in cotton treated with GF-2372 (sulfoxaflor 50% WP) to determine residues in matrices relevant to exposure of honeybees and honey bee brood, to enable estimation of a typical honey bee colony, DAS study no 110603, 2012

Klimisch score: 2

GLP: -

Test guidelines: -

Study summary: GF-2372 was applied on cotton during flight of the bees. Four application scenarios were applied: 1 x 50 g ai/ha, 2 x 50 g ai/ha, 100 g ai/ha and 150 g ai/ha. The study was performed in a tunnel without replicates and a control treatment. Observations were done up to 10 days after application in the tunnel and 7 days post tunnel period.

Results

The brood development is compared between pre and post application. The amount of larvae and pupae (%) were reduced. The percentage pollen was 0 and percentage nectar was increased compared with pre application. The percentage adult bees was within 20% of pre-application levels. The hive strength across the treatments was similar before and after application.

Conclusion: The study was designed to assess residues of sulfoxaflor in plant and hive matrices and not for biological effects. (The results of the residues are shown under the heading residues in nectar and pollen 3.6.5.) Given the design of the study (one replicate, no control, short observation period) the results are not conclusive. The results indicate adverse effects on the amount of larvae and pupae.

Note that this is a different formulation to GF-2032 and only a table with a summary of this study is available, provided in the US EPA assessment (Table 47).

General conclusion about ecotoxicity of GF-2032 to bees

GF-2032 is highly toxic to honeybees with acute oral and contact LD₅₀ values <2 µg ai/bee. GF-2032 is highly toxic to bumblebees via oral exposure (LD₅₀ 0.027 µg ai/bee) and less so via contact exposure (LD₅₀ 7.55 µg ai/bee).

Exposure to aged residues from treatment at 200 g ai/L resulted in low levels of mortality in honeybees after 24 hours, with mortality declining with increased residue ageing.

Higher tier studies to assess the effects of sulfoxaflor on bee brood using the formulated product GF-2032 were carried out. After exposure to the substance the worker bee mortality increases and effects on foraging activity and abnormal behaviour were observed. These effects were short lived (up to 3DAA). No effects on brood development were observed up to 9 days after treatment. Long term effects on brood were not evaluated. The maximum tested dose is lower than the proposed maximum rate for NZ (192 g ai/ha).

Higher tier studies to assess the effects of sulfoxaflor on bee brood using an alternative formulation GF-2626 SC did not indicate any significant adverse effects. The application rates in these studies were lower (48 g ai/ha) than the proposed maximum rate for New Zealand (192 g ai/ha).

A higher tier study to assess the effects of sulfoxaflor on bee brood using an alternative formulation GF-2372 was carried out. Given the design of the study the results are not conclusive. The results indicated that the substances may cause adverse effects on the amount of larvae and pupae.

Terrestrial invertebrate toxicity

Laboratory tests

Flag: key study

Test substance: GF-2032

Species: parasitic wasp, *Aphidius rhopalosiphi*

Type of exposure: 48 hour glass plate

Endpoint: LR₅₀ and ER₅₀

Value: 48h LR₅₀ was 0.019 g a.i./ha and the ER₅₀ was >0.015 g a.i./ha.

Reference: OECD 2011 (j)

Klimisch score: 2

GLP: yes

Test guidelines: Mead-Briggs et al. (2000) in IOBC/BART/EPPO Guidelines to evaluate side-effects of plant protection products to non-target arthropods

Study summary: In a Tier 1 laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the parasitic wasp (*Aphidius rhopalosiphi*) were determined. Wasp-imagines were exposed over a period of 48 hours to fresh dried residues on glass plates treated at nominal rates of 0.005, 0.008, 0.015, 0.026, 0.044 and 0.077 g a.i./ha. In addition, a purified water control was tested. Mortality was assessed after 48 hours. There was no mortality in the controls and the rate-response mortality ranged 0-100% in the treatment groups. Surviving female wasps in the control, 0.005, 0.008 and 0.015 treatment groups (which had at least 15 surviving females) were transferred to untreated aphid-infested barley plants for 24 hours and after a further 11 days the number of parasitized aphid mummies was determined. Control females produced 11.6 mummies/female; there was no effect on reproduction rates in the treatment groups when compared to control.

Conclusion: The 48h LR₅₀ was 0.019 g a.i./ha and the ER₅₀ was >0.015 g a.i./ha.

Flag : Key study

Test substance: GF-2032

Species: predatory mite, *Typhlodromus pyri*

Type of exposure: 14 day, glass plate

Endpoint: LR₅₀

Value: The 7d LR₅₀ was >400 g a.i./ha and the 14d ER₅₀ was >400 g a.i./ha.

Reference: OECD 2011 (j)

Klimisch score: 2

GLP: yes

Test guidelines: Blümel et al. (2000) in IOBC/BART/EPPO Guidelines to evaluate side-effects of plant protection products to non-target arthropods

Study summary: In a Tier 1 laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the predatory mite (*Typhlodromus pyri*) were determined. Protonymphs were exposed over a period of 14 days to fresh dried residues on glass plates treated at nominal rates of 25, 50, 100, 200 and 400 g a.i./ha. In addition, a purified water control was tested. Mortality was assessed after 7 days and number of eggs was determined at the end of the 14-day exposure period. Mean control mortality was 17% in the controls. Mortality in the treatment groups ranged 22-40% but a rate-response relationship was not apparent. Surviving mites produced 10 mummies/female; there was no effect on reproduction rates in the treatment groups when compared to the control.

Conclusion: The 7d LR₅₀ was >400 g a.i./ha and the 14d ER₅₀ was >400 g a.i./ha.

Extended laboratory tests

Flag : Key study

Test substance: GF-2032

Species: parasitic wasp, *Aphidius rhopalosiphi*

Type of exposure: 48 hours to fresh dried residue on barley plants

Endpoint: LR₅₀

Value: The 48h LR₅₀ was 1.28 g a.i./ha and the 48h ER₅₀ was >1.21 g a.i./ha

Reference: OECD 2011 (j)

Klimisch score: 2

GLP: yes

Test guidelines: Mead-Briggs et al. (2006) in IOBC/BART/EPPO draft guidelines being prepared by the *Aphidius* ring-testing group

Study summary: In a Tier 2 extended laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the parasitic wasp (*Aphidius rhopalosiphii*) were determined. Female wasp-imagines were exposed over a period of 48 hours to fresh dried residues on barley plants treated at nominal rates of 0.151, 0.302, 0.605, 1.21 and 2.42 g a.i./ha. In addition, a purified water control was tested. Endpoints were based on mortality after 48 hours and the number of parasitized aphid mummies was determined at the end of the 12-day untreated observation period. Repellence from treated plants was assessed after 3 hours; 40% of control wasps settled on treated plants and there was no effect on settling rates in the treatment groups when compared to control. After 48 hours, there was no mortality in the controls and the rate-response mortality ranged 0-87% in the treatment groups. Control females produced 48.6 mummies/female; there was no effect on reproduction rates in the treatment groups when compared to control..

Conclusion: The 48h LR₅₀ was 1.28 g a.i./ha and the 48h ER₅₀ was >1.21 g a.i./ha. The maximum New Zealand application rate is proposed to be 192 g ai/ha for pipfruit, stonefruit and citrus.

Flag : Key study

Test substance: GF-2032

Species: parasitic wasp, *Aphidius rhopalosiphii*

Type of exposure: aged residue

Value: Residues no longer caused unacceptable mortality by three days after treatment of 6.2 and 26 g a.i./ha and 14 days after treatment of 45 g a.i./ha.

Reference: OECD 2011 (j)

Klimisch score: 2

Amendments/Deviations:

GLP: yes

Test guidelines: Mead-Briggs et al. (2006) in IOBC/BART/EPPO draft guidelines being prepared by the *Aphidius* ring-testing group

Study summary: In an aged residue extended laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the parasitic wasp (*Aphidius rhopalosiphii*) were determined. Wasp-imagines were exposed over a period of 48 hours to fresh-dried or aged residues on barley plants treated at nominal rates of 6.2, 26 and 45 g a.i./ha. In addition, a purified water control was tested. The aged residue bioassays were initiated 3, 7 or 14 days after treatment. Endpoints were based on mortality after 48 hours and number of parasitized aphid mummies at the end of the 12-day untreated observation period. Repellence from fresh-dried residues was assessed after 3 hours; 37% of control wasps

settled on treated plants and there was no effect on settling rates in the treatment groups when compared to control. No control mortality was observed after 48 hours in any bioassay; fresh-dried residues of all treatment levels resulted in complete mortality. Reproduction rates of surviving females were not affected at any treatment level in the aged residue bioassays; therefore, mortality was identified as the response of concern.

Conclusion: Residues no longer caused unacceptable mortality by three days after treatment of 6.2 and 26 g a.i./ha and 14 days after treatment of 45 g a.i./ha. The maximum New Zealand application rate is proposed to be 192 g ai/ha for pipfruit, stonefruit and citrus.

Flag : Key study

Test substance: GF-2032

Species: rove beetle, *Aleochara bilineata*

Type of exposure: fresh residues on treated sandy soil

Endpoint: The 71d ER₅₀

Value: >24 g a.i./ha

Reference: OECD 2011 (j)

Klimisch score: 2

GLP: yes

Test guidelines: Grimm et al. (2000) in IOBC/BART/EPPO Guidelines to evaluate side-effects of plant protection products to non-target arthropods

Study summary: In a Tier 2 extended laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the rove beetle (*Aleochara bilineata*) were determined. Adult beetles were exposed over a period of 28 days to fresh dried residues on sandy soil treated at nominal rates of 3.3, 12 and 24 g a.i./ha. In addition, a purified water control was tested. The endpoint is based on the number of progeny (F₁ beetles) that successfully emerged from parasitized fly pupae after 71 days of exposure. Mean number of F₁ progeny per control replicate was 874; there was no effect on reproduction rates in the treatment groups when compared to control.

Conclusion: The 71d ER₅₀ was >24 g a.i./ha. The maximum New Zealand application rate is proposed to be 192 g ai/ha for pipfruit, stonefruit and citrus.

Flag : Key study

Test substance: GF-2032

Species: ladybird beetle, *Coccinella septempunctata*

Type of exposure: fresh dried residues on bean plants

Endpoint: 17d LR₅₀ and 17d ER₅₀

Value: 17d LR₅₀ 14 g a.i./ha and 17d ER₅₀ >12 g a.i./ha.

Reference: OECD 2011 (j)

Klimisch score: 2

GLP: yes

Test guidelines: Schmuck et al. (2000) in IOBC/BART/EPPO Guidelines to evaluate side-effects of plant protection products to non-target arthropods

Study summary: In a Tier 2 extended laboratory test, the effects of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on mortality and reproduction of the ladybird beetle (*Coccinella septempunctata*) were determined. Second-instar larvae were exposed over a period up to 17 days (until ecdysis) to fresh dried residues on dwarf French bean leaves treated at nominal rates of 6.25, 12, 24, 48 and 96 g a.i./ha. In addition, a purified water control was tested. Endpoints are based on pre-ecdysis mortality for the larvae confined to treated leaves, and an assessment of the reproductive capacity (egg production and egg viability) of the surviving insects confined to untreated Petri dishes. There was no pre-ecdysis mortality in the controls and rate-response mortality ranged 27.5-100% in the treatment groups. Only the 6.25 and 12 g a.i./ha treatment groups had sufficient survival to assess reproduction. In the controls, the mean number of eggs laid per female per day was 23.7 and the mean number of viable eggs per female per day was 17.4. There was no effect on the reproductive capacity of surviving females in either treatment group when compared to the control.

Conclusion: The 17d LR₅₀ was 14 g a.i./ha and the 17d ER₅₀ was >12 g a.i./ha. The maximum New Zealand application rate is proposed to be 192 g ai/ha for pipfruit, stonefruit and citrus.

General conclusion about ecotoxicity to non-target arthropods

Note that the maximum New Zealand application rate is proposed to be 192 g ai/ha for pipfruit, stonefruit and citrus which is well above the maximum rate tested in these studies. The applicant was asked to provide studies at higher application rates but stated that they had not conducted any.

Refer to the environmental risk assessment for an evaluation of the risks posed by GF-2032 to non-target arthropods.

Appendix B: Submission from the National Beekeepers Association

Submission on Application ERMA200886

Submission Summary

This submission is made for and on behalf of the National Beekeepers Association of New Zealand.

This submission is not in favour of the importation and release of GF-2032 due to the lack of data presented in the submission that may affect the safety and health of bees.

We believe that the applicant needs to supply more data in the application with supporting information that this product is safe to beneficial pollinators especially the honey bee.

Our concerns are with what information the applicant does not present in this application (publicly available documents) may present adverse risks to bees and other beneficial pollinators.

Application ERMA200886

This application is for a new substance GF-2032, which has an intended use as an insecticide. The applicant is Dow Agro-Sciences (NZ) Limited.

GF-2032 contains a new active ingredient Sulfoxaflor and is formulated as a liquid suspension concentrate.

The active ingredient triggers the carcinogenic, target organ/systemic and reproductive/development hazard classes of the HSNO Act classification. But the formulated product shows low toxicity when using the six pack of tests. With respect to this submission supporting beneficial pollinators such as the honey bee and bumble bee this product shows a high level of toxicity.

Reference Table 3.3.2.5 of the application where the $LD_{50} = 0.0515 \times 10^{-6}$ grams active ingredient per bee for the formulated product.

The applicant identifies that the product triggers the following Hazard Classes;

6.1D, 6.1C, 6.3B, 6.7B, 6.8B, 6.9B, 9.3B, 9.4A

The Use of GF-2032 and its mode of action

The application ERMA200886 is very deficient on how GF-2032 is intended to be used and the mode of action of the active ingredient.

According to Paragraph 5 of Section 3.5 of the application it will be used by farmers as a liquid insecticide sprayed directly to bare ground (soil) prior to sowing the crops.

This suggests (although not stated) that GF-2032 is a soil residual type insecticide that lies in the soil and provides insect protection during the germination and early growth stages of the crop from seed to plant.

We note that there is no mention of using the product as a seed treatment.

It should be noted that we had to identify four sections of the application to determine where and what crops this product will be used on. See Table 1.

Table 1: Crops where GF-2032 will be used.

	Application Section	Crops Mentioned
1	Paragraph 5, Section 3.5, page 10	Bare soil application, pre planting of crop seed
2	Section 4.1.3, Page 16	Cereals, Fruit and vegetables
3	Section 4.2.2, Page 19	Orchards, vine crops, fodder brassicas, pastures,
4	Section 7.4, Page 25	Greenhouse crops

Table 1; shows that the applicant intends to use this product over a large range of various crops in New Zealand which includes many flowering species. We note that there is no reference to using this product or the active ingredient XDE-208 as a seed treatment, but do accept this may be subject to another EPA application.

According to the application Section 4.1.1, Lifecycle Risks, the product will be applied by ground spray and aerial spray.

Section 4.1.3 details the identified benefits of using GF-2032, and points out that the product will be used for aphid control in cereal crops and control of sucking insects in fruits and vegetables. It should be noted that the applicant does not provide a full summary of insects controlled until Section 7.4 of the application.

The identity of the GF-2032 being effective against sucking insects suggests strongly that this product is systemic within the plant, and that sucking insects can access it whilst the chemical or its metabolites flow through the xylem or phloem. It would be expected that the active ingredient or its metabolites will travel through the phloem (up the plant) if GF-2032 is soil applied.

If soil applied it can be expected that the product is quite persistent in the soil with a long half-life and is mobile in the soil, to enable it to be absorbed by the plant roots.

There is no mention of how long the active ingredient works when it or its metabolites are in the plant, and for a Class 9.4A substance we believe this is very important. See Section 8 (2) of this submission.

There is no mention of whether the active ingredient or its metabolites are present in pollen or nectar of plants sprayed with GF-2032.

I believe that for the EPA and the public to properly assess a new pesticide a discussion on the mode of action of the chemical, how it works and the residues it may leave in the plant, pollen and nectar need to be included. This is a serious omission of the present ER-AH-01-1 07/2001 form supplied by the EPA for pesticides.

It is noted that in the Executive Summary of the application that a claim that this product controls, dimpling bug, *Campylomma austrina Malipatil*, a known pest of Northern Australia, especially of mangos. Landcare Research has no record of *Campylomma austrina Malipatil* being present in New Zealand. One has to ask the EPA if Dow Agro Sciences has written this application to mislead or are just plainly incompetent in putting together a coherent application.

Disposal of GF-2032

The application is conflicting when it discusses disposal of this product.

In Section 3.5 of the application, spray equipment rinsing should be disposed of in a designated disposal area or on waste land, and to avoid desirable plants which are not described.

In Section 4.2.1 of the application, disposal is mentioned to “only occur at a local authority landfill...” and diluted substance including spray equipment rinsing at the site of application. There is no mention or definition of desirable plants.

In Section 4.2.2 of the application, there is no mention of a licensed landfill, waste land and only a mention of the site of application for diluted substances to be applied to non-grazed land.

In Section 7.4 of the executive summary, none of the above disposal methods are mentioned, but any landfill will be okay.

We would like to point out to the EPA that not having a draft label makes commenting on this application very difficult.

Our recommendation to the EPA is that the draft label recommendations should be included with all pesticide application documents open to public scrutiny.

Soil activity of GF-2032

There is some concern that the applicant Dow Agro Sciences Limited has made some conflicting statements with respect to the activity of GF-2032 in the soil which we believe should be made clearer. Clearly the product is to be applied directly to the soil (ref Table 1 of the this submission), and it has some active life in the soil where plants presumably absorb the product and use the active ingredient to control sucking insects – that is clearly stated in various parts of the application, as noted above.

The applicant though states it **‘expects’** in Section 4.2.2 that repetitive spraying will not result in soil accumulation of the active ingredient or the formulated product. This is of concern, as it shows that no soil half-life studies have been conducted of the substance, the active ingredient and or the metabolites it forms. The applicant’s data does not note any toxicity to a soil dwelling organism.

The applicant does not mention the minimum or maximum number of applications to a crop in a season for an assessment of the likelihood of prolonged soil effects that may carry over to a subsequent crop.

The applicant does not discuss the likelihood of this insecticide being absorbed by flowering plants (ornamentals, wild flowers and food crops) and presenting a risk to pollinating bees.

Example; GF-2032 could be safe to bees if used to control thrips in table onions from sowing of the seed to harvest as harvest is normally just prior to onion flowering. But is GF-2032 safe to use to control aphids in Squash where flowering and pollination occurs well before harvest?

This is of a primary concern to beekeepers where it is noted that (in Table 1 of this submission) the applicant states that the product could be used on pasture but there is no mention of the effects on flowering clover which may have absorbed the product from the soil.

The application presents no discussion on the effects of foliar spraying of the insecticide on growing plants where we believe it is intended for use.

The major concern to beekeepers is that this product is a persistent soil active insecticide with strong systemic activity against sucking insects in the plant. There is no discussion on the effects that GF-2032 may have on plants before and during flowering, the residues in pollen and nectar and the likely effects on bees from the active ingredient or its metabolites at sub lethal doses. New Zealand Beekeepers need more data on this substance to determine its safety on crops and their hardworking bees.

What we have learnt from the application

Based on the above data in the application we can identify the following properties of GF-2032, which we note are not referenced in the application document;

- Active in the soil – the applicant suggests direct soil applications prior to planting.
- Has a long soil life – to be effective against sucking insects such as aphids it has to remain in the soil until the plant seed has germinated and grown above the ground surface.
- That its soil activity and perhaps its soil half-life is considerable as the applicant recommends the disposal of the product to waste areas only.
- Can be absorbed by plant roots and become systemic in the plant.
- Can be absorbed by the plant as a foliar spray (ground or aerial) and be effective against sucking insect pests.
- Controls sucking insects such as aphids, thrips and mealy bugs – confirms that the product is systemic in the plant.

Toxicity to Honey Bees

The applicant supplies data on a 48 hour oral acute toxicity to bees and bumble bees in Section 3.3.2.5. The test protocol which was conducted is not referenced.

There is no discussion or data mentioning the impact of the product, its active ingredient or metabolites in the plant or in pollen, and the possible toxicity to bees. Internet research shows that Sulfoxaflor has a mode

of action similar to the neonicotinoid insecticides¹¹ in that it affects the insect's "*nicotinic acetylcholine receptors (nAChRs) using electrophysiological and radioligand binding techniques.*"¹¹ This is of concern as that suggests it may in fact be very similar to the neonicotinoid insecticides which at sub lethal doses may lead to behaviour modification of insects, especially colony forming insects such as termites, ants and honeybees making them more susceptible to diseases, pathogens, and or pests.

This submission would like to see further testing on the impact this product through its end uses on honeybees before it is released to the environment. Testing of pollen of flowering plants for the active ingredient and its metabolites to eliminate the risk of bees taking the insecticide back to the hive. We also ask the EPA to seek data from the applicant based on the test US EPA 850.3030 – Honey Bee Toxicity of Residues on Foliage. This data is not submitted with this application but we believe that Dow Agro Sciences will be submitting it with their US EPA registration data package.

The applicant has not proposed any controls for the substance or supplied a draft label for review. This is disappointing as we do not know if they propose application of GF-2032 on flowering plants and if there is a proposed withholding period when GF-2032 should not be applied before plant flowering.

Of concern is that the applicant proposes a number of management measures that could be harmful to bees. These include the following;

- Disposal of rinsing and washing including the active ingredient on waste areas where flowering plants and weeds could be present and present a direct risk to bees. Reference Section 3.5 of the application.
- Soil applications and the soil transfer to plant activity of the product. This we believe is a significant issue with flowering plants before harvest.
- Details about the foliar activity of the active ingredient and the length of time it is active as a systemic insecticide.
- Testing to show that pollen or nectar is not made toxic to bees due to the systemic activity of the active ingredient and its metabolites.
- Proposed use in pasture and the effects of the systemic insecticide in clover. No testing data is shown that this product is safe to pollinating insects.
- There is no data to show that there are no residues in pollen or nectar of any flowering plant. There is no draft label advising how Dow Agro Sciences will manage and prevent application to plants during flowering or close to flowering.

Recommendations to the NZ EPA

¹¹ Novel nicotinic action of the sulfoximine insecticide sulfoxaflor. by Gerald B Watson, Michael R Loso, Jonathan M Babcock, James M Hasler, Theodore J Letherer, ...

Our principle recommendation to the NZ EPA is that this product, GF-2032 is not approved for release in the NZ environment for the reasons outlined in this submission and the severe information deficiencies with respect to the safety and health of beneficial pollinating insects such as the honey bee.

It is our submission that there is insufficient data to suggest that this product when in use is not without risk to the well-being of the honey bee in New Zealand.

We request that the NZ EPA ask the applicant for the following details;

- Analysis data on residues of the active ingredient Sulfoxaflor and its metabolites in the pollen and nectar of flowering plants.
- Proposed controls and withholding periods before flowering of treated plants. At the present moment Hazard Class 9.4 substances cannot be sprayed within 10 days of expected flowering date, as determined by the EPA. Class 9.4 substances should not then be applied until after complete petal fall. We do not know if this 10 day period is safe for bees for the active ingredient or its metabolites, as we do not understand its degradation within the sap of the plant. Is 10 days suitable or should this no spray period be longer before flowering so we do request more information on the substance to ensure that flowers are safe for pollination by bees. We request that the NZ EPA examine this 10 day interval for hazard Class 9.4 substances and determine if it is suitable and safe for bees for this new family of insecticide active ingredients.
- This application does not include a draft label for an assessment of how the applicant will inform users of the product on how to ensure that the product is safely used to protect beneficial insects.

We believe the EPA should request this and circulate it with the application.

- Evidence or not of the effect of sub lethal doses on colony forming insect behaviour. The neonicotinoid insecticides have demonstrated this property
- and in fact have utilised it to control some insect pests. We need to know if GF-2032 has similar properties so that its safety to bee hive populations can be determined. The beekeepers Association would like to see a behaviour response test for bees to sub lethal doses to ensure the safety of beneficial insects especially colony forming insects.
- That Dow Agro Sciences be directed (as a control) by the NZ EPA to permit access to their Sulfoxaflor residue analysis technology (at approved laboratories) for NZ Beekeepers and Bee Researchers to research and assess residues in pollen and nectar.
- The NZ EPA should note that many agrichemical manufacturers already permit growers to use their residue analysis technology/methodology to measure pesticide residues in their fruits and vegetables to protect the consuming public. To date there has been restrictions placed by agrichemical companies on access to residue analysis methodologies for research into pesticide residues in pollen and nectar (both foods) where bee keepers have believed that pesticides have adversely affected their hives. This has prevented the effective enforcement of the HSNO Act, the

monitoring of growers spraying activity and the effective management of hive health when used for pollination of crops. The reason is that the actual evidence of the specific pesticide involved in bee poisoning cannot be obtained. The National Beekeepers Association strongly believes that the NZ EPA can put in place such a control as permitted under either Section 77 (3) (c) of the HSNO Act or Section 77A (1) directing Dow Agro Sciences to provide open access to their residue analysis methodology for detecting residues of Sulfoxaflor in pollen and nectar for beekeepers and bee researchers.

Public Hearing of this Application

The National Beekeepers Association requests that their representatives are heard at a public hearing of the Authority when considering this application.

This application has been prepared and edited by

D.N. MacLeod

Member of the Technical Committee of the National Beekeepers Association.

Appendix C: Risk assessment

1. To facilitate the assessment of risks, the applicant and the staff identified the most common potential sources of risk to the environment and to human health and safety through release, spillage or exposure throughout the lifecycle of the substance, assuming no controls or regulations are complied with. These are tabulated in Table 1.
2. Staff carried out quantitative and qualitative assessments to assess risks to human health and the environment from the use of GF-2032. The results of this are shown in Section 6 of this report.
3. The process by which the risk assessment of substances is undertaken is specified in the Methodology¹². Guidance on risk assessment is provided on the EPA website¹³

Table 1: Potential sources of risks associated with hazardous substances

Lifecycle Activity	Associated Source of Risk
Manufacture / Import	An incident during the manufacture or importation of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Packing	An incident during the packing of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Transport or storage	An incident during the transport or storage of the substance resulting in spillage and subsequent exposure of people or the environment to the substance.
Use	Application of the substance resulting in exposure of users or bystanders or the environment; or an incident during use resulting in spillage and subsequent exposure of users or the environment to the substance.
Disposal	Disposal of the substance or packaging resulting in exposure of people or the environment to the substance.

Human health risk assessment

Critical endpoint definition

Deriving an AOEL

Key systemic effect	NOAEL (LOAEL) mg/kg bw/day	Uncertainty factors	Absorption factor ¹⁴	AOEL mg/kg bw/day	Justification

¹² <http://www.epa.govt.nz/publications/methodology.pdf>

¹³ [http://www.epa.govt.nz/Publications/ER-TG-05-02-03-09-\(Decision-Making\).pdf](http://www.epa.govt.nz/Publications/ER-TG-05-02-03-09-(Decision-Making).pdf)

¹⁴ %Absorption

Marked impairment of food intake and body weight loss	6 mg/kg bw/day (dog, 90 day and 52 week studies)	100	1	0.06 mg/kg bw/day	This is the lowest NOAEL from sub-chronic studies. The absorption via the oral route is high (see Metabolism studies p76) so no adjustment for the proportion absorbed is appropriate.
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Other inputs for human worker (operator) and re-entry exposure modelling¹⁵

Table 2 Derivation of dermal absorption value in humans

Active	Physical form	Concentration of each active (g/L or g/kg)	Log Kow	Maximum application rate (for each active, for each method of application) g a.i./ha	Dermal absorption (%)		AOEL mg/kg bw/day
					Concentrate	Spray	
Sulfoxaflor	liquid	240 g/L	0.802 (see p16)	192	0.26	1.5	0.06

Comments on inputs for human worker (operator) exposure modelling input parameters:

The dermal absorption study, summarised in 4.3.7, identifies the percentage absorption findings for the concentrate and dilute spray. The proportion of the absorbed dose in humans was 0.26% for the concentrate and 1.5% for the diluted product (based on the higher of the two values for diluted product).

Output of human worker (operator) mixing, loading and application exposure modelling

Exposure Scenario	Estimated operator exposure (mg/kg bw/day)	Risk Quotient
Boom		
No PPE ¹⁶ during mixing, loading and application	0.00079	0.01318
Gloves only during mixing and loading	0.00066	0.01106

¹⁵ The Staff has undertaken an assessment of risks to operator health using the United Kingdom Pesticide Safety Directorate's interpretation of the German BBA Model to estimate operator exposure. This model estimates the exposure of workers to a pesticide during mixing, loading and during spray application, in mg/kg person/day (<http://www.pesticides.gov.uk/index.htm>). The derived values consider both dermal and inhalation exposure routes. The Staff typically uses the geometric mean model. The BBA model provides for a range of different spray applications (tractor-mounted/trailed sprayers and hand-held sprayers) and formulation types (liquid, wettable powder and wettable granule). Additionally, the BBA model also allows flexibility to vary protective clothing (hands, head and body).

¹⁶ Full PPE includes: gloves, hood/visor, coveralls, and heavy boots during application. The model only provides for use of gloves at mixing loading.

Gloves only during application	0.00067	0.01124
Full PPE during mixing, loading and application (excluding respirator)	0.00006	0.00102
Full PPE during mixing, loading and application (including respirator)	0.00003	0.00048
Airblast		
No PPE during mixing, loading and application	0.00433	0.07217
Gloves only during mixing and loading	0.00419	0.06991
Gloves only during application	0.00410	0.06837
Full PPE during mixing, loading and application (excluding respirator)	0.00059	0.00983
Full PPE during mixing, loading and application (including respirator)	0.00019	0.00309
Backpack - High Level Target		
No PPE during mixing, loading and application	0.00153	0.02553
Gloves only during mixing and loading	0.00099	0.01648
Gloves only during application	0.00137	0.02283
Full PPE during mixing, loading and application (excluding respirator)	0.00039	0.00650
Full PPE during mixing, loading and application (including respirator)	0.00004	0.00061

Outcomes of the worker (operator) exposure assessment:

No PPE is recommended as necessary to reduce the risk to an acceptable level during mixing, loading, and application¹⁷.

Outcomes of the re-entry exposure assessment:

Table 3 Re-entry exposure modelling¹⁸

Active	Crop	Internal (absorbed) dose available	AOEL	Risk
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¹⁷ The Staff considers that, while the 'no PPE' exposure model leads to an acceptable level of risk, it is appropriate to retain requirements for PPE since the use of PPE when handling agrichemicals is good practice. The Staff notes that the HSNO PPE requirements are not prescriptive allowing users to select an appropriate level of PPE.

¹⁸ The Staff assessed the re-entry worker exposures using the generic exposure model for "Maintenance and harvesting activities: Dermal exposure" provided by the UK Health & Safety Executive chemical Regulation Directorate, on the following web site:

http://www.pesticides.gov.uk/applicant_guide.asp?id=1246&link=%2Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FRe%2Dentry%2520worker%2520guidance%5Ffinal%2520version%2Epdf.

		for systemic distribution (mg/kg bw/8 hours)	(mg/kg bw/day)	Quotient
Sulfoxaflor	Vegetables (boom)	0.00138	0.06	0.023
Sulfoxaflor	Fruit trees (air blast)	0.0057	0.06	0.095
Sulfoxaflor	Cereals	0.00024	0.06	0.004

A 24 hour s77A re-entry control is not recommended as necessary to reduce the level of re-entry risk

Quantitative bystander risk assessment

The Staff considers that the main potential source of exposure to the general public for substances of this type (other than via food residues which will be considered as part of the registration of this substance under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997) is via spray drift. In terms of bystander exposure, toddlers are regarded as the most sensitive sub-population and are regarded as having the greatest exposures. For these reasons, the risk of bystander exposure is assessed in this sub-population. The oral chronic reference dose (CRfD), or an equivalent threshold such as an ADE, ADI or a general population DN(M)EL is selected because these are an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Thus, the bystander exposure risk assessment estimates the life-time risk associated with repeated daily exposure of the most sensitive human sub-population over their lifespan

Critical endpoints definition

The EPA uses the AOEL derived above for the bystander risk assessment.

Output of human bystander mixing, loading and application exposure modelling¹⁹

Exposure Scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area	Risk Quotient
Boom		
High boom, fine droplets	0.24	0.0041

¹⁹ Exposure is estimated using the equations from the UK Health & Safety Chemical Regulation Directorate which account for dermal exposure, hand-to-mouth exposure and object-to-mouth exposure (http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Bystander%20exposure%20guidance_final%20version.pdf Accessed 27/01/2010a). In addition, incidental ingestion of soil is taken into account using a modified exposure equation from the United States Environmental Protection Agency (USEPA, 2007, Standard Operating Procedures (SOPs) for Residential Exposure Assessments, Contract No. 68-W6-0030, Work Assignment No. 3385.102). Spray drift is estimated using models specific to the type of application equipment. For pesticides applied by ground boom or air blast sprayer, the AgDrift model is used. Spray drift deposition from aerial application is estimated using the AGDISP model along with appropriate New Zealand input parameters

High boom, coarse droplets	0.04	0.0006
Low boom, fine droplets	0.08	0.0014
Low boom, coarse droplets	0.02	0.0003
Airblast		
Airblast sparse orchard	1.63	0.0272
Airblast dense orchard	0.55	0.0091
Airblast vineyard	0.08	0.0013
Aerial – agriculture		
Swath width 20 m, Med-coarse droplet size	0.10	0.0016
Swath width 20 m, coarse- v. coarse droplets	0.07	0.0012
Swath width 20 m, extremely coarse droplets	0.05	0.0008
Swath width 24 m, v. fine-fine droplets	0.29	0.0048
Swath width 24 m, fine-med. droplets	0.14	0.0024
Swath width 24 m, med.-coarse droplets	0.10	0.0016

Outcomes of the bystander exposure assessment

The risks to bystanders are acceptable.

Summary and conclusions of the human health risk assessment

The risks to the operator, re-entry worker and bystander are low, and no personal protective equipment is identified as necessary for the operator, but use of PPE is recommended as good practice when handling and applying agrichemicals. No re-entry interval to protect the worker entering treated crop is proposed.

Environmental risk assessment

Environmental fate and ecotoxicity list of endpoints used for risk assessment²⁰ and classification

Active ingredient

Persistency in aquatic and terrestrial environment

²⁰ Depending on the risk assessment the endpoint values used can differ from those listed in the presented tables.

Further explanation is presented in the appropriate paragraph under the environmental risk assessment section.

Test type	Test method ^a	Test results	Klimisch score (1-4)	Reference
Aqueous photolysis half-life (DT ₅₀)	OECD 316	484 days	2	OECD 2011(a)
Hydrolysis half-life (DT ₅₀)	OECD 111	Stable		
Aerobic half-life in aquatic systems (DT ₅₀)	OECD 308	37 days (silt loam) 88 days (sand)		
Adsorption/desorption	OECD 106	Kd (adsorption) 0.19 - 1.29 ; lowest non-sand value 0.31 French light clay		OECD 2011(c)
Aerobic half-life in soil (DT ₅₀ days))	USEPA 162-1; OECD 307	Lenawee light clay 0.32 Pullman light clay 0.39 Fayette silt loam 0.56 Slagle silt loam 0.44 Cranwell loamy sand 0.08 Aberford sandy clay loam 0.05 Malham sandy loam 0.05 LUFA 5M 0.26 Upper 90%CI on the mean (n=8) 0.48 day		OECD 2012(a)
Field dissipation	USEPA 835.6100	8.1 days		OECD 2011(c)

Conclusion on persistency: Sulfoxaflor is not rapidly degradable in aquatic systems with DT₅₀ >16 days; it is degradable in the soil environment with laboratory DT₅₀ <1 day. The major metabolite X11719474 is not rapidly degradable in the aquatic or terrestrial environments..

^a Unless otherwise stated, the tests were conducted according to the test method identified

Bioaccumulation

Test type	Test method ^a	Test results	Klimisch score (1-4)	Reference
Partition coefficient octanol/water	EEC A8	0.802 at pH 7	4	Dow – Document M-II (Tier 2)

Conclusion on bioaccumulation: Not likely to bioaccumulate

^a Unless otherwise stated, the tests were conducted according to the test method identified

Aquatic toxicity (acute and chronic toxicity for the most sensitive species at each trophic level)

Test species	Test method ^a	Test type and duration	Test results mg/L	Klimisch score (1-4)	Reference
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Fish sheepshead minnow, <i>Cyprinodon variegatus</i>	OECD 203	96 hour static	LC ₅₀ 266 mg ai/L	2	OECD 2011(d)
Fathead minnow, <i>Pimephales promelas</i>	OECD 210	30 day ELS, flow through	NOEC 0.65 mg ai/L (mean fry weight)		
Invertebrates Mysid shrimp, <i>Americamysis bahia</i>	850.1035	96 hour static	LC ₅₀ 0.643 mg ai/L		
	850.1350; 850.1000	28-day life-cycle, flow through	NOEC 0.11 mg ai/L (reproduction)		
Algae Freshwater diatom, <i>Navicula pelliculosa</i>	OECD 201	96 hour static	E _r C ₅₀ >95.6 mg ai/L E _b C ₅₀ 81.2 mg ai/L NOEC 3.54 mg ai/L		
Aquatic plants Duckweed <i>Lemna gibba</i>	OECD 211	7 day static renewal	>100 mg ai/L		

Conclusion on aquatic classification: Sulfoxaflor classifies as 9.1A highly toxic to the aquatic environment.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Soil toxicity

Test species	Test method ^a	Test type and duration	Test results mg/kg soil	Klimisch score (1-4)	Reference
Earthworm, <i>Eisenia fetida</i>	OECD 207	14 day, artificial soil	LC ₅₀ 0.885 mg ai/kg dw soil; NOEC 0.313 mg ai/kg dw soil	2	OECD 2011(e)
		56-day, natural soil	NOEC 0.64 mg ai/kg dw soil (umber of juveniles)		

Conclusion on soil classification: Sulfoxaflor is classified as 9.2A highly toxic to the soil environment.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Terrestrial vertebrate toxicity

Test species	Test method ^a	Test type and duration	Test results mg/kg bw/d	Klimisch score (1-4)	Reference
Bobwhite quail, <i>Colinus virginianus</i>	850.2100	Acute oral	LD ₅₀ 676 mg ai/kg bw	2	OECD 2011(h)
	OECD 205	Acute dietary	LD ₅₀ >5620 ppm diet (>1152 mg ai/kg bw)		
Mallard, <i>Anas platyrhynchos</i>		Chronic, reproductive toxicity	NOAEL 200 ppm diet (26 mg ai/kg bw/day highest test dose)		

Conclusion on terrestrial vertebrate classification: Sulfoxaflor classifies as 9.3C harmful to terrestrial vertebrates

^a Unless otherwise stated, the tests were conducted according to the test method identified

Terrestrial invertebrate toxicity

Test substance	Test species	Test method ^a	Test type and duration	Test results µg ai/bee	Klimisch Score (1-4)	Reference
Sulfoxaflor	Honeybee. <i>Apis mellifera</i>	OECD 213	48 hour oral	0.146	2	OECD 2011(i)
		OECD 214	72 hour contact	0.379		

Conclusion on terrestrial invertebrate classification: Sulfoxaflor classifies as 9.4A highly toxic to terrestrial invertebrates.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Metabolite X11719474

Persistence in aquatic and terrestrial environment of X11719474

Test type	Test method ^a	Test results	Klimisch score (1-4)	Reference
Aqueous photolysis half-life (DT ₅₀)	OECD 316	136 days	2	OECD 2011(a)
Adsorption/desorption	OECD 106	Kd adsorption 0.03 – 0.29		
Aerobic half-life in soil (DT ₅₀)	OECD 307	85-370 days		OECD 2012(a)

Conclusion on persistence: X11719474 is not rapidly degradable in the aquatic and terrestrial environments.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Aquatic toxicity

Test species	Test method ^a	Test type and duration	Test results mg/L	Klimisch score (1-4)	Reference
Fish Rainbow trout, <i>Onchorynchus mykiss</i>	OECD 203	96 hour static	LC ₅₀ >500 mg metabolite/L	2	OECD 2011(d)
Invertebrates <i>Daphnia magna</i>	OECD 202	48 hour static	EC ₅₀ >240 mg metabolite/L		

Conclusion on aquatic classification: The X11719474 metabolite does not trigger the threshold for toxicity to the aquatic environment on the basis of the data supplied by the applicant. However, it is noted that the species most sensitive to sulfoxaflor were not tested with this metabolite and no chronic data were provided.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Soil toxicity

Test species	Test method ^a	Test type and duration	Test results	Klimisch score (1-4)	Reference
Earthworm, <i>Eisenia fetida</i>	OECD 207	14-day	LC ₅₀ >1000 mg metabolite/kg dw soil	2	OECD 2011 (e)

Conclusion on soil classification: The X11719474 metabolite does not trigger the threshold for toxicity to the soil environment.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Terrestrial vertebrate toxicity

Test species	Test method ^a	Test type and duration	Test results	Klimisch score (1-4)	Reference
Bobwhite quail, <i>Colinus virginianus</i>	850.2100	Acute oral	LD ₅₀ >2250 mg metabolite/kg bw	2	OECD 2011 (h)

Conclusion on terrestrial vertebrate classification: The X11719474 metabolite does not trigger the threshold for toxicity to terrestrial vertebrates.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Formulation GF-2032

Aquatic toxicity

Test species	Test method ^a	Test type and duration	Test results mg/L	Klimisch score (1-4)	Reference
Fish Rainbow trout, <i>Onchorynchus mykiss</i>	OECD 203	96 hour static	LC ₅₀ >1000 mg formulation/L	2	DAS080074
Invertebrates <i>Daphnia magna</i>	OECD 202	48 hour static	EC ₅₀ >1000 mg formulation/L		DAS080075
Algae Freshwater diatom, <i>Navicula pelliculosa</i>	OECD 201	72 hour static	EC ₅₀ >100 mg formulation/L		DAS101301

Conclusion on aquatic classification: The data provided indicate that the formulation does not trigger the HSNO thresholds for toxicity to the aquatic environment. However, the formulation was not tested against the species demonstrated to be most sensitive to the active ingredient, ie sheepshead minnow, mysid shrimp, and chironomid larvae. Therefore the toxicity of the formulation has been estimated with mixture rules using data on the active ingredient, present at 22% in GF-2032 and classified as 9.1A (mysid LC₅₀ 0.643 mg ai/L) which results in classification of GF-2032 as 9.1B toxic to the aquatic environment

^a Unless otherwise stated, the tests were conducted according to the test method identified

Soil toxicity data

Test species	Test method ^a	Test type and duration	Test results mg/kg soil	Klimisch score (1-4)	Reference
Earthworm, <i>Eisenia fetida</i>	OECD 207	56-day natural soil	NOEC 0.64 mg ai/kg dw soil	2	OECD 2011(e)
Terrestrial plant - 11 crop species – 4 monocot (oats, ryegrass, maize, onion) and 7 dicot (oilseed rape, cabbage, soybean, carrot, cucumber, tomato, lettuce)	OECD 227	Vegetative vigour	ER ₂₅ >200 g ai/ha		OECD 2011(f)
		Seedling emergence	ER ₂₅ >400 g ai/ha		

Conclusion on soil classification: No acute test data were supplied on the toxicity of GF-2032 to earthworms therefore the toxicity of the substance has been estimated by applying mixture rules using data on the active ingredient at 22% (earthworm 14-day LC₅₀ 0.885 mg ai/kg soil, converted to EC₅₀ 0.0885 mg ai/kg soil for classification purposes) which results in classification of GF-2032 as 9.2A toxic to the soil environment.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Terrestrial vertebrate toxicity

Test species	Test method ^a	Test type and duration	Test results	Klimisch score (1-4)	Reference
Bobwhite quail, <i>Colinus virginianus</i>	850.2100	Acute oral	>2250 mg GF-2032/kg bw	2	DAS 080073
Rat	OECD 423	Acute oral	>5000 mg/kg bw	1	DAS 080049
Rat	OECD 402	Acute dermal	>5000 mg/kg bw	1	DAS 080050

^a Unless otherwise stated, the tests were conducted according to the test method identified

Conclusion on terrestrial vertebrate classification: GF-2032 does not trigger the threshold for toxicity to birds and mammals.

Terrestrial invertebrate toxicity

Test species	Test method ^a	Test type and duration	Test results µg ai/bee	Klimisch Score (1-4)	Reference
Honeybee, <i>Apis mellifera</i>	OECD 214	48 hour oral	0.0515	2	OECD 2011(i)
		72 hour contact	0.130		
Bumblebee, <i>Bombis terrestris</i>	Steen et al 1996	72 hour oral	0.027		
		72 hour contact	7.554		

Conclusion on terrestrial invertebrate classification: GF-2032 classifies as 9.4A highly toxic to terrestrial invertebrates.

^a Unless otherwise stated, the tests were conducted according to the test method identified

Risk assessment methodology

Methods used to assess environmental exposure and risk differ between environmental compartments (Table 4).

Table 4: Reference documents for environmental exposure and risk assessments

	Environmental exposure	Risk assessment
Aquatic organisms	(GEN)eric (E)stimated (E)nvironmental (C)oncentration Model Version 2.0 – 01 August 2002	Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and threatened Species Effects Determinations –

	AgDrift and EPA Software ²¹	23 January 2004
Sediment organisms	Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Version: 2 - May 2010	Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose [concentration]-response for environment – May 2008
Soil organisms, invertebrates (macro-invertebrates)	Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (FORum for the Co-ordination of pesticide fate models and their USE) – 29 February 1997	SANCO/10329/2002 rev 2 final. Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC- 17 October 2002
Terrestrial organisms, invertebrates (non-target arthropods)	Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From ESCORT 2 Workshop – 21/23 March 2000	
Terrestrial vertebrates (birds)	Guidance of EFSA. Risk assessment to birds and mammals – 17 December 2009. EFSA calculator tool - 2009 ²² SANCO/4145/2000 final. Guidance Document on risk assessment for birds and mammals under Council Directive 91/414/EEC- 25 September 2002	
Secondary poisoning and biomagnification	Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the	Guidance of EFSA. Risk assessment to birds and mammals – 17 December 2009 EFSA calculator tool - 2009 SANCO/4145/2000 final. Guidance Document on risk assessment for birds and mammals under Council Directive 91/414/EEC- 25 September 2002

²¹ The Staff used two different models for assessing the EEC and associated risks:

- Generic Estimated Environmental Concentration Model v2 (GENEEC2) surface water exposure model (USEPA, 2001) estimates the concentration of substance in surface water which may arise as a result of surface runoff and spraydrift.
- To examine how buffer zones would reduce the active ingredient concentrations in receiving waters, the Staff used the AgDRIFT[®] model (developed under a cooperative Research and Development Agreement, CRADA, between the EPA, USDA, US Forest Service, and SDTF). AgDRIFT[®] incorporates a proposed overall method for evaluating off-site deposition of aerial, orchard or ground applied pesticides, and acts as a tool for evaluating the potential of buffer zones to protect sensitive aquatic and terrestrial habitats from undesired exposures. Calculations are made assuming the receiving water is a 30 cm deep pond. The model is used to estimate the buffer zone that would reduce exposure through spray drift to such a concentration that an acute risk quotient of 0.1 cannot be calculated. It is noted that unlike GENEEC2, AgDRIFT[®] model only considers transport by spray drift, input through runoff, volatilisation, etc will pose additional risks.

²² www.efsa.europa.eu/en/efsajournal/pub/1438.htm

Council concerning the placing of
biocidal products on the market –
Part II - 2003

Aquatic risk assessment

For Class 9 substances, irrespective of the intrinsic hazard classification, the ecological risk can be assessed for a substance by calculating a Risk Quotient (RQ) based on an estimated exposure concentration. Such calculations incorporate toxicity values, exposure scenarios (including spray drift, leaching and run-off, application rates and frequencies), and the half-lives of the component(s) in water. For the aquatic environment, the calculations provide an Estimated Environmental Concentration (EEC) which, when divided by the L(E)C₅₀ or a NOEC, gives a RQ acute or chronic.

$$\text{Acute RQ} = \frac{EEC_{\text{short-term}}}{L(E)C_{50}}$$

$$\text{Chronic RQ} = \frac{EEC_{\text{long-term}}}{NOEC}$$

If the RQ exceeds a predefined level of concern, this suggests that it may be appropriate to refine the assessment or apply the approved handler control and/or other controls to ensure that appropriate matters are taken into account to minimize off-site movement of the substance. Conversely, if a worst-case scenario is used, and the level of concern is not exceeded, then in terms of the environment, there is a presumption of low risk which is able to be adequately managed by such things as label statements (warnings, disposal). The approved handler control can then be removed on a selective basis.

Levels Of Concern (LOC) developed by the USEPA (Urban and Cook, 1986) and adopted by EPA determine whether a substance poses an environmental risk (Table 5).

Table 5 Levels of concern as adopted by EPA New Zealand

Endpoint	LOC	Presumption
Aquatic (fish, invertebrates)		
Acute RQ	≥ 0.5	High acute risk
Acute RQ	0.1 - 0.5	Risk can be mitigated through restricted use
Acute RQ	< 0.1	Low risk
Chronic RQ	≥ 1	High chronic risk
Plants (aquatic and terrestrial)		
Acute RQ	≥ 1	High acute risk

GENEEC2 modelling

Calculation of expected environmental concentrations

The parameters used in GENEEC2 modelling are listed in **Error! Not a valid bookmark self-reference..**

Table 6 Input parameters for GENEEC2 analysis and scenarios evaluated for sulfoxaflor

	Fate parameters for sulfoxaflor	1 Cucurbits, leafy greens & other vegetables, at harvest – field grown (ground)	2 Citrus – mature fruit; Pipfruit – mature fruit; Stonefruit – mature fruit (mealybug)	3 Grapes – fruit ripening (table fruit); 80% capfall (wine)	4 Stonefruit – mature fruit (aphid)	5 Cereals – at harvest (aerial)- the ground application is covered by scenario 1
Application rate (g/ha)	-	Max 72 g ai/ha	Max 192 g ai/ha	Max 96 g ai/ha	Max 48 g ai/ha	Max 24 g ai/ha
Application frequency	-	4	2	4	4	2
Application interval (days)	-	14 days	14 days	14 days	14 days	14 days
Kd _(ads)	0.31					
Aerobic soil DT ₅₀ (days)	0.48					
Pesticide wetted in?	No					
Methods of application	-	Ground boom – high, fine droplet	Ground - airblast	Ground - airblast	Ground - airblast	Aerial – medium droplet
'No spray' zone	-	Nil	nil	nil	nil	Nil
Water solubility (ppm)	570					
Hydrolysis (DT ₅₀ in days)	Stable					
Aerobic aquatic DT ₅₀ (days)	88					
Aqueous photolysis DT ₅₀ (days)	484					

Output from the GENEEC2 model

Scenario 1 – Cucurbits, leafy greens and other field vegetables at harvest

RUN No. 1 FOR sulfoxaflor ON vegetables * INPUT VALUES *							
RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE (FT)	INCRP (IN)	
.064 (.064)	4 14	.3	570.0	GRHIFI (6.6)	.0	.0	
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)							
METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)		
.48	2	N/A	484.00-60016.00	88.00	87.87		
GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001							
PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC			
1.05	1.04	1.00	.92	.87			

Scenario 2 – Citrus, pipfruit, stone fruit (mealybug)

RUN No. 2 FOR sulfoxaflor ON citrus pip * INPUT VALUES *							
RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE (FT)	INCRP (IN)	
.171 (.171)	2 14	.3	570.0	ORCHAR (9.7)	.0	.0	
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)							
METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)		
.48	2	N/A	484.00-60016.00	88.00	87.87		
GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001							
PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC			
2.28	2.27	2.19	2.01	1.89			

Scenario 3 – Grapes

RUN No. 3 FOR sulfoxaflor ON grapes * INPUT VALUES *							
RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE (FT)	INCRP (IN)	
0.085 (0.085)	4 14	0.3	570.0	VINYAR (1.5)	0.0	0.0	
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)							

Application for approval to manufacture ESN containing sodium nitrite at 950 g/kg and Bait containing sodium nitrite at 100 g/kg for release (ERMA200570)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
0.48	2	0.00	484.00-60016.00	88.00	87.87

GENERIC EECs (IN NANOGRAMS/LITER (PPT_r)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
520.22	517.66	498.91	458.82	430.92

Scenario 4 – Stonefruit (aphid)

RUN No. 4 FOR sulfoxaflor ON stonefruit * INPUT VALUES *

RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE (FT)	INCRP (IN)
.043 (.043)	4 14	.3	570.0	ORCHAR (9.7)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
.48	2	N/A	484.00-60016.00	88.00	87.87

GENERIC EECs (IN NANOGRAMS/LITER (PPT_r)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
962.99	959.38	925.02	850.90	799.27

Scenario 5 – Cereals (aerial)

RUN No. 1 FOR sulfoxaflor ON cereals * INPUT VALUES *

RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE (FT)	INCRP (IN)
0.021 (0.021)	2 14	0.3	570.0	AERL_B (13.0)	0.0	0.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
0.48	2	0.00	484.00-60016.00	88.00	87.87

GENERIC EECs (IN NANOGRAMS/LITER (PPT_r)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC

358.47 357.08 344.28 316.68 297.46

Calculation of acute risk quotients using GENEEC2 expected environmental concentrations

Table 7 gives calculated acute risk quotients for each trophic level considering EEC estimated by GENEEC2 and lowest relevant toxicity figures which are:

- sheepshead minnow, 96 hour LC₅₀ 266 000 µg/L
- mysid shrimp, 96 hour EC₅₀ 643 µg/L
- freshwater diatom, 96 hour E_bC₅₀ 81 200 µg/L.

Table 7 Acute risk quotients derived from the GENEEC2 model and toxicity data

Scenario	Peak EEC (µg/L)	Acute RQ			Presumption
		Fish	Crustacea	Algae	
1 Vegetables – ground	1.05	0.000004	0.0016	0.00001	Low risk
2 Citrus, pipfruit, stonefruit (mealybug) – airblast	2.28	0.000009	0.0035	0.00003	
3 Grapes – airblast	0.52	0.000002	0.0008	0.00001	
4 Stonefruit (aphid)	0.96	0.000004	0.0015	0.00001	
5 Cereals - Aerial	0.36	0.000001	0.0006	0.000004	

Conclusion for the acute aquatic risk assessment using GENEEC2 data

Use of sulfoxaflor at the maximum application rates for all use scenarios presents a low acute risk to the aquatic environment.

Calculation of chronic risk quotients using GENEEC2 expected environmental concentrations

Table 8 gives calculated chronic risk quotients for each trophic level considering EEC estimated by GENEEC2 and lowest relevant toxicity figures which are:

- Fathead minnow, 30-day early life stage NOEC 650 µg ai/L
- Mysid shrimp, 28-day lifecycle NOEC 110 µg ai/L.

Table 8 Chronic risk quotients derived from the GENEEC2 model and chronic toxicity data

Scenario	21-day EEC (µg/L)	Chronic RQ		Presumption
		Fish	Crustacea	
1 Vegetables - ground	1.00	0.0015	0.009	Low risk

Scenario	21-day EEC ($\mu\text{g/L}$)	Chronic RQ		Presumption
		Fish	Crustacea	
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	2.19	0.0034	0.019	
3 Grapes - airblast	0.50	0.0008	0.004	
4 Stonefruit (aphid)	0.93	0.0014	0.008	
5 Cereals - Aerial	0.34	0.0005	0.003	

Conclusion for the chronic aquatic risk assessment using GENEEC2 data

Use of sulfoxaflor at the maximum application rates for all use scenarios presents a low chronic risk to the aquatic environment.

Sediment risk assessment

Sediments may act as both a sink for chemicals through sorption of contaminants to particulate matter, and a source of chemicals through resuspension. Sediments integrate the effects of surface water contamination over time and space, and may thus present a hazard to aquatic communities (both pelagic and benthic) which is not directly predictable from concentrations in the water column.

The risk for sediment-dwelling organisms has been assessed as the ratio $\text{EEC}_{\text{water}}/\text{NOEC}_{\text{porewater}}$ with the 28-day NOEC 45.5 $\mu\text{g/L}$ from the OECD 219 spiked water study. The 21-day EEC values from GENEEC2 and the chronic risk quotients for the proposed use scenarios of sulfoxaflor are set out in Table 9.

Table 9 Chronic risk quotients derived from the GENEEC2 model 21-day EEC and chronic toxicity data for sediment dwelling organisms

Scenario	21-day EEC ($\mu\text{g/L}$)	Chronic RQ	Presumption
1 Vegetables - ground	1.00	0.02	Low risk
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	2.19	0.05	
3 Grapes - airblast	0.50	0.01	
4 Stonefruit (aphid)	0.93	0.02	
5 Cereals - Aerial	0.34	0.007	

Conclusion for the sediment risk assessment

Sulfoxaflor presents a low chronic risk to sediment organisms under the proposed use scenarios with all risk quotients <1.

Terrestrial risk assessment

For terrestrial organisms, Toxicity-Exposure Ratios (TERs) are used for earthworms and birds and Hazard Quotient (HQ) are used for terrestrial invertebrates. This convention results in concern arising if a risk quotient is less than the trigger value for earthworms and more than a trigger value for terrestrial invertebrates. LOC developed by the European Union and adopted by the Staff to determine whether a substance poses an environmental risk are provided in the Table 10.

Table 10 Levels of concern as adopted by the Staff

Level of Concern (LOC)		Presumption
Earthworm/ Birds		
Acute TER	< 10	High risk
Chronic TER	< 5	High risk
Bees		
HQ _{oral/contact}	> 50	High risk
Terrestrial invertebrates		
HQ _{in-field/off-field}	≥2	High risk

For more details about the different factors used for calculating TER and HQ refer to the relevant reference documents listed in Table 4.

Earthworm risk assessment

Soil Predicted Environmental Concentration (PEC) determination

Both acute and reproductive earthworm tests are static tests where the test substance is applied to the system only once at the beginning. Therefore the nominal dose levels in the test match initial concentrations in the field and thus it is appropriate to use initial PEC values (no time-weighted averages) for the acute as well as the long-term TER.

The concentration of active substance in the soil is calculated on the basis of the FOCUS (1997) document 'Soil persistence models and EU registration'

$PEC \text{ one application (mg/kg soil)} = \frac{\text{application rate (kg a.i./ha)}}{75 \text{ kg soil}} \times 100$ Soil concentrations of the active ingredient are calculated by assuming the deposition would mix into the top 5 cm of soil, and this soil would have a bulk density of 1,500 kg/m³, i.e. the deposition expressed in mg/m² would mix into 75 kg of soil.

In case of multiple applications, the following formula has to be used:

$$PEC \text{ multiple applications} = PEC \text{ one application} \times \frac{(1 - e^{-nki})}{(1 - e^{-ki})}$$

where:

n = number of applications

k = $\ln 2 / DT_{50}$ (day^{-1})

i = interval between two consecutive applications (days)

DT_{50} = half life in soil (days) Use only DT_{50} values of lab test done at 10-20 °C and pH between 5 and 9.

e = 2.718 (constant)

When there are DT_{50} values of several soils use GENEEC2 formula for determining the relevant DT_{50} to be used.

The application rates for sulfoxaflor depend on the crop/area treated. PEC calculation results are summarized for each scenario in Table 11 and Table 12. The scenarios are the same as defined in the aquatic risk assessment. All are based on multiple applications and use the 90%CI on the mean for the soil degradation half-life (DT_{50}) of 0.48 days as used in the GENEEC2 modelling.

Calculation of TERs

$$TER_{acute} = \frac{LD_{50}}{\text{Estimated Environmental Concentration}} \\ TER_{long-term} = \frac{NOEC}{\text{Estimated Environmental Concentration}}$$

Table 11 Acute *in-field* TER value for earthworms for multiple applications

Scenarios	PEC _{multi} (mg/kg soil)	LC ₅₀ (mg/kg soil)	TER _{multi} acute	Presumption
1 Vegetables - ground	0.10	0.885	9.2	High risk
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	0.26		3.5	
3 Grapes - airblast	0.13		6.9	
4 Stonefruit (aphid)	0.06		13.8	Low risk
5 Cereals - Aerial	0.03		27.6	Low risk

Table 12 Acute *off-field* TER value for earthworms

Scenarios	PEC _{multi} (mg/kg soil)	LC ₅₀ (mg/kg soil)	TER _{multi} acute	Presumption
1 Vegetables - ground	0.006	0.885	140	Low risk
2 Citrus, pipfruit, stonefruit (mealybug)	0.025		36	

Scenarios	PEC _{multi} (mg/kg soil)	LC ₅₀ (mg/kg soil)	TER _{multi} acute	Presumption
- airblast				
3 Grapes - airblast	0.002		460	
4 Stonefruit (aphid)	0.006		143	
5 Cereals - Aerial	0.004		212	

Conclusion for earthworm acute risk assessment

The use of sulfoxaflor presents a **high acute in-field risk** to earthworms in three of the proposed use scenarios ie **Scenario 1 - field vegetable crops, Scenario 2 – citrus, pipfruit and stonefruit (mealybugs) and Scenario 3 - grapes**. Risks to earthworms off-field as a result of spray are low for all scenarios.

Table 13 Chronic *in-field* TER value for earthworms

Scenarios	PEC _{multi} (mg/kg soil)	NOEC (mg/kg soil)	TER _{multi} chronic	Presumption
1 Vegetables - ground	0.10		6.93	Low risk
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	0.26	0.665	2.60	High risk
3 Grapes – airblast	0.13		5.19	
4 Stonefruit (aphid)	0.06		10.4	Low risk
5 Cereals - Aerial	0.03		20.8	

Table 14 Chronic *off-field* TER value for earthworms

Scenarios	PEC _{multi} (mg/kg soil)	NOEC (mg/kg soil)	TER _{multi} chronic	Presumption
1 Vegetables - ground	0.006		105	
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	0.025	0.665	27	Low risk
3 Grapes – airblast	0.002		346	
4 Stonefruit (aphid)	0.006		107	
5 Cereals - Aerial	0.004		160	

Conclusion for earthworm chronic risk assessment

Sulfoxaflor presents a high chronic risk in-field for Scenario 2 – citrus, pipfruit and stonefruit (mealybug). Chronic risks to earthworms off-field as a result of spray are low for all scenarios.

Non-target plant risk assessment

Non target plants are defined as follows: Plants which are non-crop plants located outside the treatment area.

Spray drift is considered the key exposure route for terrestrial plants located in the vicinity of the treated area. The drift models produced by the BBA for the exposure assessment of aquatic organisms may be used as a surrogate to cover the exposure assessment of terrestrial plants (Ganzelmeier *et al.* 1995, recently updated by Rautmann *et al.* 2001).

Table 15 shows the drift expressed as percentage of the applied dose:

Table 15 Basic drift values for one application

Ground deposition in % of the application rate (90 th percentiles)									
Distance [m]	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruit		Field crops Water > 900 L/ha
		Early	Late	Early	late		Height < 50 cm	Height > 50 cm	
1	2.77						2.77		4.44
3		29.20	15.73	2.70	8.02	19.33		8.02	
5	0.57	19.89	8.41	1.18	3.62	11.57	0.57	3.62	0.18
10	0.29	11.81	3.60	0.39	1.23	5.77	0.29	1.23	0.05

In fruit, grapevine and hops for herbicides (but not for plant growth regulators) that are applied to the ground, the column “field crops” is applicable.

It should be noted that these drift data have been generated with regard to intake into surface waters. In particular, there is no vegetation barrier between the spray boom and the collector plates. In terrestrial scenarios, however, horizontal and vertical interception by in-crop or off-crop vegetation as well as patchy distribution is relevant (“three-dimensional-situation”); thus, when more realistic drift data become available they should be used.

The initial assessment should be conducted for a distance of 1 m from the field edge for field crops, vegetables or ground applications such as for herbicides, and 3 m for other crops. Risk mitigation measures based on buffer zones within the crop area can also be quantified using the above table. In case of aerial applications a deposition rate of 100 % is assumed as the default, however this figure may be refined by applying appropriate models (e.g. AgDrift).

This is a quantitative risk assessment using a TER approach. Both effects and exposure are expressed in terms of application rate (g/ha). Effects data are represented by ER₂₅ values from the relevant studie.

Deterministic approach

If the TER based on the most sensitive species is greater than 5 then effects on non-target plants are considered acceptable. This trigger of 5 presupposes that at least 6 species have been tested. The trigger may be reduced if information on more species is available.

Table 16 TER value for non-target plant

Scenarios	Exposure (g/ha)	EC ₂₅ (g/ha)	TER	Presumption
2 Citrus, pipfruit, stonefruit (mealybug) - airblast	30 g ai/ha (15.73% of 192 g ai/ha in single application)	>200 g ai/ha (vegetative vigour study on 11 crops)	>6.67	Low risk

The worst-case drift scenario of airblast application of 192 g ai/ha to citrus, pipfruit and stonefruit (scenario 2, as previously defined) has been used as a screening-level assessment for risks to non-target plants.

Conclusion for non-target plant risk assessment

Risks to non-target plants from the use of GF-2032 are low under all proposed use application scenarios.

Bird risk assessment

EPA uses EFSA's Bird model and Excel[®] spreadsheets²³ freely available on EFSA's website to assess the risks to birds.

The methodology calculates TERs where exposure is calculated as the dose that a bird will receive when feeding in crops that have been sprayed. To avoid doing detailed evaluations for low risk scenarios, assessments are performed in tiers of increasing complexity.

The steps for the acute assessment are:

- Screening assessment
- Tier I assessment
- Higher tier assessment

The steps for the reproductive assessment are:

- Screening assessment
- Phase-specific approach assessment
- Higher tier assessment

Progression to the next tier is only made if the threshold for concern is exceeded at the previous tier.

Screening risk assessment

²³ different spreadsheets for spray application, granular application and seed treatment. For bait applications a spreadsheet with Daily Food Intake of NZ relevant species is available (Crocker *et al.*, 2002).

- Determination of levels of exposure

The principles underlying the exposure assessment are the same for all assessments other than higher tier assessments in which more specific field exposure data may be used. The dose that a bird receives (Daily Dietary Dose or DDD) is calculated from the application rate and a so-called 'Shortcut value' for the Residue per Unit Dose (RUD), reflecting the concentration on the bird's food and the quantity of food consumed. Quantities consumed are based on a bird's energy requirements, its energy assimilation and the energy content of its food (dry weight). Birds' energy requirements are based on an algorithm based on bodyweight and bird type (e.g. passerine/non-passerine). For further details, refer to EFSA's technical guidance document.

Both screening step assessments (acute and reproduction) select from 6 'indicator species' each applicable to a particular type of crop. They are not real species, but, by virtue of their size and feeding habits, their exposure is considered worst-case for birds in a particular crop type. For example, the representative species for orchards is described as a 'small insectivorous bird'. It is assumed that the relevant indicator species feeds only on contaminated food and the concentration of pesticide on the food is not affected by the growth stage of the crop. Thus, the exposure assessment is expressed as follows depending on the number of applications:

For acute test:

$$DDD \text{ one application} = \text{application rate (kg/ha)} \times \text{shortcut value}$$

$$DDD \text{ multiple applications} = DDD \text{ one application} \times MAF_{90}$$

For reproduction test:

$$DDD = \text{application rate (kg/ha)} \times \text{shortcut value} \times TWA * \times MAF_{mean}$$

*if toxic effect is considered to be caused by long-term exposure, use TWA = 0.53 (estimates time-weighted exposure over 21 days assuming a default DT₅₀ of 10 days).

The exposure to sulfoxaflor for bird acute dietary and reproductive screening assessments is shown in the Table 17 and Table 18 respectively.

Table 17 Exposure of birds for acute screening assessment

Crop & BBCH class (where appropriate) ¹	Indicator species ²	Application rate (kg/ha)	Short-cut value (90 th %) ³	MAF (90 th %) ⁴	Number of applications	DDD
Scenario 1 – Field vegetables (at harvest)	Small omnivorous bird	0.072	158.8	1.3	4 at 14 days	DDD _{one} 11.4 DDD _{multi} 14.8
Scenario 2 Citrus, pipfruit, stonefruit (at harvest)	Small insectivorous bird	0.192	46.8	1.2	2 at 14 day interval	DDD _{one} 9.0 DDD _{multi} 10.8

Application for approval to manufacture ESN containing sodium nitrite at 950 g/kg and Bait containing sodium nitrite at 100 g/kg for release (ERMA200570)

Scenario 3 - grapes	Small omnivorous bird	0.096	95.3	1.3	4 at 14 days	DDD _{one} 9.1 DDD _{multi} 11.9
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¹ EFSA, 2009, Table 5 p27

² EFSA, 2009, Table 6 p28

³ EFSA, 2009, Table 6 p28

⁴ EFSA, 2009, Table 7 p29

* Industrial use encompass pre-plant burn in terms of exposure (4 applications *versus* 2 at the same application rate)

Table 18 Exposure of birds for reproduction screening assessment

Crop & BBCH class (where appropriate) ¹	Indicator species ²	Application rate (kg/ha)	Mean short-cut value ³	TWA ⁴	MAF (mean) ⁵	Number of applications	DDD
Scenario 1 – Field vegetables (At harvest)	Small omnivorous bird	0.072	64.8	0.53	1.6	4 at 14 days	3.96
Scenario 2 Citrus, pipfruit, stonefruit (at harvest)	Small insectivorous bird	0.192	18.2		1.4	2 at 14 day interval	2.6
Scenario 3 – grapes	Small omnivorous bird	0.096	38.9		1.6	4 at 14 days	3.17

¹ EFSA, 2009, Table 5 p27

² EFSA, 2009, Table 10 p34

³ EFSA, 2009, Table 10 p34

⁴ EFSA, 2009, Table 11 p34

⁵ The exposure assessment of the reproduction assessment uses time-weighted average (TWA) exposure estimates over 1, 2, 3 or 21 days for different phases of the assessment. 1 day = 1.0; 2 days = 0.93; 3 days = 0.9; 21 days = 0.53

* Industrial use encompass pre-plant burn in terms of exposure (4 applications *versus* 2 at the same application rate)

Note about TWA:

Table 19 Measures of exposure and toxicity used in the reproduction assessment

Breeding phase	Test endpoint used as	Short-term exposure	Long-term exposure
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surrogate			
Pair formation/ breeding site selection	0.1 x LD ₅₀ ²⁴	1 day DDD	21 day TWA DDD
Copulation and egg laying (5 days pre- laying through end of laying)	NOAEL for the number of eggs laid per hen	1 day DDD	21 day TWA DDD
	NOAEL for mean eggshell thickness	1 day DDD	21 day TWA DDD
Incubation and hatching	0.1 x LD ₅₀	1 day DDD	21 day TWA DDD
	NOAEL for proportion of viable eggs/eggs set/hen	1 day DDD	21 day TWA DDD
	NOAEL for proportion of hatchlings/viable eggs/hen	3 day TWA DDD	21 day TWA DDD
Juvenile growth and survival until fledging	0.1 x LD ₅₀ (extrinsic adult)	2 day TWA DDD	21 day TWA DDD
	0.1 x LD ₅₀ (extrinsic juvenile)	1 day DDD based on chick shortcut values of 3.8 and 22.7 ²⁵	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7 ³
	NOAEL for proportion of 14 day old juveniles/number of hatchlings/hen	3 day TWA DDD	21 day TWA DDD
Post-fledging survival	0.1 x LD ₅₀	1 day DDD based on chick shortcut values of 3.8 and 22.7 ³	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7 ³
	NOAEL for 14 day old juvenile weights/hen	3 day TWA DDD	21 day TWA DDD

² from acute study

³ The two values are to account for ground and foliar dwelling arthropods with mean residue unit doses of 3.5 and 21 respectively. Assessments are made with both values. If TER are exceeded with either value, then an assessment based on the actual composition of the diet of relevant species.

Calculation of TERs

TER calculations are detailed in Table 20.

Table 20 TER values for acute dietary and reproductive risk assessment – Screening assessment

Birds type	DDD	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	Trigger value
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²⁴ From acute study.

²⁵ The two values are to account for ground and foliar dwelling arthropods with mean residue unit doses of 3.5 and 21 respectively. Assessments are made with both values. If TER are exceeded with either value, then an assessment based on the actual composition of the diet of relevant species.

Birds type		DDD	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	Trigger value		
Scenario 1 Field vegetables at harvest							
Acute	Small omnivorous	DDD _{one} 11.4	Bobwhite quail acute dietary LC ₅₀ >1152 mg ai/kg bw Mallard duck NOEC 25.9 mg ai/kg bw/day (highest dose tested, no effects observed on any parameters)	101	<10 acute <5 chronic		
		DDD _{multi} 14.8		78			
Long-term		DDD _{multi} 3.96		6.5			
Scenario 2 citrus, pipfruit, stonefruit							
Acute	Small insectivorous	DDD _{one} 9.0		Mallard duck NOEC 25.9 mg ai/kg bw/day (highest dose tested, no effects observed on any parameters)		128	<10 acute <5 chronic
		DDD _{multi} 10.8				107	
Long-term		DDD _{multi} 2.6	9.96				
Scenario 3 grapes							
Acute	Small omnivorous	DDD _{one} 9.1	Mallard duck NOEC 25.9 mg ai/kg bw/day (highest dose tested, no effects observed on any parameters)		127	<10 acute <5 chronic	
		DDD _{multi} 11.9			97		
Long-term		DDD _{multi} 3.17		8.2			

* Normally the NOAEL has to be converted from units of ppm (mg/kg diet) to mg/kg bw/d. In the first instance a factor of 0.1 is used for such conversion. If specific information is available from the test reports, this is preferable. When reported as ppm in the studies, daily dose (mg/kg/d) = [Concentration in food (mg/kg) * Daily food consumption (g/bird/day)] / body weight (g) (over the entire exposure period).

Conclusion for bird risk assessment (screening)

The acute and chronic risks indicator species of birds were assessed for the three most likely worst-case scenarios, field vegetables, citrus/pipfruit/stonefruit, and grapes (as defined previously). In all cases, both acute and chronic risks were low.

Bee risk assessment

The acute risk to bees is assessed as follows:

$$HQ_{bees} \text{ (contact or oral)} = \frac{\text{Application rate (g a.i./ha)}}{LD_{50} \text{ (contact or oral)} (\mu\text{g a.i./bee})}$$

Calculation of HQs

Table 21 Acute HQs values for bees

Species	LD ₅₀ (µg a.s./bee)	Hazard Quotient						Presumption
		Application rate (g ai/ha)						
		12	24	48	72	96	192	
Oral								
Honey bee,	0.0515 µg	233	466	932	1398	1864	3728	

Species	LD ₅₀ (µg a.s./bee)	Hazard Quotient						Presumption
		Application rate (g ai/ha)						
		12	24	48	72	96	192	
<i>Apis mellifera</i>	ai/bee [tested as GF-2032]							High risk
Bumblebee, <i>Bombis terrestris</i>	0.027 µg ai/bee	444	889	1780	2670	3560	7110	
Contact								
Honeybee, <i>Apis mellifera</i>	0.130 µg ai/bee	92	185	369	554	735	1480	
Bumblebee, <i>Bombis terrestris</i>	7.554 µg ai/bee	1.6	3.2	6.4	9.5	12.7	25.4	

Tier 2 – cage studies

The effects of foliar residues of GF-2032 (suspension concentrate, 22% w/w sulfoxaflor) on the honeybee (*Apis mellifera*) were determined after 24 hours of contact exposure to aged residues. Alfalfa foliage was sprayed at a nominal rate of 200 g a.i./ha. Residues were allowed to weather in the field for 3, 6 and 24 hours of application. In addition, untreated alfalfa foliage was maintained for the controls. The alfalfa was harvested and placed into cages containing the bees.

After 24 hours, mean mortality in the controls was 0.7%. In the 200 g a.i./ha treatments weathered for 3, 6 and 24 hours, the corrected mean mortalities were 4.0, 2.0 and 1.3%, respectively. Sub-lethal symptoms in the surviving bees included bees lying on their back and lethargy.

In a study with another formulation (WG) applied with 200 g ai/ha the mean mortality was 15% form aged residues.

Exposure to dried and aged residues reduces the risks to bees, the results did not indicate a significant effect (mortality max. 15%). Some sublethal symptoms were observed. The impact of the sub-lethal effects on on-going survival is unknown. However, these symptoms were not observed in the semi-field tests.

Tier 3 – semi-field studies evaluated several scenarios to a maximum application rate of 96 g ai/ha (1 test), the maximum rate in the other tests was 48 g ai/ha. The results indicated no significant effect on worker bee mortality, behaviour, colony condition or strength. The effects on mortality, flight activity and behaviour were short lived (max. 3 days). The observation periods on brood were shorter than recommended in the guideline. The effects on brood development were inconclusive.

The applicant provided a position paper with a risk assessment based on the data of semi-field studies. The applicant assessed contact exposure and dietary exposure (water and food consumption).

Contact exposure: the maximum mortality caused by dried residues on an alfalfa crop sprayed with 200 g ai/ha was 15%. The applicant concluded that this residual toxicity is acceptable based on guideline 850.3030.

NOTE: the applicant referred to the guideline 850.3030. This is an ecological effects test guidelines: honey bee toxicity of residues on foliage. The test has to be continued until mortality exposed to the treated foliage is 25% or less. It is a policy decision to decide what is acceptable or not.

The applicant performed a quantitative assessment for contact exposure as well. Based on contact toxicity ($LD_{50} = 0.38 \mu\text{g ai/bee}$) and the surface area ($1 \text{ cm}^2 /\text{bee}$) the sulfoxaflor contact $LD_{50} = 380 \text{ ng/cm}^2$.

Dietary exposure: water

The applicant calculated the concentration sulfoxaflor in guttation water based on a test in which the leaf concentration was determined in lettuce. The substance was applied 4 times in the dose rate of 0.089 lb/ac (ca 96 g ai/ha) with an interval of 7 days. The exposure to a forager bee was calculated based on the concentration of the substance and the water intake per day. The risks of the intake of contaminated water is compared with the oral toxicity of an adult bee ($LD_{50} = 0.146 \mu\text{g/ bee}$). The risk quotient (RQ) did not exceed the level of concern. Based on the determined concentration in lettuce the applicant calculated the concentration of different application rates assuming a linear connection between dose rate and concentration in guttation water. The level of concern was not exceeded with the highest dose rate (149 g ai/ha).

Review: the applicant used the toxicity of the active ingredient to calculate the risk quotient. The toxicity of the formulated product is also available. The LD_{50} product is $0.0515 \mu\text{g/bee}$. Therefore the risks should be calculated using this endpoint. The maximum dose rate applied for in New Zealand is 192 g ai/ha which is higher than the dose rate used in the calculations.

Using these input values the guttation water oral exposure is $0.094 \text{ ng ai/mg bw/day}$ which results in a RQ of 0.18.

The applicant compared the risk quotients with the US EPA levels of concern used for birds and mammals for acute risks. A $RQ > 0.5$ indicates a high risk, $RQ > 0.2$ indicates risk can be mitigated. The level of concern of 0.1 is used for endangered species. The US EPA has a draft pollinator risk assessment framework in which a level of concern of 0.4 is proposed. It would be better to compare the RQs with this level of concern. The RQs do not exceed this level of concern.

Dietary exposure: pollen and nectar

The applicant used publicly available daily consumption rates of pollen and nectar to calculate the exposure via pollen and nectar. The residue levels in pollen and nectar are based on tests on cotton, pumpkin and phacelia. The peak pollen and nectar residues of the test with cotton were used to determine the daily dose via pollen and nectar. The total daily exposure via pollen and nectar was compared with the toxicity of the adult bee and the larvae to calculate the risk quotient. To determine the risk the RQ is compared with the level of concern of 0.5 (US EPA terrestrial bird/mammal). The applicant used the LD_{50} of the active ingredient

to calculate the RQ. The RQs did not exceed the level of concern for the dose rates tested (max. 2 x 150 g ai/ha).

Review: the applicant provided a risk assessment for the exposure to bees via the consumption of pollen and nectar. In the position paper the bodyweight of the bee was incorporated in the calculations which was not done in the presentation (May 2013) provided by the applicant. In principal this should not affect the calculated RQs because both the exposure as well as the toxicity are either per mg bodyweight or not. However, there are some inconsistencies between the calculated RQs (see position paper page 29 with presentation slide 42). Based on the values of the presentation the level of concern is exceeded for the forager bee and the brood attendant for the dose rate of 150 g ai/ha.

In the position paper the applicant referred to US EPA level of concern for birds and mammals (0.5), in the presentation a level of concern of 0.4 is mentioned (US EPA draft pollinator risk assessment framework).

The applicant used the toxicity of the active ingredient to calculate the risk quotient. The toxicity of the formulated product is also available. The LD₅₀ product is 0.0515 µg/bee. Therefore the risks should be calculated using this endpoint.

Using the consumption data of pollen and nectar provided by the applicant and the LD₅₀ of the formulated product the RQs exceed the level of concern of 0.4 for almost all adult bees.

US EPA performed a risk assessment for exposure to bees via pollen and nectar. US EPA used different consumption of pollen and nectar compared with the values used by the applicant. The maximum residues in plant pollen and forager nectar (6.66 mg ai/kg and 1.01 mg ai/kg respectively) determined in the test with cotton crop were used in the risk assessment. Further they used the toxicity of the formulated product (LD₅₀= 0.0515 µg ai/bee) to calculate the RQ. The level of concern (0.4) was exceeded for all adult bees (RQ range from 0.8 to 5.7). The overall conclusion of US EPA is that the potential impact of the proposed uses of sulfoxaflor at maximum application rates on the developing brood and colony strength cannot be precluded.

Uncertainties associated with the risk assessment (first and higher tier):

- The risk assessment is based on the maximum residue in pollen and nectar in cotton (flowers only one day open). Represents this the worst case situation and/or can these results be extrapolated to other crops? The dissipation half-life of the crops differs, in cotton the DT₅₀ is 10.9 days and in fruit trees ca. 17 days.
- The risks from exposure via pollen and nectar are based on the dose rate of 150 g ai/ha, while the proposed maximum rate in New Zealand is 192 g ai/ha.
- The duration of the observation period in the semi-field tests was shorter than recommended in the guidelines.
- The tested dose rates in the semi-field tested was lower than the proposed maximum rate in New Zealand.

Conclusions for bee risk assessment

The HQ_{oral} values are all above the trigger value of 50, indicating that sulfoxaflor presents a **high acute oral** risk to both honeybees and bumblebees at all application rates.

The HQ_{contact} values for honeybees exceed the trigger value of 50 for all application rates, indicating that sulfoxaflor presents a **high acute contact** risk for this species. The bumblebee HQ_{contact} values are all <50 indicating a low risk from contact exposure by this species.

The acute risks to bees are high and require management through timing of application when bees are not present within the application area.

The semi-field tests provided by the applicant failed to demonstrate that the risks to bees via food consumption and to brood development were acceptable at the highest application rate for New Zealand (192 g/ha). Therefore, in order to mitigate the risks, application rates above 100 g/ha should not be allowed for ground based applications.

Non-target arthropod risk assessment

A tiered approach is applied to the assessment of risks to non-target arthropods, both in-field and off-field. At Tier 1 the risks to two indicator species are assessed (parasitic wasp, *Aphidius rhopalosiphii* and predatory mite, *Typhlodromus pyri*) on the basis of laboratory studies and worst-case exposures. If the risks to these two species are high as a result of those tests, then further testing is required using more realistic exposures to residues on plants (Tier 2), and may progress to semi-field and field studies. Testing of additional species is also required. The organisms need to be exposed to the maximum application rate intended for use and account also needs to be made of exposure to multiple applications.

Note: Where limit tests are conducted, a low risk to non-target arthropods can be concluded when the effects at the highest application rate multiply by MAF are below 50% (ESCORT2 workshop, 2000 – p12)

Tier 1 Soil Predicted Environmental Concentration determination

The rationale for estimating the concentrations of substance in soil compartment is the same as for earthworm. Nevertheless for non-target arthropods, exposure off-field through spray drift deposition is also considered.

In-field PEC calculation:

$$PEC \text{ one application (mg/kg soil)} = \frac{\text{application rate (kg a.i./ha)}}{75 \text{ kg soil}} \times 100$$

Off-field PEC calculation

Ganzelmeier *et al.* (1995, recalculated by German BBA and UBA and published in 2000) drift percentages are used to calculate the deposition of one application off-field situation²⁶.

$$PEC \text{ one application (mg/kg soil)} = \frac{(\text{application rate (kg a.i./ha)} \times \% \text{ drift})}{75 \text{ kg soil}} \times 100$$

²⁶ ESCORT 2 (2000). Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From ESCORT 2 Workshop, 21/23 March 2000.

In – field PEC multiple applications = *In – field PEC one application* × $\frac{(1 - e^{-nki})}{(1 - e^{-ki})}$ In case of multiple applications, the following formula has to be used:

$$\text{Off – field PEC multiple applications} = \text{Off – field PEC one application} \times \frac{(1 - e^{-nki})}{(1 - e^{-ki})}$$

where:

n = number of applications

k = $\ln 2 / DT_{50}$ (day⁻¹)

i = interval between two consecutive applications (days)

DT₅₀ = half life in soil (days). Use only DT₅₀ values of lab test done at 10-20 °C and pH between 5 and 9.

e = 2.718 (constant)

Tier 1 Foliar Predicted Environmental Concentrations (Tier 1)

Calculation of HQs

$$\text{In – field HQ} = \frac{\text{Application rate (g or mL a.i./ha)} \times \text{MAF}^*}{LR_{50}^{**}}$$

** Multiple application factor, refer to Appendix V, p 45 of ESCORT 2 Workshop, 2000. MAF = 1 when there is just one application.

$$\text{Off – field HQ} = \frac{\text{application rate} \times \text{MAF} \times \left(\frac{\text{drift factor}^*}{\text{vegetation distribution factor}^{**}} \right)}{LR_{50}} \times \text{correction factor}^{***}$$

must not differ in their units, i.e. must be related to either formulation or a.i. rates

* Overall 90th percentile drift values are presented in Appendix VI , p 46 of ESCORT 2 Workshop, 2000.

** default value of 10

*** default value of 10

The resultant in-field and off-field hazard quotients for *Aphidius rhopalosiphi* and *Typhlodromus pyri* are shown in the Table 22 and Table 23.

Table 22 *In-field* HQ values for *Aphidius rhopalosiphi* and *Typhlodromus pyri*

Species	LR ₅₀ (g ai/ha)	Application rate (g ai/ha)	MAF	Hazard Quotient	Presumption
Parasitic wasp, <i>Aphidius rhopalosiphi</i>	48 hr	192 [2 at 14 days]	1.7	17178	High risk
	0.019	12 [2 at 21 days]		1073	
Predatory mite, <i>Typhlodromus pyri</i>	7-day >400	192 [2 at 14 days]	1.7	0.8	Low risk

Table 23 *Off-field* HQ values for *Aphidius rhopalosiphi* and *Typhlodromus pyri*

Species	LR ₅₀ (g a.i./ha)	Application rate (g ai./ha)	MAF	Vegetation factor	Correction factor	Drift distance (m)/% drift	Hazard Quotient	Presumption
Parasitic wasp, <i>Aphidius rhopalosiphi</i>	48 hr 0.019	192 [2 at 14 days]	1.7	10	10	3 metres 0.1573 [orchard airblast]	27000	High risk
		12 [2 at 21 days]		10	10	1 metre 0.0277 [cereal]	297	
Predatory mite, <i>Typhlodromus pyri</i>	7-day >400	192 {2 at 14 days}		10	10	3 metres 0.1573 [orchard airblast]	1.28	Low risk

The in-field and off-field HQ values for the parasitic wasp, *Aphidius rhopalosiphi*, are well above the trigger value of 2 in the Tier 1 assessment, indicating that the active substance sulfoxaflor is of high concern for non-target arthropods. However, it is noted that the standard test duration for assessment of the Tier 1 HQ is seven days, which was not provided for the parasitic wasp.

Tier 2 assessment

The applicant provided some additional test data from Tier 2 extended laboratory tests as set out in Table 31.

Table 24 Tier 2 extended laboratory tests for non-target arthropods

Species	Test	Application rate (g ai/ha)	Result
Parasitic wasp, <i>Aphidius rhopalosiphi</i>	48 hr on fresh dried residues on barley plants; reproduction assessed after 12-day untreated observation period	Maximum 2.42 g ai/ha	48hr LR ₅₀ 1.28 g ai/ha 14-day ER ₅₀ (repro) >1.21 g ai/ha
	48 hr on aged residues on barley plants; reproduction assessed after 12-day untreated observation period	Maximum 45 g ai/ha	Residues no longer caused <30% mortality by 3 DAT of 6.2 and 26 g ai/ha ad 14 DAT of 45 g ai/ha No effects on reproduction at any rate

			tested
Rove beetle, <i>Aleochara bilineata</i>	28 days on fresh residues on sandy soil; reproduction assessed after 71 days	Maximum 24 g ai/ha	71 day ER ₅₀ >24 g ai/ha
Ladybird beetle, <i>Coccinella septempunctata</i>	17 days on fresh dried residues on bean plants; mortality and reproduction	Maximum 96 g ai/ha	17 d LR ₅₀ 14 g ai/ha NOEC 12 g ai/ha (repro)

None of the Tier 2 tests were conducted at the maximum application rate proposed for New Zealand (192 g ai/ha on citrus, pipfruit and stonefruit) which makes it difficult to draw conclusions regarding the risks to non-target arthropods. The applicant was asked to provide further studies at the higher New Zealand rates, and taking into account the multiple application frequencies. Their response was that the data already provided covered 'most use scenarios'.

The following scenarios are not adequately addressed by the rates used in the Tier 2 tests summarised above:

- Field vegetables 48 – 72 g ai/ha
- Greenhouse vegetables 96 g ai/ha
- Citrus, pipfruit, stonefruit (mealybug) >24 - 192 g ai/ha
- Grapes max rate 96 g ai/ha
- Stonefruit (except mealybug) max rate 48 g ai/ha

Conclusion for non-target arthropod risk assessments

On the basis of Tier 1 testing, sulfoxaflor presents a high risk to non-target arthropods in-field and off-field. The Tier 2 data are insufficient to refine the risk assessment from Tier 1, with the exception of that for ladybird beetles, where 50% mortality occurred at 14 g ai/ha, a rate lower than most of the New Zealand use scenarios.

The applicant has claimed that the formulated product is 'safe' for beneficial invertebrates, however, this broad statement is not supported by the test data presented.

Identification of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, components, contaminants, or metabolites

Table 25 Screening criteria for Persistency, Bioaccumulation, and Toxicity

Type of data	Criterion	Screening assessment
Persistence		
Ready biodegradability test	Readily biodegradable	Not P not vP

Enhanced ready biodegradability test	Readily biodegradable	Not P not vP
Specified tests on inherent biodegradability Zahn-Wellens (OECD 302B)	≥ 70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculums	Not P
MITI II test (OECD 302C)	≥ 70% mineralisation (O ₂ uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) or Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability <0.5), and ultimate biodegradation timeframe prediction: ≥months (value < 2.2) or Does not biodegrade fast (probability <0.5) and ultimate biodegradation timeframe prediction: ≥months (value < 2.2)	P P
Bioaccumulation		
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data)	e.g. BMF > 1	B or vB, definitive assignment possible
Octanol-water partitioning coefficient (experimentally determined or estimated by QSAR)	Log Kow ≤ 4.5	Not B and not vB
Toxicity		
Short-term aquatic toxicity	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled
Short-term aquatic toxicity	EC50 or LC50 < 0.1 mg/L	T
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T

The outcome of the assessment is summarized in the Table 26

Table 26 PBT/vPvB assessment for SULFOXAFLOLOR

	Yes	No	Cannot be determined at this time
Does the substance or is likely to contain PBT components?	<input type="checkbox"/> Component(s):	<input checked="" type="checkbox"/>	<input type="checkbox"/>

	Remarks:		
Are the metabolites (mammalian and/or environmental) PBT?	<input type="checkbox"/> Metabolite(s): Remarks:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the substance contain or is likely to contain vPvB (POP) components?	<input type="checkbox"/> Component(s): Remarks:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Are the metabolites (mammalian and/or environmental) vPvB (POP)?	<input type="checkbox"/> Metabolite(s): Remarks:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the substance contain POP stipulated in the Stockholm Convention?	<input type="checkbox"/> Substance: Remarks:	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Conclusion for PBT/vPvB assessment

GF-2032 does not contain any PBT/vPvB substances.

Summary and conclusions of the ecological risk assessment

Under the proposed use scenarios for New Zealand, sulfoxaflor presents a:

- Low risk to the aquatic environment
- High risk to earthworms within the application area from both acute and chronic exposure
- Low risks to birds from both acute and chronic exposure
- High acute risk to honeybees from both oral and contact exposure, and bumblebees from oral exposure. High risk to honeybees via food consumption and to brood development.
- High risks to non-target arthropods both in-field and off-field

Appendix D: Controls applying to GF-2032

Notes

The controls for these substances apply for the indefinite duration of the approval of the substances.

Please refer to the Hazardous Substances Regulations²⁷ for the requirements prescribed for each control and the modifications listed as set out in Section 7 of this document.

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T1	11 – 27	Limiting exposure to toxic substances through the setting of TELs	No TELs values are set for any component of the substance at this time; however, the following ADE and PDE values have been set for sulfoxaflor: ADE = 0.04 mg/kg bw/day PDE _{food} = 0.028 mg/kg bw/day PDE _{drinking water} = 0.008 mg/kg bw/day PDE _{other} = 0.004 mg/kg bw/day
T2	29, 30	Controlling exposure in places of work through the setting of WESs.	No WES values have been set for any component of this substance at this time.
T3	5(1), 6	Requirements for keeping records of use	
T4	7	Requirements for equipment used to handle substances	
T5	8	Requirements for protective clothing and equipment	
E1	32 – 45	Limiting exposure to ecotoxic substances through the setting of EELs	No EEL values are set for this substance at this time and the default EELs are deleted.
E2	46 – 48	Restrictions on use of substances in application areas	Maximum application rates have been set for GF-2032 as follows: <i>100 g sulfoxaflor/ha per application; two applications per year with a minimum interval of 14 days between applications for ground-based applications</i> <i>24 g sulfoxaflor/ha per</i>

²⁷ The regulations can be found on the New Zealand Legislation website; <http://www.legislation.co.nz>

Code	Regulation	Description	Variation
			<i>application; two applications per year with a minimum interval of 14 days between applications for aerial applications.</i>
E3	49	Controls relating to protection of terrestrial invertebrates eg beneficial insects	
E5	5(2), 6	Requirements for keeping records of use	
E6	7	Requirements for equipment used to handle substances	
E7	9	Approved handler/security requirements for certain ecotoxic substances	The following control is substituted for Reg 9(1) of the Hazardous Substances (Classes 6,8 and 9 Controls) Regulations 2001: (1) The substance must be under the personal control of an approved handler when the substance is: (a) applied in a wide dispersive ²⁸ manner; or (b) used by a commercial contractor.

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I3	9	Priority identifiers for ecotoxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of generic names	
I18	27	Requirements for using concentration ranges	

²⁸ 'Wide dispersive' use refers to activities which deliver uncontrolled exposure — also refer to: <http://www.epa.govt.nz/Publications/ER-IS-33-2.pdf>

Code	Regulation	Description	Variation
I19	29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	37 – 39, 47 – 50	General Documentation requirements	
I23	41	Specific Documentation requirements for ecotoxic substances	
I28	46	Specific Documentation requirements for toxic substances	
I29	51, 52	Signage requirements	

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	5, 6, 7(1), 8	General packaging requirements	
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	19	Packaging requirements for toxic substances	
P15	21	Packaging requirements for ecotoxic substances	
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III	
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	8	Disposal requirements for toxic and corrosive substances	
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	13, 14	Documentation requirements for manufacturers, importers and	

suppliers, and persons in charge

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	35 - 41	Level 3 emergency management requirements: secondary containment	
EM13	42	Level 3 emergency management requirements: signage	

Hazardous Substances (Personnel Qualifications) Regulations 2001

Code	Regulation	Description	Variation
AH 1	4 – 6	Approved Handler requirements (including test certificate and qualification requirements)	Refer to control E7

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description
Tank Wagon	4 to 43 as applicable	Controls relating to tank wagons and transportable containers.

Additional controls

Code	Regulation	Description
Water	77A	This substance must not be applied onto, over or into water ²⁹
Label	77A	The label must include the following statement: <i>Highly toxic to bees. Will kill foraging bees directly exposed through contact during spraying and while spray droplets are still wet. For treatments made to crops in flower or upwind of adjacent plants in flower that are likely to be visited by bees at the time of application, spraying should not occur during the daytime if temperatures within an</i>

²⁹ Where "water" means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern or water used in the dilution of the substance prior to application or water used in the dilution of the substance prior to application or water used to rinse the container after use

Application for approval to manufacture ESN containing sodium nitrite at 950 g/kg and Bait containing sodium nitrite at 100 g/kg for release (ERMA200570)

Code	Regulation	Description
		<i>hour after the completion of spraying are expected to exceed 12 °C. It is recommended that flowering plants on orchard floors be mown just prior to spraying. In top fruit crops the risk to bees from spraying during flowering applies from pink/white bud until after petal fall.</i>

Appendix E: References

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OECD (2011f) OECD Joint Review Project Sulfoxaflor Volume 3 / Annex B B.9 Ecotoxicology B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk

OECD (2011g) OECD Joint Review Project Sulfoxaflor Volume 3 / Annex B B.9.8 Effects on soil non-target micro-organisms

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