Proposed Registration Decision PRD2026-11

Closer Insecticide, containing Sulfoxaflor

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Overview

Proposed registration decision for sulfoxaflor

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Closer Insecticide, containing the technical grade active ingredient sulfoxaflor, to control aphids on greenhouse ornamentals (use-site category 6: greenhouse non-food crops) and balsam woolly adelgid on field-grown fir trees, including Christmas trees (use-site category 4: forest and woodlots). This evaluation was completed under the User Requested Minor Use Label Expansion program, which is a cooperative program between Agriculture and Agri-Food Canada and Health Canada and includes participation by sponsors groups, manufacturers, and both provincial and federal governments.

Sulfoxaflor is a sulfoximine insecticide in IRAC mode of action group 4C. It is a competitive modulator of the nicotinic acetylcholine receptor in insect nerves registered for use on seed and plant propagation materials, terrestrial crops and outdoor ornamentals under use-site categories 10 (seed and plant propagation materials food and feed), 11 (seed and plant propagation materials non-food and non-feed), 13 (terrestrial feed crops), 14 (terrestrial food crops) and 27 (ornamentals outdoor). For details, see Proposed Registration Decision PRD2015-08, *Sulfoxaflor*, and Registration Decision RD2015-09, *Sulfoxaflor*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation provides detailed technical information on the human health, environmental and value assessments of Closer Insecticide, containing sulfoxaflor.

What does Health Canada consider when making a registration decision?

The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

To reach its decisions, Health Canada applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children). They also consider the unique characteristics of organisms in the environment. These methods and policies also consider the nature of the effects observed and

[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

[2] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

the uncertainties when predicting the impact of pesticides. For more information on how Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and pest management portion of Canada.ca.

Before making a final registration decision on Closer Insecticide, containing sulfoxaflor, Health Canada will consider any written comments received from the public directly related to the proposed decision in this consultation document.[3] Health Canada will then publish a Registration Decision[4] on Closer Insecticide, containing sulfoxaflor, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science evaluation of this consultation document.

What is sulfoxaflor?

Sulfoxaflor is a conventional chemical insecticide that affects the nervous system of insects. It has systemic activity in plants, being transported through the xylem, and is effective against sap-feeding insects. End-use products containing sulfoxaflor provide control or suppression of various sap-feeding insect pests on a wide range of agricultural crops.

Health considerations

Can approved uses of Sulfoxaflor affect human health?

Closer Insecticide, containing sulfoxaflor, is unlikely to affect your health when used according to label directions.

Potential exposure to sulfoxaflor may occur through the diet, when handling and applying the end-use product, or when re-entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed. The health effects noted in animals occur at dose levels more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In laboratory animals, the technical grade active ingredient sulfoxaflor was of slight to moderate toxicity via the oral route; therefore, the signal word and hazard statement "WARNING – POISON" are required on the label. Sulfoxaflor was demonstrated to be of low toxicity via the dermal and inhalation routes. It was minimally irritating to eyes and skin, and did not cause an allergic skin reaction.

The acute toxicity of the end-use product Closer Insecticide, containing sulfoxaflor, was low via the oral and dermal routes of exposure, and was not expected to pose an acute inhalation hazard. It was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction. Based on these findings, no acute hazard labelling is required.

Prior to the initial registration of sulfoxaflor, registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of sulfoxaflor to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment included reduced survival in the developing young, as well as reduced activity and effects on the testes in adult animals. There was an indication that the young animal was more sensitive than the adult animal. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose level at which these effects occurred in animal tests.

Residues in food and drinking water

Dietary risks from food and drinking water are not of health concern.

No food residue data are required to support the registration of sulfoxaflor for use in/on field-grown fir trees including Christmas trees in Canada. However, because residues from this use may enter drinking water sources, an aggregate dietary assessment was conducted to assess health risks from overall exposure to potential food residues from existing dietary uses and the proposed use.

Aggregate acute dietary (food plus drinking water) intake estimates indicated that all population subgroups (except females 13–49 years old) are exposed to less than 16% of the acute reference dose, and therefore are not of health concern. For females 13–49 years old, the exposure from food is less than 66% of the acute reference dose, and the exposure from drinking water is 3% of the acute reference dose, and therefore are not of health concern. Exposure from food and drinking water cannot be aggregated for females 13–49 years old as the acute reference doses for food and water are different and based on different toxicological effects.

Aggregate chronic dietary (food plus drinking water) intake estimates indicated that all population subgroups (except females 13–49 years old) are exposed to less than 99% of the acceptable daily intake, and therefore are not of health concern. For females 13–49 years old, the exposure from food is less than 18% of the acceptable daily intake, and the exposure from drinking water is less than 25% of the acceptable daily intake, and therefore are not of health concern. Exposure from food and drinking water cannot be aggregated for females 13–49 years old as the acceptable daily intakes for food and water are different and based on different toxicological effects.

On the strength of the overall information, it was determined that a threshold approach was appropriate for the cancer risk assessment based on the observed tumours. Overall, the endpoints selected for the chronic dietary risk assessment are considered protective of the findings, including potential cancer effects.

As no food residue data are required to support the registration of sulfoxaflor for use on field-grown fir trees including Christmas trees in Canada, maximum residue limits (MRLs) are not required for this proposed use. For the MRLs currently established for this active ingredient in/on various crop commodities, please refer to the Maximum Residue Limit Database in the Pesticides and pest management portion of Canada.ca.

Occupational risks from handling Closer Insecticide

Occupational risks are not of concern when Closer Insecticide is used according to the proposed label directions, which include protective measures.

Workers mixing, loading or applying Closer Insecticide, and workers entering recently treated areas can be exposed to sulfoxaflor residues through direct skin contact or through inhalation. Therefore, the label specifies that anyone mixing, loading and applying Closer Insecticide and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Users are not allowed to apply the product using handheld mistblower/airblast or handheld fogging equipment. The label also requires that workers do not enter or be allowed into treated areas during the restricted-entry interval (REI) of 12 hours. Taking into consideration the label statements, the number of applications and the duration of exposure for handlers and postapplication workers, the risks to these individuals from exposure to Closer Insecticide are not of health concern when the end-use product is used according to the proposed label directions.

Risks in residential and other non-occupational environments

Risks in residential and other non-occupational environments are not of health concern when Closer Insecticide is used according to the proposed label directions and restricted-entry intervals (REIs) are observed.

For greenhouse ornamentals, there are no risks in residential and other non-occupational environments as the product will only be applied in greenhouses.

For field-grown fir trees including Christmas trees, there are no risks in residential and other non-occupational environments as the product is not intended for use in residential settings.

Furthermore, exposure to sulfoxaflor residues on treated ornamental plants and conifers that are subsequently purchased at retail locations is considered negligible.

Health Risks to bystanders

Bystander risks are not of health concern when Closer Insecticide is used according to the proposed label directions.

A standard label statement to protect against drift during application is on the label. For greenhouse ornamentals, application is limited to a greenhouse environment where there is no potential for drift. For field-grown fir trees including Christmas trees, bystander exposure is considered negligible since the potential for drift to areas of human habitation or activity is expected to be minimal. Therefore, health risks to bystanders are not of concern when Closer Insecticide is used according to the proposed label directions.

Aggregate health risks from dietary and residential exposures

Aggregate risks to adults, youths and children are not of health concern when Closer Insecticide is used according to the proposed label directions.

Closer Insecticide is a commercial-class product and therefore no residential use is expected. Exposure to sulfoxaflor when individuals come into dermal contact with treated greenhouse ornamental plants or conifers purchased from retail locations is expected to be negligible. As such, the aggregate assessment for sulfoxaflor considered only food and drinking water exposure. Chronic dietary exposure to sulfoxaflor from food and drinking water was considered in the determination of aggregate risks. The aggregate risks to adults, youths and children are not of health concern when the end-use product is used according to the label directions.

Environmental considerations

What happens when Sulfoxaflor is introduced into the environment?

When used according to label directions, the environmental risks associated with the major new uses of sulfoxaflor on forest and woodlots, and greenhouse non-food crops are acceptable.

Sulfoxaflor is toxic to bees and beneficial arthropods, and its transformation products have the potential to leach into groundwater. Risk mitigation measures for these organisms and precautionary statements with best management practices to reduce leaching and runoff are present on the current registered label of Closer Insecticide.

The proposed major new use of sulfoxaflor includes application to forest and woodlots (field grown true fir (*Abies* spp.), including Christmas trees). When label directions are followed, this new use is not expected to increase the risk of sulfoxaflor to non-target organisms as compared to the registered use on field crops.

The proposed major new use of sulfoxaflor in greenhouse non-food crops (ornamentals, excluding conifers) could result in adverse effects to bees and other beneficial insects used in greenhouse production. A label statement to inform users to avoid application of sulfoxaflor when bees and other beneficial insects are in the treatment area is required.

Value considerations

What is the value of Closer Insecticide?

Closer Insecticide provides a new active ingredient for control of aphids on greenhouse ornamentals (except conifers) and balsam woolly adelgid on field-grown fir trees including Christmas trees.

Closer Insecticide can control aphids, pests that reproduce rapidly and can increase to very high densities, especially under greenhouse conditions. Closer Insecticide can also control balsam woolly adelgid on field-grown fir trees including Christmas trees, which was identified as a national priority for Canadian growers, and provides an alternative to the single pest control product currently registered for that pest.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Closer Insecticide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To reduce the potential of workers coming into contact with sulfoxaflor through direct skin contact or inhalation of sprays, workers mixing, loading and applying Closer Insecticide and performing cleaning and repair activities must wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. The label also requires that workers do not enter or be allowed entry into treated areas during the REI of 12 hours. Furthermore, a standard label statement to protect against drift during application is present on the label. Label statements are required to prohibit applications in residential areas, as well as to prohibit the use of handheld airblast, misters, and foggers for application.

Environment

The following new risk mitigation measures are required:

- Label statement to inform users to avoid application of sulfoxaflor when bees and other beneficial arthropods used in greenhouse production are in the treatment area.
- Label statement prohibiting the discharge of greenhouse releases, effluent or runoff to water.

Next steps

Before making a final registration decision on Closer Insecticide, containing sulfoxaflor, Health Canada will consider any written comments received from the public that are directly related to this proposed decision, such as comments directed to the Science evaluation, in response to this consultation document up to 30 days from the date of publication (by 2 October 2026) of this document. Please forward all comments to Pesticides Publications Section , through the Public Engagement Portal (Public Engagement Forms – Consultation Comment). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When Health Canada makes its registration decision, it will publish a Registration Decision on Closer Insecticide, containing sulfoxaflor (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information or if you have questions, please contact the Pesticides Information Service.

Science evaluation

Sulfoxaflor, Closer Insecticide

1.0 The active ingredient, its properties and uses

1.1 Directions for use

Closer Insecticide is applied as a foliar spray. For control of aphids on greenhouse ornamentals (excluding conifers), it is applied at concentrations of 100–200 mL/1000 L water in sufficient spray volume to ensure thorough coverage of all foliage, with a maximum of two applications per crop cycle applied 10–14 days apart. For control of balsam woolly adelgid on field-grown true fir including Christmas trees, it is applied at a rate of 400 mL/ha in spray volumes of 1000–1200 L/ha, with a maximum of one application per year.

1.2 Mode of action

Sulfoxaflor has systemic activity in plants where it is translocated through the xylem. It acts as an agonist at the insect nicotinic acetylcholine receptor, allowing ion flow through the associated ion channel and resulting in nervous excitation. The Insecticide Resistance Action Committee (IRAC) has placed sulfoxaflor in subgroup 4C (sulfoximines) within mode-of-action group 4 (nicotinic acetylcholine receptor competitive modulators).

2.0 Methods of analysis

2.1 Methods for residue analysis

Please refer to Proposed Registration Decision, PRD2015-08 for the analytical methods on sulfoxaflor residues in plant and animal matrices for data generation and enforcement purposes.

3.0 Impact on human and animal health

3.1 Hazard assessment

3.1.1 Toxicology summary

Sulfoxaflor is a member of the sulfoximine class of insecticides. Sulfoxaflor exerts its insecticidal activity as an agonist at the insect nicotinic acetylcholine receptor (nAChR), which plays a central role in the mediation of fast excitatory synaptic transmission in the insect central nervous system.

A detailed review of the toxicology database for sulfoxaflor was conducted previously and is summarized in PRD2015-08. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to sulfoxaflor.

Results of the toxicology studies conducted on laboratory animals with sulfoxaflor, as well as the toxicology reference values for use in human health risk assessment, and an overall summary of the data can be found in PRD2015-08. Effects following repeated oral dosing of sulfoxaflor included effects on the liver, the nervous and muscular systems, and the male reproductive system. Sulfoxaflor did not damage genetic material. There was evidence of tumours of the male reproductive system (preputial gland and testis) in the rat, but the increased tumour response was either marginal or occurred at very high doses. Liver tumours observed in rodents were deemed to occur via a mode of action that is not relevant to humans.

When sulfoxaflor was given to pregnant or nursing animals, effects on the developing fetus (limb abnormalities) and juvenile animal (neonatal deaths) were observed at doses that were not toxic to the mother, indicating that the young were more sensitive to sulfoxaflor than the adult animal. Therefore, the 10-fold *Pest Control Products Act* factor (PCPA factor) was retained for scenarios in which the endpoint of neonatal death was used to establish the point of departure for assessing risk to women of reproductive age. For exposure scenarios involving other subpopulations, including children, the risk was considered well-characterized and the PCPA factor was reduced to onefold.

The standard interspecies uncertainty factor of 10-fold was reduced to threefold for risk assessments that are based on the endpoint of developmental abnormalities or neonatal death. This was based on known differences in ontogeny and timing of the transition from fetal-type to adult-type muscle nicotinic acetylcholine receptor (nAChR) between humans and rats, as well as result of an in vitro binding assay which demonstrated that the human receptor was less responsive to the effects of sulfoxaflor than the rat fetal receptor. This information contributed to the reduction of uncertainty with respect to interspecies extrapolation and was used to inform the toxicodynamic considerations as they relate to the standard 10-fold uncertainty factor for interspecies extrapolation.

Results of toxicology data summarized by other regulatory authorities subsequent to the 2015 assessment were considered in early 2024 as part of the response to comments received on PMRL2021-25,[5] which did not impact the previous assessment. An updated search of the published literature, subsequent to the issuance of the response to comments received on PMRL2021-25, was completed in this current assessment, and no information was identified that would impact the previous hazard assessment. Toxicology reference values for use in the human health risk assessment established previously are reported in Appendix I, Table 1.

The results of acute toxicity studies conducted with the end-use product Closer Insecticide are summarized in Table 4 of PRD2015-08. Closer Insecticide was of low acute toxicity via the oral and dermal routes of exposure in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits, and was negative for dermal sensitization when tested using the local lymph node assay in mice. With respect to acute inhalation toxicity, a stable respirable aerosol could not be generated for Closer Insecticide.

[5] Response to comments received on the PMRL consultation for proposed new and revised maximum residue limits for sulfoxaflor (PMRL2021-25)

Based on the low potential for inhalation, as well as the low acute inhalation toxicity observed with Transform WG Insecticide, which contains a higher concentration of sulfoxaflor, Closer Insecticide was considered to be of low acute toxicity via the inhalation route (PRD2015-08).

3.2 Toxicology reference values

3.2.1 Route and duration of exposure

For mixers, loaders and applicators, occupational exposure to Closer Insecticide is characterized as short-term (< 30 days) in duration and is predominantly by the dermal and inhalation routes. For postapplication workers, occupational exposure to Closer Insecticide is characterized as short-term (< 30 days) for field-grown fir trees including Christmas trees (outdoor use) and long-term (> 180 days) in duration for greenhouse ornamentals (greenhouse use), predominantly by the dermal route.

3.3 Dermal absorption

A dermal absorption value of 4% was selected for the risk assessment of sulfoxaflor based on a "triple pack" approach. Refer to PRD2015-08 for further details regarding the dermal absorption of sulfoxaflor.

3.4 Occupational and residential exposure assessment

3.4.1 Acute hazards of Closer Insecticide product and mitigation measures

Closer Insecticide is of low acute oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It is not a skin sensitizer in mice by the LLNA method. Based on these acute hazards, a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes are required during mixing, loading, application, clean-up and repair. The personal protective equipment (PPE) on the proposed label is considered acceptable to protect against the acute hazard of Closer Insecticide. The results of acute toxicity studies conducted with Closer Insecticide are summarized in Appendix I, Table 4 of PRD2015-08.

3.4.2 Occupational exposure and risk assessment

3.4.2.1 Mixer, loader and applicator exposure and risk assessment

Individuals have the potential for exposure to sulfoxaflor during mixing, loading, application, clean-up and repair activities.

Exposure estimates were derived for workers mixing and loading a liquid with an open-transfer system. Dermal and inhalation exposure estimates were generated from the Agricultural Handlers Exposure Task Force (AHETF) database and the Pesticide Handlers Database (PHED, v1.1) for mixers, loaders and applicators applying Closer Insecticide to greenhouse ornamentals (using automated equipment and conventional handheld application equipment) and to field-grown fir trees including Christmas trees (using airblast and conventional handheld application equipment). The PPE in the risk assessment is based on handlers wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes (Appendix I, Table 2).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day (derived from the maximum application rate and the standard area treated per day), and the dermal absorption value of 4%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Dermal and inhalation exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the selected toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 300 for dermal and inhalation exposure of all durations. Dermal and inhalation MOEs were combined, since the dermal and inhalation endpoints are derived from the same study. For both field-grown fir trees including Christmas trees and greenhouse ornamentals, calculated MOEs are greater than the target MOE for all chemical handler scenarios and are therefore not of health concern (Appendix I, Table 3).

3.4.2.2 Postapplication exposure and risk assessment

For greenhouse ornamentals, there is potential for long-term exposure to workers entering greenhouses treated with Closer Insecticide to complete tasks such as hand harvesting, disbudding, hand pruning, and transplanting.

For field-grown fir trees including Christmas trees, there is potential for short-term exposure to workers entering treated areas to complete tasks such as hand-set irrigation, harvesting, scouting, and shaping.

Given the nature of activities performed, exposure should be primarily via the dermal route based on dermal contact with treated foliage.

Postapplication inhalation exposure is not expected as sulfoxaflor is considered non-volatile with a low vapour pressure of $\leq 1.4 \times 10^{-9}$ kPa at 20°C, which is less than the North American Free Trade Agreement (NAFTA) criterion for a non-volatile product for outdoor uses (1×10^{-4} kPa at 20–30°C) and for greenhouse uses (1×10^{-5} kPa at 20–30°C). As such, a quantitative inhalation risk assessment is not required. Inhalation risk is not of health concern for postapplication workers as sulfoxaflor is considered to be non-volatile and the restricted-entry interval of 12 hours will allow residues to dry, suspended particles to settle and vapours to dissipate.

For greenhouse ornamentals, chemical-specific dislodgeable foliar residue (DFR) data were reviewed and used for assessing human exposures during postapplication activities. The DFR study was conducted at a research greenhouse in British Columbia. In the submitted study, sulfoxaflor was applied two times on an 11-day retreatment interval to greenhouse chrysanthemums at an application rate of 100–104 g a.i./ha, which is slightly higher than the proposed maximum application rate, and is therefore not expected to underestimate exposure. Data were not corrected for recovery as the overall average field fortification recoveries for both low and high spiking groups were above 95%.

The residues in the DFR study followed a linear decline model ($R^2 = 0.93$), and therefore it is acceptable to use the predicted data from the linear equation to estimate the dissipation rate. The predicted peak DFR value from the linear regression analysis was calculated as 0.224 $\mu g/cm^2$, which is lower than the actual highest average field sample taken on the day of the second application (0.246 $\mu g/cm^2$). Based on the actual field data, the amount of sulfoxaflor that is

dislodgeable after application ranged from 15–18% of the application rate. Additionally, based on the equation of the line from the linear regression analysis, dissipation of sulfoxaflor in greenhouse chrysanthemums is 6% per day (Appendix I, Table 4). This DFR study was considered of good quality and acceptable for use in a risk assessment.

Since the submitted DFR study was conducted with a longer re-treatment interval (11 days) than proposed (10 days), the predicted peak DFR value from the study was not used. Instead, the percent deposition value of 18% was used to estimate dislodgeable foliar residues retained after each application.

For field-grown fir trees including Christmas trees, the standard DFR value of 25% of the application rate coupled with a 10% daily dissipation of residues are appropriate for use in the exposure risk assessment.

For both greenhouse ornamentals and field-grown fir trees including Christmas trees, dermal exposure to workers entering treated areas is estimated by coupling DFR values and a 4% dermal absorption factor with activity-specific transfer coefficients (TCs). Activity TCs are based on data from the Agricultural Re-entry Task Force (ARTF).

Exposure estimates were compared to the toxicology reference value (NOAEL = 1.9 mg/kg bw/day) to obtain the margin of exposure (MOE); the target MOE is 300. Only exposures and risks to the activities with the highest TCs are presented, as MOEs for these activities exceed the target MOE of 300, and are thus, not of health concern (Appendix I, Table 5).

3.4.3 Residential exposure and risk assessment

3.4.3.1 Handler exposure and risk assessment

Closer Insecticide is not a domestic class product and is not permitted for use in residential settings; therefore, a residential handler exposure assessment is not required.

3.4.3.2 Residential postapplication exposure and risk assessment

Closer Insecticide is not a domestic class product and is not permitted for use in residential settings. Furthermore, exposure to treated ornamental plants and conifers that are subsequently purchased at retail locations is considered negligible. Residues are anticipated to decline from the time of application to the time of consumer purchase. In addition, the postapplication occupational exposure risk mitigation measures would also protect the consumer purchasing treated retail plants from dermal exposure. Therefore, a residential postapplication exposure assessment is not required.

3.4.4 Bystander exposure and risk assessment

Bystander exposure is considered negligible as application is limited to within greenhouses only (for greenhouse ornamentals), or to agricultural trees only (for field-grown fir trees including Christmas trees) when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Therefore, bystander exposure and risk are not of health concern since the potential for drift is expected to be minimal.

3.5 Dietary exposure and risk assessment

3.5.1 Exposure from residues in food of plant and animal origin

Please refer to PRD2015-08 for a summary of the previously reviewed data. The information captured herein only relates to the changes in dietary exposure due to the modification in the drinking water assessments to support the registration of sulfoxaflor for use on field-grown fir trees including Christmas trees in Canada.

3.5.2 Exposure from residues in drinking water

For the human health risk assessment, estimated environmental concentrations (EECs) in potential drinking water sources were determined for both groundwater and surface water using the Pesticide in Water Calculator (PWC; version 3). The drinking water residue definition was determined as the residues of sulfoxaflor and two of its transformation products (TPs) X11719474 and X11519540.

For surface water, PWC estimates the amount of pesticide entering a drinking water reservoir by runoff, soil erosion and spray drift, and the subsequent transformation and overflow of the pesticide in and from the water system. Groundwater EECs are estimated by simulating pesticide transformation, adsorption/desorption and movement through a layered soil profile. The model determines the mean pesticide concentration in the underlying aquifer within the upper 1 metre below the water table.

Drinking water modelling follows a tiered approach consisting of progressive levels of refinement. Level 1 EECs are intended to screen out pesticides that are not expected to pose any concern related to drinking water. These are calculated using the highest proposed application rate, worst-case application methods, and widest application timing. This approach ensures that all potential use conditions are represented. A set of representative geographic scenarios, with representative regional weather and varying soil characteristics, is modelled to give the highest potential exposure across all agricultural regions of Canada. Level 2 EECs are based on crop-specific application timing and geographic scenarios, and do not cover all proposed uses in all regions of Canada.

The modelling was conducted at Level 2, using several groundwater and surface water scenarios representing different regions of Canada. All scenarios were simulated for a period of 50 years. The PWC model input parameters are reported in Appendix I, Table 6. For groundwater, parent, daughter, and granddaughter EECs were estimated separately and summed. For surface water, EECs were estimated for the parent and two TPs as combined residue.

While Level 2 EECs were calculated based on several scenarios representing different regions of Canada; only the highest EECs (Appendix I, Table 7) from across these scenarios are reported for use in the human health risk assessment.

3.5.3 Dietary risk assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 4.02, 05-10-c), which incorporates consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) for the year 2005-2010.

3.5.3.1 Acute dietary exposure results and characterization

The following assumptions were applied in the refined acute analysis for sulfoxaflor: 100% crop treated, default and experimental processing factors (where available), highest average field trial residues in/on crops, USDA PDP monitoring data (where available), anticipated residues for animal commodities, and the acute EECs for groundwater. The refined acute dietary exposure (food alone) for all supported sulfoxaflor food commodities and imported commodities was estimated to range from 3.3% to 13.7% of the ARfD for all population subgroups (except females 13–49 years old) (95th percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable ranging from 4.8% to 15.8% of the ARfD for all population subgroups (except females 13–49 years old). For females 13–49 years old, the refined acute dietary exposure from food is estimated to be 66.0% of the ARfD, and from drinking water is estimated to be 3.0% of the ARfD (95th percentile, deterministic). Exposure from food and drinking water cannot be aggregated for females 13–49 years old as the ARfDs for food and water are different and based on different toxicological effects.

3.5.3.2 Chronic dietary exposure results and characterization

The following assumptions were applied to the refined chronic analysis for sulfoxaflor: 100% crop treated, default and experimental processing factors (where available), residues in/on crops based on supervised trial median residue (STMdR) values, USDA PDP monitoring data (where available), anticipated residues for animal commodities and yearly EECs for groundwater. The refined chronic dietary exposure (food alone) from all supported sulfoxaflor food commodities and imported commodities for all population subgroups (except females 13–49 years old) is less than 9% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. Health Canada estimates that chronic dietary exposure to sulfoxaflor from food and drinking water is less than 99% of the ADI for all population subgroups (except females 13–49 years old). The highest exposure and risk estimate is for all infants (< 1 year). For females 13–49 years old, the refined chronic dietary exposure to sulfoxaflor from food is less than 18% of the ADI and from drinking water is 25% of the ADI. Exposure from food and drinking water cannot be aggregated for females 13–49 years old as the ADIs for food and water are different and based on different toxicological effects.

3.6 Aggregate exposure and risk assessment

For sulfoxaflor, the aggregate assessment consisted of combining food and drinking water exposure only, since residential exposure through purchased retail plants and conifers is expected to be negligible.

3.7 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for the active ingredient sulfoxaflor.

Sulfoxaflor is a member of the sulfoximine class of insecticides. Sulfoxaflor exerts its insecticidal activity as an agonist at the insect nicotinic acetylcholine receptor (nAChR), which plays a central role in the mediation of fast excitatory synaptic transmission in the insect central nervous system. Other competitive modulators of the nAChR include the neonicotinoids, butenolides, and mesoionics. Collectively, these nAChR modulators are sometimes referred to broadly as neonicotinoid insecticides. The broader group of neonicotinoid insecticides, despite displaying certain structural similarities that may result in shared modes of action and effects, do not possess uniform toxicity profiles. Currently, Health Canada has not identified a common mechanism of toxicity or a common metabolite for the neonicotinoids. Health Canada is considering evidence that neonicotinoids are agonists (of varied affinity among different species) of the nicotinic acetylcholine receptor in the central nervous system and may disturb synaptic signal transmissions. As noted in the Information Note – Cumulative Health Risk Assessment Operational Planning Framework, the cumulative effects assessment for neonicotinoids is in the planning stage. This work will be prioritized in consideration with the resources available and leverage the assessments completed by other jurisdictions.

For the proposed expansion of use of sulfoxaflor for the control of insect pests on ornamentals, as residential exposure is expected to be negligible, the contribution of exposure to cumulative risk of the neonicotinoids will not be impacted from the new use of sulfoxaflor.

3.8 Maximum residue limits

As no food residue data are required to support the registration of sulfoxaflor for use on field-grown fir trees, including Christmas trees, in Canada, maximum residue limits (MRLs) are not required for this proposed use. Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management portion of Canada.ca for the established MRLs for sulfoxaflor.

The nature of the residues in animal and plant matrices, analytical methodologies, and field trial data were assessed in PRD2015-08. The acute and chronic dietary risk estimates are summarized in Appendix I, Table 8.

3.9 Health incident reports

As of 16 January 2026, one human incident involving sulfoxaflor was submitted to the Pesticide Incident Reporting Database. The incident occurred in the U.S. and involved inhalation and dermal exposure to a product containing sulfoxaflor while mixing the product for dilution. Symptoms reported in the individual were considered unlikely to be related to sulfoxaflor, given the lack of consistency of the reported effects with scientific literature, short duration of exposure, delayed onset, and non-specific nature of the symptoms.

Given the limited incident information (in other words, low number of incident reports), no health concerns could be discerned following this incident report review.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Refer to Proposed Registration Decision PRD2015-08, *Sulfoxaflor*, and Registration Decision RD2015-09, *Sulfoxaflor*, for details on the environmental fate of sulfoxaflor and its transformation products. When sulfoxaflor is applied as a foliar spray, this compound will move from the surface of the leaf to internal leaf tissue. Sulfoxaflor can be deposited directly on pollen and nectar if applied when plants are in bloom, or since it is systemic, it can also reach pollen and nectar through its movement inside the plant. When spray droplets reach the soil, sulfoxaflor is rapidly broken down by soil microorganisms. Sulfoxaflor transformation products that are formed in soil are persistent and have the potential to leach through the soil profile and enter groundwater. When sulfoxaflor enters surface water, it also breaks down in the presence of microbes, albeit more slowly than in soil.

4.2 Environmental risk characterization

The original environmental risk assessment of sulfoxaflor, described in Proposed Registration Decision PRD2015-08, *Sulfoxaflor*, evaluated its application to field crops. The risk to non-target organisms was determined to be acceptable, with the inclusion of label statements indicating toxicity to bees and beneficial arthropods as well as statements for application timing to minimize the exposure to bees and bee brood.

The proposed application rates and methods for use on forests and woodlots (field grown true fir (*Abies* spp.), including Christmas trees; 1 application with a maximum of 96 g a.i./ha per year) and for use on greenhouse non-food crops (ornamentals, excluding conifers; 48 g a.i./ha with a maximum of 96 g a.i./ha per crop cycle) are within the registered rates of Closer Insecticide on field crops (2–3 applications, with a maximum of 192 g a.i./ha per year; maximum single application rate of 96 g a.i./ha) and within the registered rates among all sulfoxaflor products (maximum of 200 g a.i./ha per year; maximum single application rate of 100 g a.i./ha). Therefore, the environmental risk characterization detailed in PRD2015-08 encompasses the risk associated with the proposed uses. While an updated risk assessment is not required, updated label statements are needed to address the major new uses and to align with current label guidance. Additional considerations for pollinators, beneficial arthropods, and aquatic organisms based on the proposed uses are described below.

4.2.1 Risks to terrestrial organisms

Pollinators

Sulfoxaflor is toxic to bees. Foraging bees could be exposed directly to sulfoxaflor spray droplets during application or to sulfoxaflor residues found on the surface of leaves (contact exposure). Foraging bees could also be exposed to sulfoxaflor through the ingestion of pollen and nectar contaminated from direct spray or the systemic movement in the plant (oral exposure). In addition, brood may be exposed to sulfoxaflor, as foraging bees bring contaminated pollen and nectar back to the hive.

As field grown true fir (*Abies* spp.), including Christmas trees, are not a bee attractive crop, additional crop-specific label statements to mitigate risk to bees are not required.

For greenhouse use, exposure could occur inside the greenhouse (in other words, for bees used in pollinator services) and if the treated ornamental plants are moved outdoors (in other words, wild populations of pollinators). Additional label statements to mitigate risks to bees used in greenhouse production are required.

With respect to the possibility of treated greenhouse non-food crops (ornamentals, excluding conifers) being moved outdoors, PRD2015-08 indicates that the residues of sulfoxaflor are not hazardous to adult bees based on contact exposure after a period of 3 hours. The registered label for Closer Insecticide specifies a 12-hour restricted-entry interval for treated areas which would prevent plants from being moved outdoors until residue levels are no longer hazardous to bees from contact exposure. Additionally, while sulfoxaflor is systemic and can reach pollen and nectar by movement through the treated plant, estimated exposures from residues in pollen and nectar of plants sprayed at greenhouse application rates were calculated and determined to be at levels that are not expected to be hazardous to bees (Appendix I, Table 9). Therefore, no additional label statements related to the movement of treated greenhouse plants outdoors are required.

Predators and parasitoids

Sulfoxaflor is toxic to beneficial arthropods (such as predatory and parasitic insects). Beneficial arthropods could be exposed to sulfoxaflor in the soil or in spray droplets during application and to residues on plant surfaces. In the greenhouse, exposure could occur to beneficial arthropods used in pest control. No additional label statements are required for the major new use on field grown true fir (*Abies* spp.), including Christmas trees, but a hazard label statement is required for the use of sulfoxaflor in greenhouse non-food crops (ornamentals, excluding conifers).

4.2.2 Risks to aquatic organisms

PRD2015-08 indicates that the level of concern was not exceeded for aquatic organisms. As the major new uses fall within the registered use, there is no additional risk to aquatic organisms. The registered label for Closer Insecticide already contains best management practice statements to reduce runoff for outdoor use. Therefore, for greenhouse use, only standard statements regarding prevention of releases from greenhouses are required.

4.3 Environmental incident reports

As of 16 January 2026, no environmental incident reports involving sulfoxaflor have been submitted to Health Canada.

5.0 Value

The use of Closer Insecticide to control aphids on greenhouse ornamentals excluding conifers was supported by results of three greenhouse efficacy trials and extrapolation from registered uses. The use of Closer Insecticide to control balsam woolly adelgid on field-grown true firs including Christmas trees is consistent with the registered use pattern for other pests on other crops, including the very similar woolly apple aphid on pome fruit trees. Canadian growers have designated the use of Closer Insecticide for control of balsam woolly adelgid on Christmas trees as a national priority at the Canadian Minor Use Priority Setting Workshop and as such, the use is deemed to have acceptable value according to the PMRA Guidance Document, *Value Assessment of Pest Control Products*. Closer Insecticide provides a new active ingredient for both of these uses, and for balsam woolly adelgid there is only a single other pest control product registered.

6.0 Pest control product policy considerations

6.1 Toxic Substances Management Policy considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity, and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process described in PRD2015-08, sulfoxaflor and its transformation products were assessed in accordance with the PRD Regulatory Directive DIR99-03[6] and evaluated against the Track 1 criteria. Health Canada reached the conclusion that sulfoxaflor and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Table 26 in PRD2015-08, *Sulfoxaflor*, for further information on the TSMP assessment.

[6] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*[7]. The list is used as described in the Science Policy Note SPN2020-01[8] and is based on existing policies and regulations, including the *Toxic Substance Management Policy* and *Formulants Policy*[9], and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999, (*substances designated under the *Montreal Protocol).*

Health Canada has reached the conclusion that sulfoxaflor does not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. Its end-use product, Closer Insecticide, contains as a component, the preservative 1, 2-benzisothiazolin-3-one at significantly less than 0.1%, which contains low levels of polychlorinated dibenzodioxins and furans (TSMP Track 1). The use of this preservative in pest control products at a maximum of 0.1% was reassessed by Health Canada in 2012 and found to be acceptable because dioxin and furan levels are low and being managed as outlined in Regulatory Directive DIR99-03 for the implementation of TSMP. The Agency position at this time is that no further action is required.

The use of formulants in registered pest control products is assessed on an ongoing basis through Health Canada formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of Closer Insecticide, containing the technical grade active ingredient sulfoxaflor, to control aphids on greenhouse ornamentals and balsam woolly adelgid on field-grown fir trees, including Christmas trees.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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7 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

8 PRD's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the Pest Control Products Act*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document*

List of abbreviations

%	percent
>	greater than
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
a.i.	active ingredient
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATPD	area treated per day
bw	bodyweight
ºC	degree Celsius
CAF	composite assessment factor
cm^2	square centimetre(s)
CR	chemical-resistant
DAA	day(s) after application
DFR	dislodgeable foliar residue
DIR	directive
EEC	estimated environmental concentration
g	gram(s)
ha	hectare(s)
hr	hour(s)
IRAC	Insecticide Resistance Action Committee
J	joule(s)
kg	kilogram(s)
K_{oc}	soil organic carbon-water partition coefficient
kPa	kilopascal(s)
L	litres(s)
LD_{50}	lethal dose causing 50% mortality
LOD	limit of detection
LOQ	limit of quantitation
mg	milligram(s)
MPHG	mechanically pressurized handgun
MPHW	manually pressurized handwand
mL	millilitre(s)
M/L	mixer/loader
MOE	margin of exposure
mol	mole(s)
MRL	maximum residue limit
nAChR	nicotinic acetylcholine receptor
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effects levels
PCPA	*Pest Control Product Act*
PMRA	Pest Management Regulatory Agency
PHED	Pesticide Handler Exposure Database
PPE	personal protective equipment
ppm	parts per million
PRD	proposed registration decision

PWC	pesticide in water calculator
RD	registration decision
RQ	risk quotient
R^2	coefficient of determination
REI	restricted-entry interval
SPN	science policy note
STMdR	supervised trial median residue
TC	transfer coefficient
TP	transformation product
TSMP	Toxic Substances Management Policy
µg	microgram(s)

Appendix I Tables and figures

Table 1 Toxicology Reference Values for Use in Health Risk Assessment for Sulfoxaflor

Exposure scenario	Study	Point of departure and endpoint	CAF or Target MOE[1]
Acute dietary – general population	Acute oral neurotoxicity study in the rat	NOAEL = 25 mg/kg bw Reduced motor activity	100
	ARfD (general population) = 0.25 mg/kg bw		
Acute dietary – females 13-49 years of age	Developmental neurotoxicity study in the rat	NOAEL = 1.9 mg/kg bw Decreased neonatal survival	300[2]
	ARfD (females 13–49 years) = 0.006 mg/kg bw		
Chronic dietary – general population	Two-year chronic dietary study in the rat	NOAEL = 1.04 mg/kg bw/day Decreased food consumption, increased liver and testes weights, decreased epididymidal weight, bilateral atrophy of the seminiferous tubule, decreased spermatic elements	100
	ADI (general population) = 0.01 mg/kg bw/day		
Chronic dietary – females 13-49 years of age	Developmental neurotoxicity study in the rat	NOAEL = 1.9 mg/kg bw Decreased neonatal survival	300[2]
	ADI (females 13–49 years) = 0.006 mg/kg bw/day		
Short- to long-term dermal[3] and inhalation[4]	Developmental neurotoxicity study in the rat	NOAEL = 1.9 mg/kg bw Decreased neonatal survival	300[2]
Aggregate (“pick your own”)	Developmental neurotoxicity study in the rat	NOAEL = 1.9 mg/kg bw Decreased neonatal survival	300[2]
Cancer	Evidence of liver tumours in rats and mice (not relevant to humans) and Leydig cell tumours in rats (low level of concern to humans). Equivocal increase in preputial gland carcinomas in rats. Endpoints selected for non-cancer risk assessment are protective of any residual concerns regarding the carcinogenic potential of sulfoxaflor.		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE (margin of exposure) refers to a target MOE for occupational and residential assessments.

[2] For toxicology reference values based on the finding of reduced neonatal survival in rats, the standard 10-fold uncertainty factor for interspecies extrapolation was reduced to threefold. This was based on available evidence indicating that humans may be less sensitive than rats to sulfoxaflor-mediated toxicity stemming from interaction with the nicotinic acetylcholine receptor in muscle, which likely plays a role in the neonatal mortality observed in rats.

[3] Since an oral NOAEL was selected, a dermal absorption factor of 4% was used in a route-to-route extrapolation.

[4] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 2 AHETF/PHED Unit exposure estimates for mixers, loaders and applicators handling closer insecticide (µg/kg a.i. handled)

Exposure scenario and PPE		Dermal	Dermal absorbed[1]	Inhalation[2]	Total unit exposure[3]
PPE: Single layer and chemical-resistant gloves					
Mixer/loader AHETF estimates					
A	Open Mix/Load Liquids	58.50	2.34	0.63	2.97
Applicator AHETF estimates					
B	Open Cab Airblast Liquid Application (no CR hat)	3769.3	150.77	9.08	159.85
Mixer/loader/applicator PHED estimates					
C	Manually Pressurized Handwand (MPHW)	943.37	37.73	45.20	82.93
D	Backpack sprayer	5445.85	217.83	62.10	279.93
E	Mechanically Pressurized Handgun (MPHG)	5585.49	223.42	151	374.42
Mixer/loader + Applicator AHETF estimates					
A+ B	Open Mix/Load Liquids + Open Cab Airblast Liquid Application	3827.8	153.11	9.71	162.82

[1] DAF of 4% was applied to the dermal exposure estimates
[2] Light inhalation rate except for backpack, which has a moderate inhalation rate
[3] Total unit exposure = Dermal exposure + inhalation exposure

Table 3 Mixer/Loader/Applicator exposure and risk assessment

Exposure scenario		Unit exposure (µg/kg a.i. handled)[1]	ATPD (ha/day)[2]	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day)[3]	MOE[4]
PPE: Single layer and chemical-resistant gloves						
Field-grown fir trees, including Christmas trees	(A+B) Open M/L Liquids + Open Cab Airblast Application	162.82	20	0.096	3.9×10^{-3}	486
	(C) MPHW	82.93	3.8	0.096	1.5×10^{-5}	127 283
	(D) Backpack sprayer	279.93	0.15	0.096	5.0×10^{-5}	37 708
	(E) MPHG	374.42	0.15	0.096	1.7×10^{-3}	1113
Greenhouse ornamentals	(A) Open M/L Liquids	2.97	1.6	0.096	5.7×10^{-6}	333 193

Exposure scenario		Unit exposure (µg/kg a.i. handled)[1]	ATPD (ha/day)[2]	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day)[3]	MOE[4]
PPE: Single layer and chemical-resistant gloves						
	(automated equipment)					
	(C) MPHW	82.93	1.6	0.096	1.6×10^{-4}	11 933
	(D) Backpack sprayer	279.93	1.6	0.096	5.4×10^{-4}	3535
	(E) MPHG	374.42	1.6	0.096	7.2×10^{-4}	2643

1 Unit exposure based on AHETF/PHED

2 Area treated per day (ATPD) based on: Health Canada default ATPD for airblast; Health Canada defaults of 3800 L/day for MPHG, 150 L/day for MPHW/backpack sprayer (with minimum spray volume of 1000 L/ha); 95th percentile "greenhouse cut flowers" area of 1.6 ha from Statistics Canada 2021 Agricultural Census data.

3 Daily exposure = (AHETF/PHED Unit exposure × ATPD x Rate) / (80 kg bw × 1000 µg/mg)

4 Target MOE = 300; based on NOAEL of 1.9 mg/kg bw/day for short-term dermal and inhalation exposure

Table 4 Sulfoxaflor dislodgeable foliar residue results on greenhouse ornamentals

Location	Greenhouse in Agassiz, British Columbia
Predicted Peak DFR	0.224 ug/cm^2
Actual Peak DFR	0.246 ug/cm^2 (Day 0 after the 2nd application)
% DFR on Day 0 after the first application*	18%
% Dissipation per day	6%
Equation of linear regression	y = -0.0644× – 1.4982
Coefficient of determination (R^2)	0.9328
Correlation coefficient (R)	-0.97
Slope	-0.0644

* The % DFR was calculated as the average amount of sulfoxaflor deposited divided by the application rate on that day × 100 (in other words, 0.186 µg/cm^2 ÷ 104 g a.i./ha × 100 = 18%).

Table 5 Postapplication exposure and risk estimates to workers for sulfoxaflor on day 0 after the last application

Postapplication activity	Peak DFR[1] (µg/cm^2)	Transfer coefficient[2] (cm^2/hr)	Dermal Exposure[3] (mg/kg bw/day)	MOE[4]	REI[5]
Greenhouse ornamentals: disbudding, hand harvesting, hand pruning	0.2659	4000	0.0043	447	12 hours

Postapplication activity	Peak DFR[1] (µg/cm^2)	Transfer coefficient[2] (cm^2/hr)	Dermal Exposure[3] (mg/kg bw/day)	MOE[4]	REI[5]
Field-grown fir trees, including Christmas trees: hand-set irrigation	0.2400	1750	0.0017	1131	12 hours

1 Peak DFR values for greenhouse ornamentals calculated from submitted study data, based on percent deposition value of 18% retained on foliage on Day 0, plus daily dissipation rate of 6%. For field-grown fir trees, including Christmas trees, calculated using the standard 25% dislodgeable on the day of application and 10% dissipation per day.
2 Transfer coefficients obtained from Health Canada Agricultural TCs Table (2024-10-29)
3 Exposure = (Peak DFR [µg/cm^2] × TC [cm^2/hr] × 8 hours/day × 4% dermal absorption) / (80 kg bw × 1000 µg/mg)
4 Based on a NOAEL of 1.9 mg/kg bw/day; Target MOE = 300
5 Minimum REI is 12 hours to allow residues to dry and vapours to dissipate.

Table 6 Input parameters used to model drinking water EECs

Parameter	Groundwater			Surface water
	XDE-208 (Parent)	X11719474 (Daughter)	X11519540 (Granddaughter)	Combined residues
K_{oc} (L/kg)	19.4	14.8	5	5.0
Aerobic aquatic half-life at 20°C (days)	N/A[1]	N/A	N/A	1100
Anaerobic aquatic half-life at 20°C (days)	N/A	N/A	N/A	415
Photolysis half-life at 40°N latitude (days)	N/A	N/A	N/A	Stable
Hydrolysis half-life at pH 7 at 25°C (days)	Stable	Assumed stable	Assumed stable	Stable
Aerobic soil half-life at 20°C (days)	0.46	1838 (1.0)	2919 (0.52)	5.46×10^{15}
Molecular weight (g/mol)	277.27	295.28	253.24	277.27
Vapour pressure (torr)	1.05×10^{-8}	8.25×10^{-10}	8.25×10^{-10} (assumed same as X11719474)	8.25×10^{-10}
Solubility (mg/L)	570	7200	7200 (assumed same as X11719474)	7200
Henry's law constant	2.75×10^{-10}	1.82×10^{-12}	1.56×10^{-12}	1.56×10^{-12}
Air Diffusion Coefficient (cm^2/d)	4.17×10^{3}	4.10×10^{3}	4.49×10^{3}	4.17×10^{3}
Heat of Henry (J/mol)	50 000	50 000	50 000	50 000

1 Not applicable for groundwater.

Table 7 Level 2 EECs (expressed as parent equivalents) for sulfoxaflor and two of its transformation products (X11719474 and X11519540) in potential sources of drinking water

Use pattern	Groundwater (µg a.i./L)		Surface water (µg a.i./L)		
	Peak[1]	Average[2]	Daily[3]	Yearly[4]	Overall[5]
1 × 96 g a.i./ha	138	126	1.9	1.1	0.7

1 Peak concentration.
2 Post-breakthrough average concentrations.
3 90th percentile of the highest 1-day average concentration from each year.
4 90th percentile of yearly average concentrations.
5 Average of all yearly average concentrations

Table 8 Food residue chemistry overview of risk assessment

Dietary risk from food and drinking water			
	Population	Estimated risk % of acute reference dose (ARfD)	
		Food alone	Food and drinking water
Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.25 mg/kg bw (food and drinking water)** **Estimated acute drinking water concentration = 0.143 ppm**	All infants <1 year	9.34	14.79
	Children 1–2 years	13.68	15.76
	Children 3–5 years	10.41	12.35
	Children 6–12 years	5.76	7.49
	Males 13–19 years	3.28	4.79
	Males 20+ years	3.35	5.17
	Adults 50+ years	3.45	5.39
	Total population	4.94	7.09
	Population	**Food alone**	**Drinking water alone**

Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.0063 mg/kg bw (food)** **ARfD = 0.25 mg/kg bw (drinking water)** **Estimated acute drinking water concentration = 0.143 ppm**	Females 13–49 years	65.77	3.01

	Population	**Estimated risk % of acceptable daily intake (ADI)**	
		Food alone	**Food and drinking water**
Refined chronic non-cancer and cancer dietary exposure analysis **ADI = 0.01 mg/kg bw/day (food and drinking water)** **Estimated chronic drinking water concentration = 0.126 ppm**	All infants <1 year	3.8	98.9
	Children 1–2 years	8.3	43.4
	Children 3–5 years	6.8	35.3
	Children 6–12 years	3.8	25.0
	Males 13–19 years	2.0	18.7
	Males 20+ years	2.3	25.9
	Adults 50+ years	2.6	27.2
	Total population	2.9	28.3
	Population	**Food alone**	**Drinking water alone**

Refined chronic non-cancer and cancer dietary exposure analysis **ADI = 0.0063 mg/kg bw/day (food)** **ADI = 0.01 mg/kg bw/day (drinking water)** **Estimated chronic drinking water concentration = 0.126 ppm**	Females 13–49 years	17.2	24.9

Table 9 Updated bee risk assessment for the movement of treated greenhouse plants outdoors when considering residues of sulfoxaflor in pollen and nectar following an application rate of 48 g a.i./ha*

Forager nectar	**Forager pollen**	**Estimated exposure[1] (mg a.i./kg) based on highest residues on day 0**		**RQ[2]**	
		Adult	**Larvae**	**Adult**	**Larvae**
The highest residues decline from 0.0889 mg a.i./kg on 0 DAA to below LOQ by 6 DAA.	The highest residues decline from 0.809 mg/kg on 0 DAA to 0.0191 mg a.i./kg at 5 DAA and 0.0325 mg/kg at 6 DAA, which represents a decline to 4% of day 0 residues.	0.026	0.014	0.5	0.1

* Study reported in PRD2015-08 (PMRA No. 2055636; maximum pollen and nectar residues reported for *Phacelia* treated during bloom at 1 × 48 g a.i./ha rate). This study is relevant to potential exposures should treated greenhouse plants be moved outdoors.

1 Oral dose (µg/bee/day) = exposure from pollen + exposure from nectar = [(residue concentration in pollen × pollen consumption rate) + (residue concentration in nectar × nectar consumption rate)]/1000.
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total; Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total.

2 Screening level RQs were calculated based on the following endpoints (as reported in PRD2015-08): Adult oral: 0.0515 µg/bee; larva: >0.2 µg/bee. Acute LD_{50} values for adult bees range from 0.0515 to >100 µg/bee. While the RQ for adults (0.5) slightly exceeds the Level of Concern (0.4), this value is considered conservative, given that there was a range of adult toxicity values and the most sensitive was used, the residues were the maximum from day 0 after direct application to blooming plants, residues declined rapidly, and there will be a delay to moving treated plants outdoors. Risks are considered acceptable for oral exposure when considering this updated risk assessment, as well as higher-tiered study results reported in PRD2015-08.

References

A. List of studies/Information submitted by registrant

1.0 Human and animal health

PMRA Document Number	Reference
2680052	2016, Residue report - "Sulfoxaflor: Magnitude of Dislodgeable Foliar Residue from Greenhouse Chrysanthemum", DACO 5.9

2.0 Impact on the environment

PMRA Document Number	Reference
2055636	2011, GF-2626: A Semi-field Study to Investigate Residues in Honeybee Products (*Apis mellifera carnica* L.; Hymenoptera, Apidae) in *Phacelia tanacetifolia* in Germany in 2010, DACO: 9.2.4.

3.0 Value

PMRA Document Number	Reference
2680055	2016, Value data summary report - Closer Insecticide (sulfoxaflor) on greenhouse ornamentals, DACO: 10.1
2680056	2015, Value data summary tables - Closer Insecticide (sulfoxaflor) on greenhouse ornamentals, DACO: 10.2.3.1
2680057	Field trial reports - Closer Insecticide (sulfoxaflor) on greenhouse ornamentals, DACO: 10.2.3.3