Proposed Registration Decision PRD2016-02

Sulfoxaflor

(publié aussi en français)

26 January 2016

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2016-2E (print version)
H113-9/2016-2E-PDF (PDF version)

Table of Contents

Overview

Proposed Registration Decision for Sulfoxaflor

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Isoclast Active and Rascendo, containing the technical grade active ingredient sulfoxaflor, as seed treatment to control flea beetles on oilseeds (canola, rapeseed and oilseed mustard).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Isoclast Active (Registration Number 30824) is currently registered in Canada for use in other foliar applied end-use products to control or suppress aphids, leafhoppers, San Jose scale and Lygus bug on field vegetable, cereal grain, oilseed, fruit and nut crops. The detailed review for the foliar use can be found in the Proposed Registration Decision PRD2015-08, *Sulfoxaflor* and Registration Decision RD2015-09, *Sulfoxaflor*.

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 Isoclast Active and Rascendo.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people 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 special precautionary measures on the product label to further reduce risk.

---

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."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on sulfoxaflor, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on sulfoxaflor, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA'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 an insecticide that causes excitation of insect nerves. This active ingredient can be formulated into products that provide control or suppression of a variety of sucking insects on field vegetables, cereal grains, oilseeds and fruit and nut crops when sprayed on the foliage, or applied as a seed treatment in combination with thiamethoxam or clothianidin to provide control of flea beetles on canola, rapeseed and oilseed mustard.

Health Considerations

Can Approved Uses of Sulfoxaflor Affect Human Health?

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

Potential exposure to sulfoxaflor may occur through the diet or when handling and applying the end-use 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 established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

---

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*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses 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.

In laboratory animals, sulfoxaflor was demonstrated to be 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 end-use product, Rascendo, containing sulfoxaflor, was of low acute toxicity by the oral, dermal and inhalation routes of exposure, 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.

Registrant-supplied short-term 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 these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Drinking Water and Food

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

Aggregate chronic dietary intake estimates (food plus drinking water) for the general population and all population subgroups (except for the females 13-49 years old) revealed that infants, the subpopulation which would ingest the most sulfoxaflor relative to body weight, is expected to be exposed to less than 86% of the acceptable daily intake (ADI). Based on these estimates, the chronic dietary risk from sulfoxaflor is not of health concern for all subpopulations. There are no lifetime cancer risks of concern from the use of sulfoxaflor.

Aggregate acute dietary intake estimates (food plus drinking water) for the general population and all population subgroups (except for the females 13-49 years old) were less than 24% of the acute reference dose (ARfD), and are not of health concern. The highest exposed subpopulation was infants less than one year old.

For females 13-49 years old, the ARfD and the ADI for sulfoxaflor from exposure to metabolite X11719474 residues in drinking water (no sulfoxaflor present in drinking water sources) is different from the ARfD/ADI from exposure to sulfoxaflor residues in food, hence aggregate dietary intake estimates (food plus drinking water) were not conducted. For females 13-49 years old, the chronic dietary risks from food are less than 9% of the ADI and, the chronic dietary risks from drinking water are less than 20% of the ADI. For this subgroup, the acute dietary risks from food and drinking water are 117% and 6.6% of the ARfD, respectively.

A single dose of sulfoxaflor is not likely to cause acute health effects to any population subgroup (including infants and children) in light of the conservatisms inherent in the risk assessment (for example, assumed maximum rates, maximum number of applications, and shortest preharvest interval).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using sulfoxaflor on treated canola seeds are acceptable. The MRL for this active ingredient has been established for Rapeseed Crop Subgroup 20A (CSG 20A) based on data generated following foliar application of canola. The seed treatment use of sulfoxaflor on canola, rapeseed, and oilseed mustard is not expected to result in residues exceeding the established MRL.

Occupational Risks From Handling Rascendo

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

Commercial facility seed treaters who mix, load, treat, or bag, sew, or stack bags of treated seeds, as well as farmers planting seeds treated with Rascendo can come in direct contact with sulfoxaflor residues on the skin. Therefore, the label specifies that anyone mixing, loading, and treating seeds with Rascendo must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, work boots and socks. Baggers, sewers, stackers, forklift operators and others handling treated seed, including planters, must wear cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, work boots and socks. Cleaners must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear and socks. Taking into consideration these label statements, the risks to seed treatment workers and farmers are not a concern.

For bystanders, exposure is expected to be much less than that for workers. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Sulfoxaflor Is Introduced Into the Environment?

When used according to label directions, sulfoxaflor is not expected to pose an unacceptable risk to the environment.

Sulfoxaflor enters the environment when used as Rascendo for use on canola, rapeseed and oilseed mustard (*Brassica* spp.) seeds. A risk assessment was conducted considering all seed treatment exposure routes. A risk assessment of potential exposure pathways through foliar application was conducted previously (PRD2015-08).

Sulfoxaflor is rapidly broken down by microbes in the soil. 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. Sulfoxaflor and its transformation products are not expected to be found in air. Sulfoxaflor is a systemic insecticide and can move from the seed through the plant. Residues in or on canola flowers, pollen and nectar were not detected in plants when seeds were treated with sulfoxaflor.

Sulfoxaflor is toxic to bees; however, based on residue studies in canola flowers, exposure to bees through treated seed is not a concern. Transformation products of sulfoxaflor are persistent in the environment but are not toxic to bees. Therefore, when used according to label directions as a seed treatment, risk to bees is not a concern. Risks to birds and wild mammals were identified and are expected to be mitigated through label statements which instruct users to cover seeds exposed on the surface of the soil following planting.

Value Considerations

What Is the Value of Rascendo?

Rascendo, when applied as a seed treatment in combination with thiamethoxam or clothianidin, controls flea beetles in canola, rapeseed and oilseed mustard in regions where species composition of the flea beetle population has changed.

Flea beetles are early season pests of canola, rapeseed and oilseed mustard and are predominately controlled using seed treatments, though foliar insecticides are also available. In Western Canada, the crucifer flea beetle has historically been the dominant species; however, the flea beetle species composition has been shifting to include more striped flea beetles, which are less susceptible to thiamethoxam and clothianidin seed treatments. Sulfoxaflor cannot be used as a stand-alone seed treatment to control flea beetles; however when used on canola, rapeseed, or oilseed mustard, the combination of sulfoxaflor and thiamethoxam or clothianidin as a seed treatment is expected to improve control of flea beetles where species composition has been shifting.

Measures to Minimize Risk

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

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

Key Risk-Reduction Measures

Human Health

As there is a concern with users coming in direct contact with Rascendo on the skin or through inhalation of dust, anyone mixing, loading, and treating seeds with Rascendo must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, work boots and socks. Baggers, sewers, stackers, forklift operators and others handling treated seed, including planters, must wear cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, work boots and socks. Cleaners must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear and socks. In addition, standard label statements to protect against drift during planting are on the label.

Environment

Sulfoxaflor product labels inform the user of the leaching potential of sulfoxaflor transformation products. Label instructions will direct the user to cover seeds that have been left exposed following planting to mitigate the potential for exposure to birds and mammals.

Next Steps

Before making a final registration decision on sulfoxaflor, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on 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 PMRA's Reading Room (located in Ottawa).

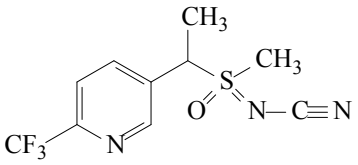
Science Evaluation

Sulfoxaflor

Isoclast Active (Registration Number 30824) is currently registered in Canada for use in foliar applied end-use products. The detailed review for the foliar use can be found in the Proposed Registration Decision PRD2015-08, *Sulfoxaflor* and Registration Decision RD2015-09, *Sulfoxaflor*.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Sulfoxaflor
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide
2. Chemical Abstracts Service (CAS)	*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-λ^4-sulfanylidene]cyanamide
CAS number	946578-00-3
Molecular formula	$C_{10}H_{10}F_3N_3OS$
Molecular weight	277.3
Structural formula	
Purity of the active ingredient	97.9%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product – Isoclast Active

Property	Result
Colour and physical state	Off-white powder
Odour	Sharp odour
Melting range	112.94°C
Boiling point or range	N/A
Density	1.54 g/cm^3
Vapour pressure at 20°C	≤ 1.4 × 10^{-6} Pa
Ultraviolet (UV)-visible spectrum	λ_{max}, nm neutral: 192, 211, 260 acidic: 210, 260 basic: 218, 260
Solubility in water at 20°C	pH — Solubility (mg/L) Unbuffered — 670 5 — 1380 7 — 570 9 — 550
Solubility in organic solvents at 20°C	Solvent — Solubility (g/L) Methanol — 93.1 Acetone — 217 Xylene — 0.743 1,2-Dichloroethane — 39.6 Ethyl acetate — 95.2 n-Heptane — 2.42 × 10^{-4} n-Octanol — 1.66
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 5 — 0.806 7 — 0.802 9 — 0.799
Dissociation constant (pK_a)	No measurable ionization constant within environmentally relevant pH range (pH 2–10).
Stability (temperature, metal)	No chemical degradation of the test substance at 54 ± 2°C and in the presence of metals (copper, brass, 304 stainless steel, 316 stainless steel) and metal ions (copper (I) chloride and nickel (II) chloride) was noted through 14 days of storage. A substantial degradation of the test substance, ~ 50% of the initial assay, was noted in the presence of $FeCl_3 \cdot 6H_2O$.

End-Use Product – Rascendo

Property	Result
Colour	White
Odour	Aromatic
Physical state	Liquid
Formulation type	Suspension
Guarantee	500 g/L
Container material and description	Plastic jug or tote
Density	1.20 g/cm^3
pH of 1% dispersion in water	6.8
Oxidizing or reducing action	Product is not compatible with strong oxidizers
Storage stability	Stable under accelerated storage at 54°C for 14 days in commercial packaging.
Corrosion characteristics	Not corrosive to commercial packaging under the conditions of accelerated storage
Explodability	Does not contain potentially explosive ingredients

1.3 Directions for Use

Rascendo is a seed treatment product for use on canola, rapeseed or oilseed mustard to control flea beetles. The application rate is 200 g sulfoxaflor/100 kg seed applied in combination with a registered seed treatment containing thiamethoxam or clothianidin. Rascendo is not a stand-alone product for control of flea beetles.

1.4 Mode of Action

Sulfoxaflor has systemic activity in plants where it is translocated through the xylem. Sulfoxaflor acts as an agonist at the insect nicotinic acetylcholine receptor, allowing ion flow through the associated ion channel and resulting in nervous excitation. There is physiological evidence that the mechanism of this action is different from that of neonicotinoid insecticides, and insects resistant to neonicotinoids show no cross-resistance to sulfoxaflor (Zhu et al. 2010). Consequently, the Insecticide Resistance Action Committee (IRAC) has placed sulfoxaflor in a subgroup (4C) separate from the neonicotinoid compounds (4A) within the Nicotinic Acetylcholine Receptor Competitive Modulator mode-of-action group (Group 4).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Isoclast Active have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Please refer to 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 Toxicology Summary

A detailed review of the toxicological 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 endpoints for use in human health risk assessment, and an overall summary of the data can be found in PRD2015-08.

In acute toxicity testing, the end-use product, Rascendo, was found to be of low acute toxicity in rats via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin of rabbits, and was not a skin sensitizer when tested in the local lymph node assay (LLNA) in mice. Results of the toxicology studies conducted on laboratory animals with the end-use product Rascendo can be found in Appendix I, Table 1.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 10 June 2015, one human incident report involving sulfoxaflor has been reported to the PMRA. The incident report information was incorporated into the evaluation of sulfoxaflor and did not impact the risk assessment.

3.2 Occupational and Residential Risk Assessment

3.2.1 Toxicological Endpoints

Occupational exposures to Rascendo are characterized as short- to intermediate-term for seed treatment workers and short-term for farmers planting treated seeds, and are by the dermal and inhalation routes.

3.2.1.1 Dermal Absorption

The detailed review for dermal absorption can be found in PRD2015-08.

The dermal absorption value of 4%, derived from previously submitted data, was considered acceptable for assessment of the seed treatment and planting of canola, rapeseed, and oilseed mustard treated with Rascendo.

3.2.2 Occupational Exposure and Risk

3.2.2.1 Dust-off Study

A dust-off study was submitted to support the occupational exposure assessment of Rascendo to bridge surrogate canola seed treatment and surrogate corn planting exposure studies to canola, rapeseed, and oilseed mustard treated with Rascendo.

The study adequately shows that the dust-off potential of canola, rapeseed, or oilseed mustard treated with Rascendo tank mixed with other insecticides are generally lower than that from surrogate exposure study test material-treated crops. Therefore, the surrogate studies are not expected to underestimate exposures to Rascendo-treated seeds based on the dust-off data provided.

3.2.2.2 Seed Treatment Worker Exposure and Risk Assessment

Individuals have potential for exposure to Rascendo during seed treatment and handling treated seed. Dermal and inhalation exposure estimates were derived for workers treating canola seeds (representing Crop Group 20A (Rapeseed Subgroup)) with Rascendo using closed transfer commercial treating equipment, as well as workers bagging, sewing and stacking bags of treated seeds and cleaners. The exposure estimates are based on treaters and cleaners wearing chemical-resistant coveralls over a long-sleeved shirt, long pants, and chemical-resistant gloves. Baggers, sewers, stackers, and forklift operators were wearing coveralls over a long-sleeved shirt, long pants, and chemical-resistant gloves.

Chemical-specific data for assessing worker exposures during seed treatment activities were not submitted. Therefore, a surrogate canola seed treatment exposure study was considered appropriate to estimate exposures to workers in a commercial seed treatment facility which used closed mix, load, and transferring equipment while treating canola, rapeseed, or oilseed mustard with Rascendo.

Dermal exposures were estimated by coupling the unit exposure values with the amount of product handled per day, and accounting for 4% absorption of residues. Inhalation exposures were estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to relevant toxicological endpoints, based on the no observed adverse effect level (NOAEL), to obtain the margin of exposure (MOE); the target MOE is 300 for each of the dermal and inhalation routes.

Table 3.2.1 Exposure and Risk Estimates for Workers Treating Canola Seeds (also Representative of Rapeseed and Mustard Seed) in Commercial Seed Treatment Facilities

Scenario [1]	Unit-exposure [1] (µg/kg a.i. handled)		kg seed treated per day[2]	App rate (g a.i./100 kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		Combined MOE [6]
	Dermal	Inhalation				Dermal	Inhalation	
Treater: Closed Transfer : Chemical-resistant coveralls over single layer; chemical-resistant gloves	7.36	0.27	67000	200	134	0.000493	0.000452	2011
Bagger/Sewer/Stacker: Coveralls over single layer; chemical-resistant gloves	1.29	0.25				0.0000864	0.000419	3759
Forklift Operator: Cotton/polyester coveralls over single layer; chemical-resistant gloves	0.72	0.105				0.0000482	0.000176	8475
Cleaner [5]: Chemical-resistant coveralls over single layer; chemical-resistant gloves (Normalized to application rate)	µg/kg bw/day		------	------	-------	0.000387	0.00077	1642
	19.37	1.54						

[1] Scenarios and unit-exposure values are from the surrogate exposure study.
[2] Commercial seed treatment throughput value (AHETF)
[3] kg a.i. handled per day = kg seed treated per day × application rate (g a.i./100 kg seed) × (1 kg/1000 g)
[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day} \times \text{absorption}}{\text{80 kg bw} \times \text{1000 µg/mg}}$
dermal absorption (4%); inhalation absorption (100%)
[5] Cleanout personnel unit exposures presented as (µg/kg bw/day) were normalized based on application rate.
Therefore:
Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg bw)} \times \text{(200 g a.i./100 kg seed / 400 g a.i./100 kg seed)} \times \text{absorption}}{\text{1000 µg/mg}}$
dermal absorption (4%); inhalation absorption (100%)
[6] Sulfoxaflor: intermediate-term dermal and inhalation NOAELs = 1.9 mg/kg bw/day, target MOE= 300;
Margin of Exposure (MOE) = NOAEL/Exposure (dermal + inhalation)

The MOEs are above the target MOE of 300 when treaters (including mixing and loading) and cleaners are wearing chemical-resistant coveralls over a long-sleeved shirt and long pants, and chemical-resistant gloves; and when baggers/sewers/stackers and forklift workers are wearing coveralls over a long-sleeved shirt and long pants, and chemical-resistant gloves. Closed transfer, including mixing, loading, and calibration equipment is required.

3.2.2.3 Exposure and Risk Assessment for Farmers Planting Treated Seeds

There is potential for exposure to farmers planting canola, rapeseed, or oilseed mustard treated with Rascendo. The duration of exposure for farmers planting treated seeds is considered to be short-term, likely less than a month, and through the dermal and inhalation routes of exposure.

There was no chemical-specific planting exposure data. Therefore, a surrogate corn seed planting exposure study was considered appropriate to estimate exposures of farmers planting canola, rapeseed or, oilseed mustard treated with Rascendo. Farmers were wearing a long-sleeved shirt, long pants, and chemical-resistant gloves and using closed-cab planting equipment.

The planting rate of 9 kg seed/ha is coupled with an area planted per day of 100 ha to derive the amount of sulfoxaflor handled per day. The area planted and seeding rate of canola are not expected to under-estimate those of rapeseed and oilseed mustard.

Dermal exposures were estimated by coupling the unit exposure values with the amount of product handled per day and accounting for 4% absorption of residues. Inhalation exposures were estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints, based on the NOAEL, to obtain the MOE; the target MOE is 300 for each of the dermal and inhalation routes.

Table 3.2.2 Exposure and Risk Estimates for Farmers Planting Canola, Rapeseed and Oilseed Mustard Treated with Rascendo

Scenario	Unit exposure (µg/kg a.i. handled)[1]		kg seed planted per day[2]	Appl. rate (g a.i./100 kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		Combined MOE [5]
Planting	Dermal	Inhalation				Dermal	Inhalation	
Canola seeds (covers rapeseed and oilseed mustard)	1515	82.83	900	200	1.8	0.001364	0.00186	589

[1] Unit exposure values for planters of treated canola, rapeseed, and oilseed mustard based on a surrogate planter exposure study; workers are wearing a long-sleeved shirt, long pants, and chemical-resistant gloves and using closed-cab planting equipment

[2] kg seed planted per day = Area planted per day (100 ha/day) × Seeding Rate (9 kg seeds/ha)

[3] kg a.i. handled per day = kg seed planted per day × application rate (g a.i./100 kg seed) × (1 kg/1000 g)

[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day} \times \text{absorption}}{80 \text{ kg bw} \times 1000 \text{ µg/mg}}$

dermal absorption (4%); inhalation absorption (100%)

[5] Sulfoxaflor: dermal and inhalation NOAELs = 1.9 mg/kg bw/day, target MOE= 300;
Combined MOE = NOAEL/Exposure (dermal + inhalation)

The MOEs exceed the target MOE of 300. Planting equipment is required to be closed-cab.

3.2.3 Residential Exposure and Risk Assessment

Rascendo is a commercial product proposed for use in commercial seed treatment facilities. No residential exposure is anticipated.

3.2.3.1 Bystander Exposure and Risk

Bystander exposure is expected to be negligible since bystanders are not expected to be in the vicinity where seeds are treated. Furthermore, the product is liquid and applied using closed-transfer treatment equipment in commercial seed treatment facilities. Exposure from dust of treated seeds during planting is not quantified, but expected to be negligible.

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant and Animal Foodstuffs

Sulfoxaflor is currently registered for foliar application on various crops including canola. Please refer to PRD2015-08 for the residue definition for risk assessment and enforcement purposes and for the frozen storage stability of sulfoxaflor in plant and animal foodstuffs. The information captured herein only relates to the seed treatment use on canola, rapeseed and oilseed mustard, for which data were reviewed (Appendix I, Table 2). The previous acute and chronic dietary exposure assessments are briefly presented in this document, even though the assessment for foliar uses (PRD2015-08) did not need to be updated for canola, rapeseed, and oilseed mustard seed treatment.

Based on foliar applications, a maximum residue limit (MRL) for Rapeseed Crop Sub-Group 20A was established at 0.4 ppm. The seed treatment use of sulfoxaflor on this crop subgroup at a lower rate and longer preharvest interval (PHI) is not expected to result in residues exceeding the established MRL. The residue data reviewed for seed treatment confirms this.

3.3.2 Dietary Risk Assessment

Acute and chronic (non-cancer and cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.3.2.1 Chronic Dietary Exposure Results and Characterization

The assumptions made in the refined chronic analysis included median residue values for all crops, experimental processing factors (where available), limited projected percent crop treated information, and anticipated residues in/on animal commodities based on the Maximum Reasonably Balanced Diet (MRBD). The refined chronic dietary exposure, from all supported sulfoxaflor food uses (alone) for all representative population subgroups, including infants and children, is <39 % of the acceptable daily intake (ADI). The highest aggregate (food and drinking water) exposure and risk estimate is for all infants (<1 year) at 86% of the ADI.

Therefore, aggregate exposure from food and drinking water is not of health concern. For female 13-49 years old, the chronic dietary exposure to sulfoxaflor from food is 9% of the ADI and from drinking water is 19.3% of the ADI. For more details on the dietary risk assessment, refer to PRD2015-08.

3.3.2.2 Acute Dietary Exposure Results and Characterization

For all population subgroups, except females 13-49 years old, the aggregate acute dietary risk from food and drinking water is not of health concern (<24% of the acute reference dose (ARfD)).

For females 13–49 years old, the refined acute dietary exposure to drinking water is 6.6% of the ARfD. The assumptions made in the refined probabilistic acute analysis (99.9^{th} percentile) to food included the field trial residue distributions, adjustments of residues for approved Canadian application rates, limited projected percent crop treated information together with domestic production, experimental processing factors (where available) and anticipated residues in/on animal commodities based on MRBD. The refined acute dietary exposure (food alone) to sulfoxaflor residues for all supported commodities is estimated to be 117% of the ARfD for females 13–49 years old.

A single dose of sulfoxaflor is not likely to cause acute health effects to any population subgroup (including infants and children) in light of the conservatisms inherent in the risk assessment (for example, assumed maximum rates, maximum number of applications, and shortest preharvest interval, and common household practices such as peeling, washing, and cooking were not considered).

For more details on the dietary risk assessment, refer to PRD2015-08.

3.3.3 Aggregate Exposure and Risk

The aggregate risk for sulfoxaflor consists of exposure from food and drinking water sources only; there are no residential uses.

3.3.4 Maximum Residue Limits

No revision is required for the established MRLs. Please refer to PRD2015-08 for detailed discussion of the nature of the residues in animal and plant matrices, analytical methodologies, field trial data for foliar uses, and the acute and chronic dietary risk assessments.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Characterization of the fate and behaviour of sulfoxaflor in soil and water was reported previously (PRD2015-08 and RD2015-09) for its use as a foliar spray. In summary, sulfoxaflor is rapidly broken down by microbes in the soil. 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. Sulfoxaflor and its transformation products are not expected to be found in air.

As sulfoxaflor is a systemic insecticide, a residue study on canola plants (from treated seed) was conducted to determine potential concentrations of this active ingredient in pollen and nectar (Appendix I, Table 3). The seed treatment rate used in the study was the same as the label rate proposed for this use (200 g a.i./100 kg seed). Sampling of flowers, nectar and pollen occurred during 50-75% flowering and before petal fall. Residues of sulfoxaflor in all canola samples were less than 0.56 µg/g (in other words, the limit of detection, LOD, in plant materials from this study).

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with effects concentrations. The primary environmental concern for this risk assessment is for birds and small wild mammals, as they may be exposed to sulfoxaflor through direct ingestion of treated seeds, and for bees, as sulfoxaflor may translocate within plants from the treated seed to nectar and pollen. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

4.2.1.1 Birds and small wild mammals

The general method for conducting the screening level risk assessment, for birds and small wild mammals for a seed treatment, is to determine the amount of sulfoxaflor present on individual seeds based on the label application rate, and then to determine the amount of treated seeds required to be consumed to equal the relevant toxicity endpoint (in other words, acute oral, dietary or reproductive) as a daily dose (see Appendix I, Tables 4, 5, 6).

The screening level risk assessment uses a conservative approach by assuming that the daily diet of birds and mammals consists of 100% treated seeds and that the seeds are treated at the proposed maximum application rate (200 g a.i./100 kg seed). The lethal dose for 50% of the population (LD_{50}) and no observed effect concentration (NOEC) values for toxicity of sulfoxaflor to birds and small, wild mammals have previously been established (PRD2015-08 and Appendix I, Table 4 of this document) and were used for this assessment. Risk quotients are reported in Appendix I, Table 6.

As screening level RQs for acute and reproductive endpoints exceeded the LOC for birds and small mammals, the risk assessment was expanded.

To further characterize the risk to birds and mammals, surface seed availability and the surface area required for a bird or mammal to search to find and consume enough treated seeds to reach the toxicity endpoint (search area) were considered. The search area is calculated based on the predicted (%) seed availability for three types of seeding methods: broadcast seeding without soil incorporation (where 100% of applied seeds are assumed to be available), standard drilling (3.3%), and precision drilling (0.5%). This refinement indicates the area required for a bird or mammal to find enough seeds to reach the toxicity endpoint under each of these situations.

Sulfoxaflor should not pose a risk to birds on a short-term dietary basis (RQ < 1). For acute and reproductive exposure to birds and small mammals, both the number of seeds that a bird or mammal is required to consume (to equal the endpoint dose, acute oral or reproductive) and the search area required to find this number of seeds are relatively large. This makes it unlikely that a bird or small mammal would find and consume a dose within a short period of time that could cause harm. Broadcast seeding could present a worse scenario with a greater potential for exposure (as more seeds are available within a smaller area). However, considering that broadcast seeding of canola and mustard seeds is typically only used when conditions in the field are exceptionally wet (Canola Council of Canada website, http://www.canolacouncil.org/), this is not expected to pose an unacceptable risk to birds or small mammals. It should also be noted that, for reproduction, the endpoint selected was at a test concentration where no effects were observed in the chronic exposure studies. Relatively higher concentrations (doses) would, therefore, be needed to elicit an adverse effect. For mammals, the lowest observed adverse effect level (LOAEL) from the reproduction study (Appendix I, Table 7) was used and indicated that search areas and the number of seeds needed to be consumed to reach the endpoint would be greater, further supporting that it is not expected that small mammals would be likely to consume a dose from within the planted field that could cause significant harm.

Seeds spilled at row ends or released when the drilling machinery lifts from the soil during turning, could, however, be more easily available for birds and mammals to consume as the seeds may be more concentrated in small piles. Therefore, label statements are required informing the user that seeds treated with Rascendo are toxic to birds and mammals, and that any spilled or exposed seeds should be soil incorporated or cleaned up from the surface of the soil.

4.2.1.2 Pollinators

Risk to pollinators was assessed by examining the likelihood of acute mortality and chronic effects on survival, development and reproduction of bees/colonies, from use of sulfoxaflor as a seed treatment. Bees may be exposed to sulfoxaflor residues through food sources (nectar and pollen). Measurement endpoints for the screening-level assessments were based on individual bees (adults and/or larvae) and consisted of LD_{50} and NOEC values (previously established in PRD2015-08 and reported here in Appendix I, Table 8).

The Tier I default risk assessment considers residues that may be present in pollen and nectar through systemic transport from treated seed. Potential oral exposure to adults and larvae of bees are estimated using the food consumption rates for adults and larvae. An acute RQ for bee adults and larvae is calculated by dividing the exposure value by the available oral LD_{50} value (Appendix I, Table 9). As the oral toxicity of sulfoxaflor to bumble bees is in the same range as that for honey bees, the risk assessment with honey bees is considered to be appropriate to account for potential risk to non-Apis species.

As calculated RQs exceeded the LOC (LOC = 0.4) for oral consumption, based on default pollen and nectar values, a Tier I refined risk assessment was conducted using residue values generated from field trials with canola to further characterise exposure estimates.

For the Tier I refined oral risk assessment (Appendix I, Table 10), the residue detected in the canola crop was compared to the oral consumption values for bees. The residue level was below the limit of detection (LOD = 0.56 µg/g) and, therefore, ½ LOD (0.00028 ppm or 0.28 ppb) is used as the level in both nectar and pollen for the risk assessment. This was multiplied by 292 mg/day for nectar and 0.041 mg/day pollen for nectar foragers; 140 mg/day nectar and 9.6 mg/day for pollen for nurse bees; and 120 mg/day nectar and 3.6 mg/day pollen for larvae. This resulted in a value for the total daily exposure (TDE) expected for each caste or life-stage of bee, which was then compared to the toxicity endpoint to determine the RQ. Based on the submitted residue data, the risk identified to bees from consumption of pollen/nectar from plants grown with sulfoxaflor-treated seed was considered to be negligible.

Foraging worker bees may be exposed to contaminated dust generated from seeding equipment during planting of treated seed. Rascendo is proposed for use as a seed treatment for canola, rapeseed and oilseed mustard. Planting of these types of seeds in Canada is not associated with dust-generation, and bees are not expected to be harmed from exposure to dust through planting of canola, rapeseed and oilseed mustard seeds.

Overall, based on this assessment, sulfoxaflor is not expected to pose an unacceptable risk to bees from consumption of pollen/nectar from plants grown with Rascendo treated seed or potential exposure to dust during application/seeding. Although the risk of Rascendo to bees is not of concern, label statements are required to identify bee toxicity for this active ingredient, sulfoxaflor.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms may be exposed to sulfoxaflor and its transformation products through overland runoff to aquatic systems. A risk assessment of sulfoxaflor and the major transformation product X11719474 was undertaken for freshwater and marine aquatic organisms in a previous assessment for foliar uses (PRD2015-08). The screening level RQs for all freshwater and marine/estuarine organisms exposed to sulfoxaflor or its transformation product, X11719474, did not exceed the LOC. The risk assessment for foliar uses was conducted using application rates that exceed those proposed for seed treatment (based on rates in units of g a.i./ha). Therefore, risk to aquatic non-target organisms from runoff is not expected when sulfoxaflor is used according to label directions as a seed treatment.

5.0 Value

5.1 Consideration of Benefits

In the spring, overwintered adult flea beetles emerge from shelterbelts or plant stubble and begin to feed on the cotyledons of host plants causing developmental delays and uneven maturity, ultimately affecting yield. Flea beetles are widespread in canola growing regions and failure to control populations in the spring, either through seed treatments or foliar applied insecticides, can impact yields. In Canada, crucifer flea beetle was the predominant species that attacks canola, rapeseed and oilseed mustard. In some areas it has been observed that the flea beetle species composition has been shifting to include more striped flea beetles which are less susceptible to thiamethoxam and clothianidin seed treatments. The combination of sulfoxaflor and thiamethoxam or clothianidin as a seed treatment tank mix is expected to improve control of the overall population in locations where the presence of striped flea beetles has been increasing.

Sulfoxaflor is classified by the IRAC as a group 4C insecticide. Alternative insecticides applied as seed treatments for the control of flea beetles on canola include active ingredients in IRAC mode of action groups 4A (4 neonicotinoids) and 28 (cyantraniliprole). Alternative insecticides applied as a foliar treatment include 1B (malathion), 3A (4 pyrethroids), and 28 (2 diamides). Sulfoxaflor offers an additional active ingredient for use as a seed treatment to control flea beetles in regions where species composition is shifting.

5.2 Effectiveness Against Pests

Sulfoxaflor is to be applied as a seed treatment in combination with a registered thiamethoxam or clothianidin seed treatment product at a rate of 200 g sulfoxaflor/100 kg of canola, rapeseed or oilseed mustard to control flea beetles.

A total of six trials were submitted to support the claim, one laboratory trial and five field trials. The laboratory trial indicated that striped flea beetles are not as susceptible to thiamethoxam or clothianidin as crucifer flea beetles. Field trials demonstrated less damage to canola plants when the combination of sulfoxaflor + thiamethoxam at the labelled rates was compared to thiamethoxam or clothianidin alone. Increased canola yield was also observed in four of five trials for the sulfoxaflor + thiamethoxam seed treatment combination compared to a thiamethoxam or clothianidin seed treatment alone. These trials supported the use of 200 g sulfoxaflor/100 kg seed in combination with a registered thiamethoxam or clothianidin seed treatment for control of flea beetles on canola, rapeseed and oilseed mustard.

5.3 Non-Safety Adverse Effects

No phytotoxicity to the host crop was observed in field and controlled environment trials as a result of treatment with the combination of sulfoxaflor and thiamethoxam or clothianidin.

5.4 Supported Uses

Claims supported by the submitted value information are 200 g sulfoxaflor/100 kg seed applied in combination with a registered thiamethoxam or clothianidin seed treatment to control flea beetles on canola, rapeseed, and oilseed mustard.

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 [i.e. those that meet all four criteria outlined in the policy: in other words, 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*.

During the review process, sulfoxaflor and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Sulfoxaflor does not meet Track 1 criteria, and is not considered a Track 1 substance. See Appendix I, Table 11 for comparison with Track 1 criteria.

- Transformation products of sulfoxaflor are not Track 1 substances based on a log K_{ow} of less than 0.3 which is below the Track 1 criterion for bioaccumulation.

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

- Rascendo contains the preservative 1,2-benzisothiazoline-3-one, which contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade sulfoxaflor does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

- Rascendo is expected to contain the following impurities of concern: 2-butoxyethanol, 1,4-dioxane, ethylene oxide and propylene oxide at maximum levels of 0.35 ppm, 0.175 ppm, 0.175 ppm and 0.0175 ppm, respectively. The low levels of impurities identified in the chemistry evaluation are not considered to be of toxicological or environmental concern.

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for sulfoxaflor was reviewed previously, and was adequate to define the majority of toxic effects that may result from exposure. 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 toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which

---

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the *New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

these effects occurred in animal tests. The end-use product, Rascendo, was of low acute toxicity by the oral, dermal and inhalation routes of exposure, was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction.

Workers in a commercial seed treatment facility handling Rascendo and farmers planting canola, rapeseeds, or oilseed mustard treated with Rascendo are not expected to be exposed to levels of sulfoxaflor that will result in an unacceptable risk when Rascendo is used according to label directions. The personal protective equipment on the product label is adequate to protect commercial seed treatment workers and farmers planting treated seeds.

The proposed seed treatment use of sulfoxaflor on canola, rapeseed, and oilseed mustard does not constitute a health risk of concern for acute and chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. No revision is required for the established MRLs.

7.2 Environmental Risk

When used for seed treatment of canola, rapeseed and oilseed mustard for control of flea beetles, Rascendo does not pose an unacceptable risk to bees, birds and wild mammals, provided that the label directions regarding burial and cleanup of spilled treated seed are followed.

Sulfoxaflor product labels will inform the user of the leaching potential of sulfoxaflor transformation products. Label instructions will direct the user to cover seeds that have been left exposed following planting to mitigate the potential for exposure to birds and mammals.

7.3 Value

The value information provided to support Rascendo when applied in combination with a registered seed treatment of thiamethoxam or clothianidin was sufficient to demonstrate its value in the management of flea beetles on canola, rapeseed or oilseed mustard. Sulfoxaflor is already registered for use as a foliar treatment on canola to control aphids and lygus bugs; however, use as a seed treatment is the first for this active ingredient on any crop.

Use of Rascendo applied in combination with thiamethoxam or clothianidin will assist canola, rapeseed and oilseed mustard growers in regions where species composition has been shifting and now includes more striped flea beetles.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Isoclast Active and Rascendo, containing the technical grade active ingredient sulfoxaflor, as seed treatment to control flea beetles on oilseeds (canola, rapeseed and oilseed mustard).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

>	greater than
<	less than
≥	greater than or equal to
λ	wavelength
µg	microgram(s)
a.i.	active ingredient
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
App	application
ARfD	acute reference dose
atm	atmosphere
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
BW	generic body weight
℃	degree(s) Celsius
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm^3	centimetre(s) cubed
d	day(s)
DA	dermal absorption
DACO	data code
DAP	days after planting
DEEM	Dietary Exposure Evaluation Model
DIR	Regulatory Directive
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
EEC	estimated environmental concentration
EDE	estimated dietary exposure
EFSA	European Food Safety Authority
F_1	first generation
F_2	second generation
FDA	*Food and Drugs Act*
FIR	food ingestion rate
g	gram(s)
h	hour(s)
ha	hectare(s)
HAFT	highest average field trial
HQ	hazard quotient
IRAC	Insecticide Resistance Management Committee
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LAFT	lowest average field trial

LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOC	level of concern
LOQ	limit of quantitation
m^2	square metre(s)
m^3	cubic metre(s)
mg	milligram(s)
MAS	maximum average score
MIS	maximum irritation score
MOE	margin of exposure
mol	mole(s)
MRL	maximum residue limit
MRBD	Maximum Reasonably Balanced Diet
n	number of field trials
N	number of treated samples
N/A	not applicable
NAFTA	North American Free Trade Agreement
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOI	Notice of Intent
Pa	Pascal(s)
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
PRD	Proposed Registration Decision
RD	Registration Decision
RQ	risk quotient
SD	standard deviation
spp.	sub-species
TDE	total daily exposure
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of Rascendo Containing Sulfoxaflor

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Wistar rats PMRA #2400566	LD_{50} > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Wistar rats PMRA #2400567	LD_{50} > 5000 mg/kg bw Low toxicity
Acute inhalation toxicity (nose-only) Wistar rats PMRA #2400568	LC_{50} > 4.1 mg/L Low toxicity
Dermal irritation New Zealand white rabbits PMRA #2400570	MAS = 0, MIS = 0.3 (at 1 hour) Non-irritating
Eye irritation New Zealand white rabbits PMRA #2400572	MAS = 0.22, MIS = 8.0 (at 1 hour) Minimally irritating
Dermal sensitization (LLNA) CBA/J Rj mice PMRA #2400574	Non-sensitizer

Table 2 Integrated Food Residue Chemistry Summary

CROP FIELD TRIALS & RESIDUE DECLINE ON CANOLA | **PMRA # 2400579**

Field trials were conducted in 2012 in Canada. Trials were conducted in NAFTA Growing Regions 5 (1 trial), 7 (1 trial) and 14 (9 trials) for a total of 11 trials. Canola seeds were treated with Sulfoxaflor FS at 200 g a.i./ 100 kg seed. Canola plants were subsequently treated using two foliar applications at 50 g a.i./ha, for a total foliar application rate of 100 g a.i./ha. The foliar applications were made at 14-day intervals with the last application occurring approximately 14 days before harvest.

Commodity	Total Application Rate (g a.i./100 kg seed; g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT *	HAFT *	Median *	Mean *	SD *
Canola seed	200 (seed); 100 (foliar)	13-15	11	<0.01	0.13	0.039	0.045	0.034

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of independent field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CANOLA | **PMRA # 2400580**

Field trials were conducted in 2012 in the United States. Trials were conducted in NAFTA Growing Regions 5 (4 trials), 7 (4 trials) and 11 (2 trials) for a total of 10 trials. Canola seeds treated with A19103A FS at 200 g a.i./100 kg. Canola plants were subsequently treated by two foliar applications at 50 g a.i./ha, for a total foliar application rate of 100 g a.i./ha. The applications were made at 14-day intervals with the last application occurring approximately 14 days before harvest.

Residue decline data show that residues of sulfoxaflor decreased in harvested canola seeds with increasing preharvest intervals (PHIs).

Commodity	Total Application Rate (g a.i./100 kg seed; g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT *	HAFT *	Median *	Mean *	SD *
Canola seed	200 (seed); 100 (foliar)	14	10	<0.01	0.14	0.033	0.045	0.045
		0	1	- (0.0784)#		-	-	-
		7	1	- (0.0683)#		-	-	-
		10	1	- (0.0570)#		-	-	-
		14	2	0.03	0.03	-	0.03	-
		21	1	- (0.0127)#		-	-	-

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
#Values in parenthesis denote cases where only one independent field trial was conducted.
n = number of independent field trials.

Table 3 Residue Levels in Canola Plants (50-75% flowering; 45-62 days after planting) From Seed Treatment Application of Sulfoxaflor at Sites in Saskatchewan and Alberta, Canada

Nominal Application Rate (g a.i./100 kg seed)	Sample Matrix and Timing	N[1]	Range of Measured residues (ppb)
200	Flowers 45-62 DAP[2]	9	<LOD
200	Pollen 45-62 DAP	9	<LOD
200	Nectar 45-62 DAP	9	<LOD
N/A (soil not treated)	Soil 45-62 DAP	N/A (soil not treated)	<LOD – 0.727
Limit of Quantitation for **flowers, pollen and nectar** (LOQ) = 0.0010 ppm (1.0 ppb), Limit of Detection (LOD) = 0.00056 ppm (0.56 ppb) Limit of Quantitation for **soil** (LOQ) = 0.0010 ppm (1.0 ppb), Limit of Detection (LOD) = 0.00017 ppm (0.17 ppb) N[1] = number of treated samples DAP[2] = Days After Planting			

Table 4 Bird and Mammal Endpoints Used in the Risk Assessment for Sulfoxaflor and Rascendo (Canola, Rapeseed, and Oilseed Mustard)

Organism	Exposure	Endpoint	Value	Uncertainty factor applied	Reference
Birds					
Bobwhite quail (*Colinus virginianus*)	Acute	LD_{50} Sulfoxaflor	676 mg a.i./kg bw	10	1941481
		LD_{50} X11719474	>2250 mg/kg bw	10	1941483
Mallard duck (*Anas platyrhynchos*)	Dietary	5-day LD_{50}/NOEL* Sulfoxaflor	>1049 mg a.i./kg bw/day	1*	1941485
Mallard duck (*Anas platyrhynchos*)	Reproduction 20 week	NOAEL Sulfoxaflor	26 mg a.i./kg bw/day	1	1941487
Mammals					
Mouse	Acute	LD_{50} Sulfoxaflor	750 mg a.i./kg bw	10	1941263
Rat	Acute	LD_{50} X11719474	2000 mg a.i./kg bw	10	1941323
Rat	Reproduction 2-generation (dietary exposure)	NOAEL LOAEL	6.07 mg a.i./kg bw/day 24.6 mg a.i./kg bw/day (based on decreased pup survival in F_1 and F_2 generations)	1	1941292

*The LD_{50} of >1049 mg a.i./kg bw/day is equivalent to an NOEL as no effects were seen at that test concentration; therefore, the uncertainty factor of 10 was not applied to this toxicity value for the risk assessment.

Table 5 Seed Application Parameters

Seed	Mustard – Yellow*	
label rate (g a.i./ × kg seeds)	200 g a.i./100 kg	
amount of seeds treated (kg)	100 kg	
EEC (mg a.i./kg seeds)	2000	
Number of seeds per kg	171500	
mg a.i./seed	0.0117	
Seeding rate (kg seeds/ha)	5	11
Application rate per ha (g a.i./ha)	9.00	22.40

* According to the seed treatment data provided by the applicant, the highest rate of sulfoxaflor is 12 µg/seed and 21.6 g/ha when applied to yellow mustard seeds.

Table 6 Bird and Mammal Risk Assessment for Yellow Mustard Seeds Treated With Rascendo at the Maximum Application Rate of 400 mL of Product/100 kg Seed (200 g a.i./100 kg seed, 12 µg/seed, 21.6 g a.i./ha)

Study Endpoint (mg a.i./kg bw/day / UF)		EDE (mg a.i./kg bw/day)	RQ	Number of seeds needed to reach endpoint	Area required (m^2)		
					Broadcast - no drilling or incorporation	Standard drilling – spring*	Precision drilling*
Small bird (0.02 kg)							
Acute	67.6	507.9	8	116	0.6	18.3	121
Dietary	1049	507.9	0.5	180	0.9	28.4	187
Reproduction	26.0	507.9	20	45	0.2	7.0	46
Medium bird (0.10 kg)							
Acute	67.6	398.9	6	580	3.0	91.5	604
Dietary	1049	398.9	0.4	900	4.7	141.9	937
Reproduction	26.0	398.9	15	223	1.2	35.2	232
Large bird (1.00 kg)							
Acute	67.6	116.3	2	5797	30.2	914.5	6036
Dietary	1049	116.3	0.1	8995	46.8	1419.1	9366
Reproduction	26.0	116.3	4	2230	11.6	351.7	2321
Small mammals (0.015 kg)							
Acute	75.0	290.2	4	96	0.5	15.2	100
Reproduction	6.07	290.2	48	8	0.04	1.2	8
Medium mammals (0.035 kg)							
Acute	75.0	249.6	3	225	1.2	35.5	234
Reproduction	6.07	249.6	41	18	0.1	2.9	19
Large mammals (1.00 kg)							
Acute	75.0	137.4	2	6431	33.5	1014.6	6696
Reproduction	6.07	137.4	23	521	2.7	82.1	542

* 3.3%: Standard drilling; 0.5%: Precision drilling

[a] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where:
FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) 0.850
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) 0.651.
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(BW in g) 0.822
BW: Generic Body Weight
EEC: Concentration of pesticide on food item. At the screening level, relevant food items representing the most

conservative EEC for each feeding guild are used.
RQ = Risk Quotient = EDE/Toxicity. The RQ is compared to a level of concern (LOC) of 1; these are screening level RQs.
UF = uncertainty factor

Table 7 Mammalian Refined Reproductive Risk Assessment for Yellow Mustard Seeds Treated With Rascendo at the Maximum Application Rate of 400 mL of Product/100 kg Seed (200 g a.i./100 kg seed, 12 µg/seed, 21.6 g a.i./ha), Using an LOAEL of 24.6 mg a.i./kg bw/day for Rat (based on decreased pup survival in F_1 and F_2 generations)

	Study Endpoint (mg a.i./kg bw/day / UF)	EDE (mg a.i./kg bw/day)	LOAEL RQ	Number of seeds needed to reach endpoint	Area required to reach endpoint		
					Broadcast - no drilling or incorporation	Standard drilling - spring	Precision drilling
Small mammals (0.015 kg)	24.6	290.238	12	32	0.2	5	33
Medium mammals (0.035 kg)	24.6	249.605	10	74	0.4	11.6	77
Large mammals (1.00 kg)	24.6	137.435	6	2109	11	332.8	2196

Table 8 Pollinator Endpoints Used in the Risk Assessment for Rascendo (sulfoxaflor)

Organism	Lifestage	Exposure	Compound	Endpoint	Value (µg a.i./bee)	Reference
Honey bee, *Apis mellifera*	Adult	Acute oral	Sulfoxaflor	48-h LD_{50}	0.146	1941502
			GF-2032*	48-h LD_{50}	0.0515	1941151
			X11719474**	48-h LD_{50}	>100	1941503
			X11721061**	48-h LD_{50}	>100	2044394
		Acute contact	Sulfoxaflor	72-h LD_{50}	0.379	1941504
			GF-2032	48-h LD_{50}	0.130	1941153
	Larvae	Acute oral single dose	Sulfoxaflor	7-d LD_{50}	> 2	2219817
		Acute oral multiple dose	Sulfoxaflor	7-d LD_{50}	> 0.2	2173237
Bumble bee, *Bombus terrestris*	Adult	Acute oral	GF-2032	72-h LD_{50}	0.027	1941152
		Acute contact	GF-2032	72-h LD_{50}	7.554	1941152

*Formulation of sulfoxaflor (21.8%).
** Transformation products of sulfoxaflor.

Table 9 Tier I Default Risk Assessment: Toxicity Values, Estimated Oral Exposure and Risk Quotient (RQ) Values for Bees Based on Seed Treatment Applications

Organism	Lifestage	Exposure	Compound	Endpoint	Value (µg a.i./bee)	Oral Exposure Estimate* (µg a.i./bee)	RQ

Organism	Lifestage	Exposure	Compound	Endpoint	Value (µg a.i./bee)	Oral Exposure Estimate* (µg a.i./bee)	RQ
Honey bee *Apis mellifera*	Adult	Acute oral	Sulfoxaflor	48-h LD_{50}	0.146	0.292	**2.00**
			GF-2032**	48-h LD_{50}	0.0515	0.292	**5.67**
	Larvae	Acute oral Single dose	Sulfoxaflor	7-d LD_{50}	>2	0.124	0.06
		Acute oral Multiple dose	Sulfoxaflor	7-d LD_{50}	>0.2	0.124	0.62

*The Tier I exposure is based on the International Commission for Plant-Bee Relationships' (ICP-BR) 1 mg a.i./kg (1 µg a.i./g) concentration to represent an upper-bound concentration in nectar and pollen. This value is multiplied by the nectar consumption rate for adult worker bees (0.292 g/day) to determine the upper-bound doses potentially received by adult worker bees consuming contaminated nectar and pollen.
**Formulation of sulfoxaflor (21.8%).

Table 10 Refined Risk Assessment for Bees and Canola Seed Treated With Rascendo

Test Crop	Maximum residues in test crop (ppm)		Total daily exposure (TDE) based on food consumption [a] (µg a.i./bee/day)			RQ [e]		
	Pollen	Nectar	Forager bees [b]	Nurse bees [c]	Bee larvae [d]	Forager bees (LD_{50} of 0.0515 µg a.i./bee)	Nurse Bees (LD_{50} of 0.0515 µg a.i./bee)	Bee Larvae (LD_{50} of >2 µg a.i./bee)
Canola treated at 200 g a.i./100 kg seed	0.00028 (1/2 LOD)	0.00028 (1/2 LOD)	Nectar =8.2 × 10^{-5} Pollen = 1.1 × 10^{-8} **Combined EEC = 8.2 × 10^{-5}**	Nectar =3.9 × 10^{-5} Pollen = 2.7 × 10^{-6} **Combined EEC = 4.2 × 10^{-5}**	Nectar =3.4 × 10^{-5} Pollen = 1.0 × 10^{-6} **Combined EEC** = 3.5 × 10^{-5}	0.000082 µg a.i./bee / 0.0515 µg a.i./bee = **0.00159**	0.000042 µg a.i./bee / 0.0515 µg a.i./bee = **0.00082**	0.000035 µg a.i./bee /> 2 µg a.i./bee = **<0.000018**

[a] Total exposure is equal to the highest residue in nectar [(nectar consumption rate (mg/day) × highest nectar residue (µg/kg)/ 1.0 × 10^6)] + highest residue in pollen [(pollen consumption rate (mg/day) × highest pollen nectar residue (µg/kg)/1.0 × 10^6)]
[b] Daily consumption rate used for nectar foragers: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
[c] Daily consumption rate used for nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149 mg/day total
[d] Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total
[e] Toxicity endpoint: adult acute oral LD_{50} = 0.0515µg a.i./bee for TGAI; >2 µg a.i./bee for larvae.

Note: Level of Concern (LOC) is 0.4 for acute studies and 1 for chronic studies.

Table 11 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria.

TSMP Track 1	TSMP Track 1	Sulfoxaflor	Transformation Products

Criteria	Criterion value			X11719474	X11579457	X11519540
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes	Yes	Yes	Yes
Predominantly anthropogenic[2]	Yes		Yes	Yes	Yes	Yes
Persistence[3]	Soil	Half-life ≥ 182 days	DT_{50}: 0.05 to 0.6 d	DT_{50}: 85 to > 1000 d	DT_{50}: 96 to 670 d	DT_{50}: 71 to > 1000 d
	Water	Half-life ≥ 182 days	DT_{50}: 11 to 65 d	DT_{50}: Aerobic half-life not available. Anaerobic DT_{50} > 1000 d.	DT_{50}: Not available	DT_{50}: Not available
	Sediment	Half-life ≥ 365 days	DT_{50}: 46 to 102 d	DT_{50}: Aerobic half-life not available. No degradation in anaerobic systems.	DT_{50}: Not available	DT_{50}: Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	Estimated photochemical oxidation half-life: 7.8 h In addition, volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (<2.5 × 10^{-6} Pa) and Henry's law Constant (6.7 × 10^{-12} atm m^3/mol).	Volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (2.7 × 10^{-7} Pa) and Henry's law Constant (4.5 × 10^{-14} atm m^3/mol).	Not available	Not available
Bioaccumulation[4]	Log K_{OW} ≥ 5		0.802	< 0.3	< 0.3	< 0.3
	BCF ≥ 5000		Not available	Not available	Not available	Not available
	BAF ≥ 5000		Not available	Not available	Not available	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

[1]All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4]Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over

chemical properties (for example, log K_{OW}).

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

No new MRLs were established as a consequence of the major new use of sulfoxaflor as a seed treatment for canola, rapeseed, and oilseed mustard.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2400529	2013, Sulfoxaflor - A19103A: Document J - Product Chemistry Volume, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, Document J, IIIA 1.2.1, IIIA 1.2.2, IIIA 1.4.1, IIIA 1.4.2, IIIA 1.4.4, IIIA 1.4.5.1, IIIA 1.4.5.2, IIIA 5 CBI
2400530	2013, Sulfoxaflor - A19103A: Document H - Product Chemistry Volume, DACO: 3.2.1, Document H, Document J CBI
2400556	2012, Sulfoxaflor - A19103A: Analytical Method ST-22/1 Determination of Sulfoxaflor in Formulation Sulfoxaflor FS (500), DACO: 3.4.1, IIIA 5.2.2
2400557	2013, Sulfoxaflor - A19103A: Validation of Analytical Method ST-22/1, DACO: 3.4.1, IIIA 5.2.2
2400555	2013, Sulfoxaflor - A19103A: Physico-Chemical Studies of the Formulation, Product Chemistry Volume, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7, 8.2.2.1, 8.2.3.6, IIIA 2.1, IIIA 2.11, IIIA 2.13, IIIA 2.14, IIIA

2.0 Human and Animal Health

PMRA Document Number	Reference
2400566	2013, Sulfoxaflor FS (A19103A) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure), DACO: 4.6.1, IIIA 7.1.1
2400567	2013, Sulfoxaflor FS (A19103A) - Acute Dermal Toxicity Study in Rats, DACO: 4.6.2, IIIA 7.1.2
2400568	2013, Sulfoxaflor FS (A19103A) - Acute Inhalation Toxicity Study (Nose-Only) in the Rat, DACO: 4.6.3, IIIA 7.1.3
2400570	2013, Sulfoxaflor FS (A19103A) - Primary Skin Irritation Study in Rabbits, DACO: 4.6.5, IIIA 7.1.4
2400572	2013, Sulfoxaflor FS (A19103A) - Acute Eye Irritation Study in Rabbits, DACO: 4.6.4, IIIA 7.1.5
2400574	2013, Sulfoxaflor FS (A19103A) - Local Lymph Node Assay in the Mouse, DACO: 4.6.6, IIIA 7.1.6

2400576	2013, Sulfoxaflor (A19103A): Occupational Exposure Risk Assessment for Rascendo on Canola, Rapeseed and Oilseed Mustard, DACO: 5.10, 5.3, 5.6, 5.7, 5.9, IIIA 7.3.1, IIIA 7.3.2, IIIA 7.5.1, IIIA 7.5.2
2400577	2013, Sulfoxaflor (A19103A): Laboratory Dust-Off Data in Support of the Registration of Rascendo on Canola, Rapeseed and Oilseed Mustard, DACO: 4.6.8, 4.7.7, 4.8, 5.14, IIIA 7.11
2400579	2014, Sulfoxaflor FS (A19103A) and Sulfoxaflor WG (GF-2372) Residue Levels in Canola Seed in Canada During 2012, DACO: 7.4.1, 7.4.2, 7.4.6, IIIA 8.3.1
2400580	2014, Sulfoxaflor FS (A19103A) and Sulfoxaflor WG (A20103A) - Magnitude of the Residues in or on Rapeseed, Including Canola Varieties, from Seed Treatment Followed by Foliar Application USA 2012, DACO: 7.4.1, 7.4.2, 7.4.6, IIIA 8.3.1
1941147	2010, XDE-208: The In Vivo Percutaneous Absorption of Radiolabelled XDE-208 in Formulation (GF-2032) and Two In-Use Spray Dilutions in the Rat (OECD 427), DACO: 5.8, IIIA 7.6.1
1941148	2010, XDE 208: The In Vitro Percutaneous Absorption of Radiolabelled XDE 208 in Formulation (GF 2032) and Two In Use Spray Dilutions Through Rat and Human Skin (OECD 428), DACO: 5.8, IIIA 7.6.2

3.0 Environment

PMRA Document Number	Reference
2400581	2014, Sulfoxaflor FS (A19103A) - Residue Levels in or on Canola (Flowers, Pollen and Nectar) from Trials Conducted in Canada During 2012, DACO: 8.5, 9.2.9, 9.3.6, 9.4.7, 9.5.5, 9.6.5, 9.6.6, 9.7.2, 9.8.7, 9.9, IIIA 10.10.2

4.0 Value

PMRA Document Number	Reference
2400536	2014, Sulfoxaflor: Rascendo - Document M-III, Section 7 - Efficacy Data and Information, DACO: 10.2.3.1, 10.2.3.3, 10.2.3.4, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 12.7, Document M, IIIA 6.1.2 , IIIA 6.1.3, IIIA 6.1.4.1, IIIA 6.1.4.3, IIIA 6.2.1, IIIA 6.2.6, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3, IIIA 6.6
2400559	2014, Rascendo - Value Data Summary Table, DACO: 10.2.3.4, IIIA 6.1.3
2400560	2012, Laboratory and Field Tests to Evaluate the Efficacy of Seed Treatments for Control of Flea Beetles in Canola, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.2.1
2400561	2014, Efficacy Trial Summary: Sulfoxaflor Seed Treatment in Spring Canola to Control Flea Beetle Damage - Trial DDH1103, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.1.4.3, IIIA 6.2.1

2400562	2014, Efficacy Trial Summary: Sulfoxaflor Seed Treatment in Spring Canola to Control Flea Beetle Damage - Trial DDH1104, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.1.4.3, IIIA 6.2.1
2400563	2014, Efficacy Trial Summary: Sulfoxaflor Seed Treatment in Spring Canola to Control Flea Beetle Damage - Trial CASKOU3432013, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.1.4.3, IIIA 6.2.1
2400564	2014, Efficacy Trial Summary: Sulfoxaflor Seed Treatment in Spring Canola to Control Flea Beetle Damage - Trial CAMBOU6432013, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.1.4.3, IIIA 6.2.1
2400565	2014, Efficacy Trial Summary: Sulfoxaflor Seed Treatment in Spring Canola to Control Flea Beetle Damage - Trial CAMBOU6442013, DACO: 10.2.3.4, 10.3.2, IIIA 6.1.3, IIIA 6.1.4.3, IIIA 6.2.1
2044400	2010, Zhu, Y., Loso, M.R., Watson, G.B., Sparks, T.C., Roger, R.B., Huang, J.X., Gerwick, B.C., Babcock, J.M., Kelley, D, Hedge, V.B., Nugent, B.M., Renga, J.M., Denholm, I., Gorman, K., DeBoer, G.J., Hasler, J., Meade, T., Thomas, J.D., Discovery and Characterization of Sulfoxaflor, a Novel Insecticide Targeting Sap-Feeding Pests. Journal of Agricultural and Food Chemistry (DOI: 10.1021/jf102765x), DACO: 9.9

B. Additional Information Considered

i) Unpublished Information

1.0 Human and Animal Health

PMRA Document Number	Reference
1349637	2000, Occupational Risk Exposure Assessment for HELIX 289FS, DACO: 5.4
1571553	2008, Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy, DACO: 5.6
2396870	2013, Agricultural Handler Exposure Task Force (AHETF) - Survey Results of Commercial and Downstream Seed Treating Facilities, DACO: 5.3,5.4