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Proposed Registration Decision

PRD2024-04

Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide

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Overview

Proposed Registration Decision for Extract of *Swinglea glutinosa*

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of EcoSwing Technical and EcoSwing Botanical Fungicide, containing the technical grade active ingredient Extract of *Swinglea glutinosa*, for the control, suppression or partial suppression of common fungal diseases that reduce harvest quality and yields of these crops and fungicide resistance management on field-grown blueberry, certain pome fruits, stone fruits, berries and small fruits, cucurbit vegetables and greenhouse-grown berries and small fruits, cucurbit vegetables, stone fruits and ornamentals.

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 Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide.

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 individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ 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 value² 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, the PMRA 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.

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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of the Canada.ca website.

Before making a final registration decision on Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide, Health Canada's PMRA will consider any written comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide, 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 Extract of *Swinglea glutinosa*?

Extract of *Swinglea glutinosa* is a nonconventional contact biofungicide with a unique mode of action. It is derived from the leaves of the tropical citrus tree Tabog (*Swinglea glutinosa*), which is used for food and medicinal purposes. It acts at multiple sites in fungal pathogens to disrupt cellular integrity, leading to cell leakage, inhibition of fungal growth and the induction of plant defences.

Health considerations

Can approved uses of Extract of *Swinglea glutinosa* affect human health?

Extract of *Swinglea glutinosa* is unlikely to affect human health when it is used according to label directions.

Potential exposure to Extract of *Swinglea glutinosa* may occur through the diet (food and water) or when handling and applying 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 levels used to assess risks are established 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.

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.

In laboratory animals, Extract of *Swinglea glutinosa* is of low acute toxicity by the oral, dermal, and inhalation routes of exposure, non-irritating to the eyes and skin, and not a dermal sensitizer.

Short-term oral toxicity testing, prenatal developmental toxicity testing, genotoxicity/mutagenicity, and phototoxicity testing on Extract of *Swinglea glutinosa* were also assessed. There were no treatment related findings when animals received multiple doses of Extract of *Swinglea glutinosa*. There was no indication that the young were more sensitive than the adult animal. Extract of *Swinglea glutinosa* is not considered to be mutagenic or genotoxic and is not phototoxic.

The end-use product, EcoSwing Botanical Fungicide, is of low acute toxicity by the oral, dermal, and inhalation routes of exposure, mildly irritating to the eye, non-irritating to the skin, and not a dermal sensitizer.

The risk assessment protects against the findings noted above as well as any other potential effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal studies.

Residues in water and food

Dietary risks from food and water are acceptable.

Residues of Extract of *Swinglea glutinosa* on treated crops are possible at the time of harvest. Due to its low toxicity profile, and the rapid biodegradation postapplication, dietary exposure to Extract of *Swinglea glutinosa* present in EcoSwing Botanical Fungicide is not expected to pose a health risk when the end-use product is applied as directed by the label. Similarly, the likelihood of Extract of *Swinglea glutinosa* residues in drinking water will be low. Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

EcoSwing Botanical Fungicide is proposed as a commercial fungicide and there are no residential uses proposed. The product is proposed for use on field and greenhouse food crops, berries and small fruits, pome fruits, cucurbit vegetables and stone fruits, as well as greenhouse ornamentals. The product labels will include measures to prevent bystander exposure such as reducing spray drift, and restricting access to the treated area until sprays have dried. Residential and non-occupational exposure to EcoSwing Botanical Fungicide is expected to be low when label directions are observed. Consequently, the health risk to residents and the general public is acceptable.

Occupational risks from handling EcoSwing Botanical Fungicide

Occupational risks are acceptable when EcoSwing Botanical Fungicide is used according to the label directions, which include protective measures.

Workers handling EcoSwing Botanical Fungicide can come into direct contact with Extract of *Swinglea glutinosa* on the skin or by inhalation during mixing, loading, application, clean-up and repair.

To protect workers from exposure to EcoSwing Botanical Fungicide, the labels require workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab. In addition, workers will be required to wear protective eyewear (goggles or face shield) during open cab airblast application.

A restricted-entry interval of 4 hours, or until sprays have dried, is prescribed for all uses. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate personal protective equipment (PPE) as specified by the method of application.

The health risks to workers are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when Extract of *Swinglea glutinosa* is introduced into the environment?

When used according to label directions, environmental risks associated with Extract of *Swinglea glutinosa* and its associated end-use product, EcoSwing Botanical Fungicide, are acceptable.

Extract of *Swinglea glutinosa* would enter the environment when its end-use product, EcoSwing Botanical Fungicide, is used to control diseases in labelled crops. Extract of *Swinglea glutinosa* is derived from the leaves of a subtropical tree in the Rutaceae family commonly known as tabog. It is a natural substance that is very soluble in water and is expected to rapidly biodegrade in the environment. As such, accumulation in the environment is not expected.

Extract of *Swinglea glutinosa* is classified as practically non-toxic to non-target organisms. After a scientific review of the available information, the PMRA has concluded that the environmental risks from the proposed uses of Extract of *Swinglea glutinosa* are acceptable when EcoSwing Botanical Fungicide is used according to the label directions.

Value considerations

What is the value of EcoSwing Botanical Fungicide?

EcoSwing Botanical Fungicide, containing Extract of *Swinglea glutinosa* at a concentration of 82.0%, is a nonconventional contact commercial biofungicide that attacks targeted fungal pathogens at multiple sites.

Multi-site fungicides with unique modes of action are important elements in a fungicide resistance management strategy. For this reason, the registration of EcoSwing Botanical Fungicide will provide growers of field-grown pome fruit crops, field- and greenhouse-grown Berries and Small Fruits (CG13-07), Cucurbit Vegetables (CG9) and Stone Fruit (CG12-09) crops and greenhouse-grown ornamental crops with a product that may be used to combat several common diseases and possibly delay the development of fungicide resistance to single-site fungicides. Use of this product may also help to reduce reliance on conventional chemical alternatives. A similar fungicide product has been registered in the US since July 2018 and is listed for organic use.

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 EcoSwing Technical and EcoSwing Botanical Fungicide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The hazard signal words “CAUTION – EYE IRRITANT” are required on the principal display panel of the EcoSwing Botanical Fungicide label. Standard precautionary statements are also required on the labels to inform of the potential to cause eye irritation and to avoid contact with eyes.

Workers are required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab. In addition, workers will be required to wear protective eyewear (goggles or face shield) during open cab airblast application.

There will be a restricted-entry interval of 4 hours, or until sprays have dried. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate PPE as specified for the method of application.

To limit bystander exposure, the end-use product label requires a drift statement.

Environment

None, beyond what is already identified on the label.

Next steps

Before making a final registration decision on Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide, Health Canada's PMRA will consider any written comments received from the public in response to this consultation document up to 45 days from the date of publication (12 April 2024) of this document. Please forward all comments to Publications (contact information on the cover page of this document). 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 Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide (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. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

Extract of *Swinglea glutinosa* and EcoSwing Botanical Fungicide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Extract of <i>Swinglea glutinosa</i>
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product— EcoSwing Technical

Property	Result
Colour and physical state	Brown with green tint liquid.
Odour	Sharp odour characteristic of a plant extract.
Melting range	Not applicable.
Boiling point or range	96–98°C
Density	1.044–1.066 g/mL at 25°C
Vapour pressure	3×10^6 mPa at 25°C
Ultraviolet (UV)-visible spectrum	$\lambda_{\max} \sim 200$ nm. A very small absorbance observed above 300 nm.
Solubility in water at 20°C	> 1000 g/L

Property	Result	
Solubility in organic solvents at 25°C	Solvent	Solubility (g/L)
	n-heptane	< 10
	p-xylene	< 10
	1,2-dichloroethane	< 10
	Methanol	> 250
	Acetone	< 10
	Ethyl acetate	<10
<i>n</i> -Octanol-water partition coefficient (K_{ow})	The requirement is waived.	
Dissociation constant (pK_a)	The requirement is waived.	
Stability (temperature, metal)	Stable at ambient conditions. Avoid excessive heat.	

End-use product— EcoSwing Botanical Fungicide

Property	Result
Colour	Dark green
Odour	Characteristic odour
Physical state	Viscous liquid
Formulation type	Solution
Label concentration	82.0%
Container material and description	Ultra-high molecular weight polyethylene bottles, jugs, pail, drum and tote.
Density at 20°C	1.059–1.085 g/mL
pH of 1% dispersion in water	5.2–5.4
Oxidizing or reducing action	The end-use product is not expected to exhibit oxidizing or reducing properties.
Storage stability	The end-use product is stable when stored in ultra-high molecular weight polyethylene containers.
Corrosion characteristics	The product is not corrosive to ultra-high molecular weight polyethylene containers.
Explosibility	The end-use product is not expected to be explosive.

1.3 Directions for use

EcoSwing Botanical Fungicide is applied at a rate of 1.75 to 2.35 L/ha a maximum of 10 times per year for field uses. For greenhouse uses, it is applied at a concentration of 1.88 to 2.5 mL/L and a maximum of 10 times per crop cycle. For all uses, directions indicate preventative applications with thorough coverage by ground equipment at a re-application interval of 7–14 days.

In the field, EcoSwing Botanical Fungicide is applied to control mummy berry on blueberry, to suppress apple scab on certain pome fruit, to control brown rot/blossom blight on Stone Fruits (CG12-09) and to partially suppress grey mould/bunch rot on Berries and Small Fruits (CG13-07), Cucurbit Vegetables (CG9) and Stone Fruits (CG12-09).

In the greenhouse, EcoSwing Botanical Fungicide is applied to control powdery mildew on Cucurbit Vegetables (CG9) and to partially suppress grey mould/bunch rot on Berries and Small Fruits (CG13-07), Cucurbit Vegetables (CG9), Stone Fruits (CG12-09) and ornamentals.

1.4 Mode of action

Extract of *Swinglea glutinosa* is classified as a FRAC Group BM 01 fungicide with multiple modes of action involving cell membrane and cell wall disruption, attributable to the terpene constituents in the essential oil fraction of the leaf extract, and the induction of plant defences. Exposed fungal cells leak contents and desiccate, leading to an inhibition of fungal growth and spore germination.

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 impurities in the technical product have been validated and assessed to be acceptable.

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.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of the technical grade active ingredient, EcoSwing Technical, and the end-use product, EcoSwing Botanical Fungicide. The data package for EcoSwing Technical and EcoSwing Botanical Fungicide is considered acceptable (Appendix I, Tables 1–2) to assess the toxic effects that may result from exposure to Extract of *Swinglea glutinosa*.

The data package consisted of acute toxicity studies (acute oral, dermal and inhalation toxicity, eye and skin irritation, and dermal sensitization), short-term oral toxicity, prenatal developmental toxicity, in vitro bacterial gene mutation, in vitro mammalian gene mutation, in vivo mammalian cytogenetics, and in vitro phototoxicity studies in support of EcoSwing Technical, as well as acute toxicity studies (acute oral, dermal and inhalation toxicity, eye and skin irritation, and dermal sensitization) for EcoSwing Botanical Fungicide.

EcoSwing Technical is of low acute toxicity by the oral, dermal, and inhalation routes of exposure, non-irritating to the eyes and skin, and not a dermal sensitizer.

In a 90-day oral (gavage) toxicity study in rats, there were no treatment-related effects. The no observable adverse effects level (NOAEL) was >1000 mg a.i./kg/day, the highest dose tested.

In an oral (gavage) prenatal developmental toxicity study in rats, there were no treatment-related effects and no evidence of sensitivity of the young. The maternal and developmental NOAEL was >1000 mg a.i./kg/day, the highest dose tested.

While Extract of *Swinglea glutinosa* produced evidence of structural chromatid (not chromosome) aberrations in an in vitro mammalian cell gene mutation assay, it was not mutagenic in a reverse gene mutation assay in bacteria, and was negative in an in vivo mammalian cytogenetics assay in rats. Considering the available evidence, Extract of *Swinglea glutinosa* is not considered to be mutagenic or genotoxic.

In an in vitro phototoxicity study, there were no phototoxic effects observed at any dose level.

The end-use product, EcoSwing Botanical Fungicide, is of low acute toxicity by the oral, dermal, and inhalation routes of exposure, mildly irritating to the eye, non-irritating to the skin, and not a dermal sensitizer.

3.2 Dermal absorption

No dermal absorption studies on Extract of *Swinglea glutinosa* were provided. However, based on the physicochemical properties of the constituents in Extract of *Swinglea glutinosa*, dermal absorption is expected to be low for the majority of components. A small fraction of components may be readily absorbed.

3.3 Occupational, residential and bystander exposure and risk assessment

3.3.1 Use description

EcoSwing Botanical Fungicide is proposed as a commercial fungicide end-use product and there are no residential uses proposed. The product is proposed for use on field and greenhouse food crops, berries and small fruits, pome fruits, cucurbit vegetables and stone fruits, as well as greenhouse ornamentals.

EcoSwing Botanical Fungicide is a liquid formulation that is mixed with water and applied as a foliar spray using conventional ground spray equipment (airblast, groundboom, hand wand, and backpack sprayer). For outdoor applications, EcoSwing Botanical Fungicide is applied at a rate of 1.75–2.35 L/ha, with a minimum spray volume of 100 L/ha. For indoor applications, the product is applied at a rate of 1.88–2.5 mL/L, with a minimum spray volume of 100 L/ha. There is a re-application interval of 7–14 days, and a maximum of 10 applications per crop cycle. The product is not to be sprayed to run off.

3.3.2 Occupational exposure and risk assessment

3.3.2.1 Mixer, loader, and applicator exposure and risk assessment

When used according to label directions, occupational exposure to EcoSwing Botanical Fungicide is characterized as short- and intermediate-term in duration and is expected to occur primarily by the inhalation and dermal routes during handling, mixing, loading, and application. During clean-up and repair, occupational exposure would be primarily by the dermal route. Ocular exposure is expected to be minimal.

To protect workers from exposure to EcoSwing Botanical Fungicide during handling, mixing, loading, or applying the product by ground application equipment, workers are required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Gloves are not required during application within a closed cab. In addition, workers will be required to wear protective eyewear (goggles or face shield) during open cab airblast application.

Precautionary statements on the end-use product labels, such as the wearing of personal protective equipment (PPE), aimed at mitigating exposure are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed, which include PPE.

3.3.2.2 Postapplication exposure and risk assessment

There is a potential for post-application exposure to workers entering areas treated with EcoSwing Botanical Fungicide. Given the nature of the postapplication activities typically performed (for example, scouting, harvesting, thinning and pruning), dermal contact with treated plants is possible. Workers must remain out of the treated area for 4 hours, or until sprays have dried. If early entry is required, workers must wear the appropriate PPE as specified by the application method.

Precautionary (for example, wearing of PPE) statements on the end-use product label aimed at mitigating exposure are adequate to protect workers from risk due to postapplication exposure. Consequently, the risks to workers due to post-application exposure are acceptable.

3.3.3 Residential and bystander exposure and risk assessment

There are no residential uses for EcoSwing Botanical Fungicide. While the commercial use of EcoSwing Botanical Fungicide may result in residential bystander exposure due to drift, this will be mitigated by the inclusion of a spray drift statement on the label advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Consequently, the health risks to bystanders and individuals in residential areas from the use of EcoSwing Botanical Fungicide are acceptable.

3.4 Dietary exposure assessment

3.4.1 Food

While dietary exposure to Extract of *Swinglea glutinosa* may occur through consumption of treated crops, residues are expected to be low based on the rapid biodegradation of the active ingredient after application. Furthermore, Extract of *Swinglea glutinosa* has a low toxicity profile. Consequently, when the end-use product is applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.4.2 Drinking water

Dietary exposure from drinking water is expected to be low as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of Extract of *Swinglea glutinosa*.

Health risks from residues of Extract of *Swinglea glutinosa* in drinking water are acceptable due to the low toxicity profile and limited exposure following application of EcoSwing Botanical Fungicide.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

As noted above, when the end-use product is applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.5 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Extract of *Swinglea glutinosa* is considered to be of low toxicity by the oral, dermal, and inhalation routes, and the end-use product will not be applied near, or to, drinking water. Furthermore, non-occupational exposure will be low when EcoSwing Botanical Fungicide is used as directed on the label. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of Extract of *Swinglea glutinosa*. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.6 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. While constituents of Extract of *Swinglea glutinosa* may share structural similarities to components found in essential oil-based pest control products, it is difficult to determine which constituents share a common mechanism of action as it is often not possible to fully identify and characterize the constituent(s) responsible for toxicity. However, based on the low toxicity profile of Extract of *Swinglea glutinosa* and rapid biodegradation postapplication, there is no requirement for a cumulative health risk assessment at this time.

3.7 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Dietary risk from the proposed use of Extract of *Swinglea glutinosa* is acceptable, given the low toxicity profile of Extract of *Swinglea glutinosa* and the low application rates of the end-use product. Consequently, the specification of MRLs, under the *Pest Control Products Act*, will not be required for Extract of *Swinglea glutinosa*.

3.8 Health Incident Reports

As of 1 November 2023, no human, or domestic animal incidents involving Extract of *Swinglea glutinosa* had been submitted to the PMRA.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Extract of *Swinglea glutinosa* is derived from the leaves of a subtropical tree. It is a natural substance that is very soluble in water and is expected to rapidly biodegrade in the environment. Accumulation in the environment is not expected.

4.2 Environmental risk characterization

An environmental risk assessment integrates environmental exposure and ecotoxicology information in order to estimate the potential for adverse effects to non-target species. This integration is achieved by comparing estimated environmental concentrations (EECs) to the concentrations at which adverse effects occur. The EECs are estimated using standard models considering application rate(s), and chemical and environmental fate properties, including the dissipation of the pesticide between applications.

Extract of *Swinglea glutinosa* is a non-conventional pest control product, with low toxicity to non-target organisms, that is derived from plant sources. As such, fate data were not required and Extract of *Swinglea glutinosa* was assumed to be stable in soil and water for the purposes of the environmental risk assessment. The environmental risk assessment was conducted based on the maximum cumulative application rate of ten applications of 2091 g a.i./ha, unless otherwise noted. This is a very conservative assumption that overestimates EECs given that Extract of *Swinglea glutinosa* is expected to degrade rapidly in the environment. The EECs used in the risk assessment are presented in Appendix I, Table 3.

Acute ecotoxicological data for non-target terrestrial and freshwater organisms were submitted by the applicant; a chronic study for bees was also provided (Appendix I, Table 4). In the risk assessment, toxicity endpoints were adjusted to calculate an effects metric. The effects metric accounts for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level). For characterizing acute risk, the effects metric was calculated by dividing acute toxicity values (for example, LC₅₀, LD₅₀, and EC₅₀) by an uncertainty factor (UF; for example, 10 for fish, birds and small wild mammals, 2 for aquatic invertebrates and aquatic plants, and 1 for bees and non-target terrestrial plants (when using a ER₂₅)). The effects metrics used in the risk assessment are presented in Appendix I, Table 5.

Initially, a screening level risk assessment was conducted to identify uses that do not pose a risk to non-target organisms, and groups of organisms for which there may be a potential risk. The screening level risk assessment used simple methods, conservative exposure scenarios and sensitive toxicity endpoints. A risk quotient (RQ) was calculated by dividing the EEC by the effects metric and was then compared to the level of concern (LOC). If the screening level RQ was below the LOC, risk was considered negligible, and no further risk characterization was required. If the screening level RQ was equal to, or greater than the LOC, a refined risk assessment was performed to further characterize the risk.

The refined risk assessment evaluated more realistic exposure scenarios, including consideration of spray drift to off-field sites. Refinements to the risk assessment were continued until the risk was adequately characterized or no further refinements were possible.

4.2.1 Risks to terrestrial organisms

Terrestrial organisms, such as bees, birds, wild mammals and terrestrial vascular plants could be exposed to Extract of *Swinglea glutinosa* through direct contact with spray or spray drift, contact with sprayed surfaces or from ingestion of contaminated food. The screening level risk assessment for terrestrial organisms is shown in Appendix I, Tables 5 (bees and terrestrial plants) and 6 (birds and mammals).

Bees

Extract of *Swinglea glutinosa* is to be applied to several bee-attractive crops (berries, pome fruit, cucurbits and stone fruits). Foraging bees could be exposed to Extract of *Swinglea glutinosa* spray droplets during application (contact exposure) or through the ingestion of contaminated

pollen and nectar (oral exposure). Individual flowers generally only bloom for a short period of time. As such, it is unlikely that the same forager bee would be exposed to a flower that was sprayed with Extract of *Swinglea glutinosa* multiple times. Given this, risks to bees were evaluated using the maximum single application rate to estimate the highest potential exposure.

Extract of *Swinglea glutinosa* is classified as practically non-toxic to bees on an acute basis. The screening level RQs for acute contact and chronic oral exposure (<0.05 and 0.46, respectively) were below the LOCs of 0.4 for acute exposure and 1 for chronic exposure; however, the acute oral RQ of <0.60 exceeded the LOC of 0.4.

The acute oral toxicity study was a limit test conducted at 100 µg a.i./bee. The resulting LD₅₀ value of >100 µg a.i./bee used to calculate the RQ was associated with a control-corrected adult bee mortality of 8.9%. The 10-day chronic oral bee toxicity study resulted in a no-observed effects concentration (NOEC) of ≥ 131 µg a.i./bee/day; the highest concentration tested. No test item-related effects on mortality, behaviour or food consumption were observed in the chronic study. The results of both the acute and chronic oral toxicity tests indicate that low toxicity to bees is expected at the tested concentrations. The RQ exceedance of the LOC for acute oral exposure is a mathematical artifact of the maximum concentration used in the toxicity tests rather than a toxicity concern. As such, risks to bees from the use of Extract of *Swinglea glutinosa* are considered to be negligible.

Birds and wild mammals

A screening level risk assessment was conducted to evaluate acute risks to birds and mammals based on the estimated concentration of Extract of *Swinglea glutinosa* in various food items in the diet (the estimated daily exposure). In order to estimate the concentration of Extract of *Swinglea glutinosa* in food items, a default 10-day foliar half-life was considered when calculating the cumulative foliar application rate. This accounts for dissipation of the active ingredient from plant material, which may occur through various routes including volatilization, wash-off, photolysis, abiotic and biotransformation and dilution due to plant growth.

Exposure is dependent on the body weight of the organism and the amount and type of food consumed. As such, a set of generic body weights was used to represent a range of species (20, 100, and 1000 g for birds and 15, 35, and 1000 g for mammals) and specialized feeding guilds (in other words, herbivore, frugivore, insectivore and granivore) were considered for each category of animal weights.

The screening level risk assessment evaluated a conservative exposure scenario based on:

- The maximum residue concentrations of Extract of *Swinglea glutinosa* in food items;
- A diet that is composed entirely (100%) of a particular dietary item; and
- The feeding guild assumed to have the highest exposure for each animal weight category.

If a concern was identified at the screening level (in other words, RQ > LOC of 1), the risk was then further characterized.

Extract of *Swinglea glutinosa* is classified as practically non-toxic to birds and mammals. The acute RQs of ≤ 0.98 for all mammal sizes were below the LOC of 1. The acute RQs for small and medium birds (RQs of < 1.95 and < 1.52 , respectively) slightly exceeded the LOC of 1. No treatment-related effects were observed at the highest concentration tested in the acute oral and acute dietary toxicity tests for birds (in other words, endpoints were empirically determined to be greater than 2250 and 1616 mg a.i./kg bw for the acute oral and dietary studies, respectively). Furthermore, it is unlikely that the diets of these animals would be composed 100% of items contaminated with Extract of *Swinglea glutinosa*, particularly given that it is expected to rapidly degrade in the environment. As such, the screening level risk assessment is considered to overestimate risk to these organisms. Risks to birds and wild mammals from the use of Extract of *Swinglea glutinosa* are considered to be negligible.

Non-target terrestrial plants

The screening level risk assessment for non-target terrestrial plants considered risk due to a direct overspray of Extract of *Swinglea glutinosa*. Two approaches were used to determine EECs for the screening level risk assessment for terrestrial plants:

- (1) For seedling emergence, the maximum cumulative application rate to soil was considered; and,
- (2) For vegetative vigour, the cumulative foliar application rate was used.

The RQs of 1.25 and < 2.79 for seedling emergence and vegetative vigour exceeded the LOC of 1.

Given that the RQs in the screening level risk assessment exceeded the LOC, risks to non-target terrestrial plants were further characterized. As discussed above, the cumulative application rates overestimate the EECs because Extract of *Swinglea glutinosa* is expected to rapidly degrade in the environment. The maximum single application rate (2091 g a.i./ha), which is more representative of the actual exposure of non-target terrestrial plants, was used to refine the on-field risk estimates. Additionally, off-field risk estimates were evaluated by considering spray drift deposition of EcoSwing Botanical Fungicide one-metre downwind from the point of application (11% spray drift for field sprayer application using fine-sized droplets). Off-field RQs were calculated based on the cumulative application rates to provide an upper bound (worst-case scenario) on the risk estimates.

The on-field RQs based on the maximum single application rate and the off-field RQs based on the cumulative application rates were below the LOC of 1 (≤ 0.50 and < 0.31 , respectively; Appendix I, Table 7) for both seedling emergence and vegetative vigour. Risks to non-target terrestrial plants are considered to be negligible when considering the conservative assumptions used in the screening level risk assessment, the more realistic on-field exposure scenario and the negligible off-field risk using a worst-case scenario.

4.2.2 Risks to aquatic organisms

Aquatic organisms, such as invertebrates, fish, amphibians and aquatic plants could be exposed to Extract of *Swinglea glutinosa* if spray drift or runoff enter aquatic habitats. For the screening level risk assessment, EECs in surface water were calculated based on a direct overspray to a one-hectare wetland at the maximum cumulative application rate. Water bodies of two different depths were evaluated: an EEC in surface water 15-cm deep was used to determine risk to amphibians while an EEC at an 80-cm depth was used to evaluate risks to all other aquatic organisms.

Extract of *Swinglea glutinosa* is classified as practically non-toxic to aquatic organisms. In the screening level risk assessment (Appendix I, Table 5), risks to non-target aquatic organisms were negligible (RQs ≤ 0.25), with the exception of amphibians.

The RQ for amphibians (< 1.32) marginally exceeded the LOC of 1. This RQ was calculated using a fathead minnow endpoint as a surrogate. Extract of *Swinglea glutinosa* is classified as practically non-toxic to the fathead minnow. No treatment-related effects were observed in the fathead minnow toxicity study (in other word, the endpoint was empirically determined to be greater than the highest concentration tested). Additionally, the RQ was calculated without considering dissipation of the active ingredient between applications which also likely overestimates the risk because this product is expected to rapidly degrade in the environment. As with non-target terrestrial plants, risks were further characterized to consider both a more realistic exposure scenario (the maximum single application rate) as well as a worst-case scenario for off-field spray drift (11% spray drift of the maximum cumulative application rate to water). The RQs for both scenarios were < 0.15 , below the LOC of 1. When considering the conservative assumptions used in the screening level risk assessment and the results of the refined assessment, risks to amphibians from the use of Extract of *Swinglea glutinosa* are negligible.

4.2.3 Incident reports

As of 1 November 2023, no environment incidents reports involving Extract of *Swinglea glutinosa* had been submitted to the PMRA.

5.0 Value

Field blueberry efficacy trials conducted in the US and field and greenhouse cucumber efficacy trials conducted in Canada and Italy established that EcoSwing Botanical Fungicide has activity at the level of control ($> 80\%$ reduction of disease symptoms) against mummy berry on field-grown blueberry and powdery mildew on greenhouse cucurbit vegetables.

Apple field efficacy trials conducted in Poland, Greece and Germany and nectarine, peach and apricot field efficacy trials conducted in Greece and Italy established that EcoSwing Botanical Fungicide has activity at the level of suppression (60-80% reduction of disease symptoms) against apple scab on field-grown pome fruit and brown rot/blossom blight on field-grown stone fruit.

Raspberry and grape field efficacy trials and strawberry, geranium, diascia and cyclamen greenhouse efficacy trials established that EcoSwing Botanical Fungicide has activity at the level of partial suppression (significant disease management with < 60% reduction of disease symptoms) against grey mould/bunch rot. Because grey mould/bunch rot is a host non-specific disease, it is reasonable to expect that EcoSwing Botanical Fungicide will also partially suppress this disease on field- and greenhouse-grown berries and small fruits, cucurbit vegetables, stone fruits and greenhouse ornamentals.

EcoSwing Botanical Fungicide will provide commercial growers of the listed crops with an effective nonconventional multi-site biofungicide product with a new mode of action to combat common and challenging diseases and manage fungicide resistance to registered active ingredients. Use of this product may help to reduce reliance on conventional chemical alternatives. Also, as EcoSwing Botanical Fungicide was identified as a potential solution to manage mummy berry on highbush blueberry, apple scab on apple and grey mould/bunch rot on sweet cherry at the 2022 Minor Use Priority Setting Workshop, the registration of these uses will provide growers of these minor crops with an anticipated disease management solution. Finally, as Agriculture and Agri-Food Canada is working to support the expansion of berry crop production in protected environments to provide alternatives to US berry imports, the registration of EcoSwing Botanical Fungicide for use against grey mould/bunch rot on greenhouse berries and small fruits would complement this initiative.

6.0 Pest Control Product Policy considerations

6.1 Assessment of the active ingredient under the Toxic Substances Management Policy

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, Extract of *Swinglea glutinosa* and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that Extract of *Swinglea glutinosa* and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Appendix I, Table 8 for further information on the TSMP assessment.

⁵ 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 product are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁶

The list is used as described in the PMRA Science Policy Note SPN2020-01⁷ and is based on existing policies and regulations, including the *Toxic Substance Management Policy and Formulants Policy*,⁸ 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*).

The PMRA has reached the conclusion that EcoSwing Technical and the end-use product, EcoSwing Botanical Fungicide, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health 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 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of EcoSwing Technical and EcoSwing Botanical Fungicide, containing the technical grade active ingredient Extract of *Swinglea glutinosa*, for the control, suppression or partial suppression of common fungal diseases that reduce harvest quality and yields of these crops and fungicide resistance management on field-grown blueberry, certain pome fruits, stone fruits, berries and small fruits, cucurbit vegetables and greenhouse-grown berries and small fruits, cucurbit vegetables, stone fruits and ornamentals.

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.

⁶ 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*.

⁷ PMRA'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*

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

List of abbreviations

♀	female
♂	male
λ	wavelength
μg	microgram
μm	micron
°C	degrees centigrade
a.i.	active ingredient
bw	body weight
BAF	bioaccumulation factor
BCF	bioconcentration factor
CAS	Chemical Abstracts Service
CG	Crop Group
cm	centimetres
CEPA	<i>Canadian Environmental Protection Act</i>
d	day
DIR	Directive
EC ₅₀	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ER ₂₅	effective rate for 25% of the population
FIR	food ingestion rate
FRAC	Fungicide Resistance Action Committee
g	gram
g/ml	gram per millilitre
GSD	geometric standard deviation
h	hour(s)
ha	hectare
HDT	highest dose tested
HPLC	high performance liquid chromatography
hr(s)	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
kDa	kiloDalton
kg	kilogram
<i>K</i> _{ow}	<i>n</i> -octanol-water partition coefficient
L	litre
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOC	level of concern
LOEC	low observed effect concentration
MAS	maximum average score
MIS	maximum irritation score
mg	milligram
mL	millilitre
MAS	maximum average irritation score
MIS	maximum irritation score

MMAD	mass median aerodynamic diameter
MRLs	maximum residue limits
MW	molecular weight
n/a	not applicable
nm	nanometres
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no-observed effect dose
NOEDD	no-observed effect dietary dose
NOER	no observed effect rate
NZW	New Zealand white
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
RQ	risk quotient
SPN	Science Policy Note
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and figures

Table 1 Toxicity profile of EcoSwing Technical containing Extract of *Swinglea glutinosa*

(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 No.	Study results
Acute toxicity studies	
Acute oral toxicity Sprague Dawley rats PMRA No. 3302797	LD ₅₀ > 5000 mg/kg bw No clinical signs of toxicity. Low acute toxicity
Acute dermal toxicity Sprague Dawley rats PMRA No. 3302798	LD ₅₀ > 5000 mg/kg bw No clinical signs of toxicity. Low acute toxicity
Acute inhalation toxicity (nose-only) Sprague Dawley rats PMRA No. 3302799	LC ₅₀ > 5.08 mg/L Clinical signs of toxicity included irregular respiration in all rats upon removal from the exposure tube. Symptoms resolved by Day 4. MMAD: 2.35, 2.10 µm; GSD: 2.18, 2.09 µm Low acute toxicity
Primary Eye irritation NZW rabbits PMRA No. 3302800	MAS (24, 48, 72 hr) = 0 MIS = 0 Non-irritating
Primary Skin irritation NZW rabbits PMRA No. 3302801	MAS = 0 MIS = 0 Non-irritating

Study type/ Animal/PMRA No.	Study results
Dermal sensitization (Buehler method) Guinea pig, Harley albino PMRA No. 3302802	Negative
Short-term toxicity studies	
90-day oral toxicity study (gavage) (2016) Sprague Dawley rats PMRA No. 3302803	NOAEL (♂/♀) > 1000 mg/kg bw/day No adverse effects up to HDT
Developmental/Reproductive toxicity studies	
Prenatal developmental toxicity (gavage) (2016) Sprague Dawley rats PMRA No. 3302806	Maternal NOAEL > 1000 mg/kg bw/day No adverse effects up to HDT Developmental NOAEL > 1000 mg/kg bw/day No adverse effects up to HDT No evidence of sensitivity of the young.
Genotoxicity studies	
Bacterial reverse mutation assay (2016) <i>S. typhimurium</i> (TA1535, TA1537, TA98 and TA100); E.coli (WP2 uvrA) PMRA No. 3302805	Negative ± metabolic activation Tested up to a limit concentration
In vitro mammalian gene mutation (2016)	Positive ± metabolic activation Evidence of structural chromatid (not chromosome) aberrations induced over background.

Study type/ Animal/PMRA No.	Study results
Chromosome aberration assay, Chinese hamster ovary (CHO) cells PMRA No. 3302808	
In vivo mammalian cytogenetics (gavage) (2017) Erythrocyte Micronucleus Assay Sprague Dawley rats PMRA No. 3302809	Negative Tested up to a limit concentration
Other Studies	
In Vitro Phototoxicity Test (2019) 3T3 BALB/c 3T3 cells PMRA No. 3302810	Negative

Table 2 Toxicity profile of EcoSwing Botanical Fungicide

(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 No.	Study results
Acute oral toxicity Rat, Sprague Dawley (♀) PMRA No. 3303464	LD ₅₀ > 5000 mg/kg bw Clinical signs included ano-genital staining on Day 1 and irregular respiration with recovery by day 4. Low acute toxicity
Acute dermal toxicity	LD ₅₀ > 2000 mg/kg bw No clinical signs of toxicity

Study type/ Animal/PMRA No.	Study results
Rat, Sprague Dawley PMRA No. 3303465	Low acute toxicity
Acute inhalation toxicity (nose-only) Rat, Sprague Dawley PMRA No. 3303467	LC ₅₀ > 5.08 mg/L No clinical signs of toxicity Low acute toxicity
Primary eye irritation Rabbit, New Zealand White (♀) PMRA No. 3303468	MAS (24, 48, and 72 hr) = 9.10 MIS = 19.30 (at 24 h) Corneal opacity and positive conjunctivitis at 24 hr. All signs of ocular irritation resolved by Day 7. Mildly irritating
Primary skin irritation Rabbit, New Zealand White (♂) PMRA No. 3303469	MAS = 0 MIS = 0 Non-irritating
Dermal sensitization (LLNA) CBA/J mice (♀) PMRA No. 3303471	Negative

Table 3 EECs for Extract of *Swinglea glutinosa* in the environment

EEC	Method of calculation	Notes
Cumulative application rate: Screening level risk assessment		
20 910 g a.i./ha	Cumulative application rate to soil and water based on 10×2091 g a.i./ha. Extract of <i>Swinglea glutinosa</i> was considered to be stable in soil and water (no dissipation between applications considered).	Used in the screening level risk assessment to evaluate risks to non-target terrestrial plants (seedling emergence).
5398 g a.i./ha	Cumulative application rate on plant surfaces based on 10×2091 g a.i./ha, with a 7-day re-application interval, considering a default foliar half-life of 10 days.	Used in the screening level risk assessment to evaluate risks to birds and mammals and non-target terrestrial plants (vegetative vigour).
Cumulative application rate: Refined risk assessment (Spray drift)		
2300 g a.i./ha	Off-field EEC based on the cumulative soil application rate and considering 11% spray drift deposition of fine sized droplets 1-metre downwind of the point of application (field sprayer application).	Used in the refined risk assessment to evaluate off-field risks to non-target terrestrial plants (seedling emergence).
594 g a.i./ha	Off-field EEC based on the cumulative foliar application rate and considering 11% spray drift deposition of fine sized droplets 1-metre downwind of the point of application (field sprayer application).	Used in the refined risk assessment to evaluate off-field risks to non-target terrestrial plants (vegetative vigour).
Single application rate: Refined risk assessment		
2091 g a.i./ha	Maximum single application rate	Used in the refined risk assessment to evaluate risks to non-target plants.

EEC		Method of calculation	Notes
Water			
15 cm	80 cm		
13.94 mg a.i./L	2.614 mg a.i./L	For the screening level risk assessment, the EEC in surface water was calculated considering a direct overspray of Extract of <i>Swinglea glutinosa</i> to a one-hectare wetland with depths of 15 and 80 cm at the above cumulative application rate (20 910 g a.i./ha) to water.	The EECs in surface water at 15-cm depth were used to determine risk to amphibians while the 80-cm depth EECs were used to evaluate risks to all other aquatic organisms.
1.39 mg a.i./L	Not required	For the refined risk assessment for amphibians, the EEC in 15-cm deep surface water was calculated considering a single direct overspray of Extract of <i>Swinglea glutinosa</i> .	
1.53 mg a.i./L		For the refined risk assessment for amphibians, the off-field EEC was calculated based on the cumulative application rate and considering 11% spray drift deposition from the field sprayer application of fine sized droplets 1-metre downwind of the point of application.	
Bee Matrices			
59.84 µg a.i./bee (adult)		Oral exposure estimate for bees = maximum single application rate (2.091 kg a.i./ha) × adjustment factor <ul style="list-style-type: none"> Adult adjustment factor of 28.62 µg a.i./bee per kg a.i./ha was calculated as the food consumption of 0.292 g/bee per day × 98 µg a.i./g per kg a.i./ha (default tall grass residues). 	Used to evaluate risks to pollinators (bees).
5.02 µg a.i./bee		Estimated contact exposure (µg a.i./bee) = 2.4 µg a.i./bee/1 kg a.i./ha × maximum single application rate (2.091 kg a.i./ha)	
See Appendix I, Table 6 for the estimate dietary doses for the birds and mammals risk assessment.			

Table 4 Toxicity to non-target species

Organism	Exposure ⁽¹⁾	Endpoint	Comments/Degree of toxicity ⁽²⁾	PMRA No.
Terrestrial organisms				
Invertebrates				
Honey bee (<i>Apis mellifera</i> L.)	48-h Contact	LD ₅₀ > 100 µg a.i./honey bee	Practically non-toxic	3302814
	48-h Oral	LD ₅₀ > 100 µg a.i./honey bee	N/A	
	10-d Chronic Oral	NOEDD ≥ 131 µg a.i./honey bee/day	N/A	3302815
Birds				
Bobwhite quail (<i>Colinus virginianus</i>)	Acute oral	LD ₅₀ > 2250 mg a.i./kg bw NOED ≥ 2250 mg a.i./kg bw	Practically non-toxic	3302818
	5-d Dietary	LD ₅₀ > 1612 mg a.i./kg bw NOED ≥ 1612 mg a.i./kg bw	Practically non-toxic	3302819
Mammals				
Rat (Sprague-Dawley)	Acute oral	LD ₅₀ > 5000 mg a.i./kg bw	Practically non-toxic	3302797
Non-target vascular plants				
Non-target terrestrial plants	Seedling emergence (seven species)	ER ₂₅ > 7490 g a.i./ha NOER ≥ 7490 g a.i./ha	N/A	3302823
	Vegetative vigour (dry weight, onion)	ER ₂₅ = 4329 g a.i./ha NOER = 3745 g a.i./ha ⁽³⁾	N/A	3302822
Freshwater organisms				
<i>Daphnia magna</i>	48-h Acute	EC ₅₀ = 695 mg a.i./L NOEC = 495 mg a.i./L	Practically non-toxic	3302816
Fathead minnow (<i>Pimephales promelas</i>)	96-h Acute	LC ₅₀ > 106 mg a.i./L NOEC ≥ 106 mg a.i./L	Practically non-toxic	3302817
Amphibian	96-h Acute (fathead minnow surrogate)	LC ₅₀ > 106 mg a.i./L NOEC ≥ 106 mg a.i./L	Practically non-toxic	3302817
Freshwater algae (<i>Raphidocelis subcapitata</i>)	96-h Acute	EC ₅₀ > 73.4 mg a.i./L	Practically non-toxic up to the highest	3302820

Organism	Exposure ⁽¹⁾	Endpoint	Comments/Degree of toxicity ⁽²⁾	PMRA No.
		NOEC = 36.8 mg a.i./L	concentration tested	
		LOEC = 100 mg a.i./L	Level of effect associated with the LOEC was not reported.	3302821
Freshwater algae (<i>Oscillatoria perornata</i>)	96-h Acute	LOEC = 10 mg a.i./L		
Vascular plants (<i>Lemna gibba</i>)	7-d	EC ₅₀ > 93.9 mg a.i./L NOEC = 45.5 mg a.i./L	Practically non-toxic up to the highest concentration tested	3302824

EC₅₀ = effective concentration to 50% of the population

ER₂₅ = effective rate to 25% of the population

LOEC = lowest-observed effect concentration

NOEC = no-observed effect concentration

NOED = no-observed effect dose

NOEDD = no-observed effect dietary dose

NOER = no-observed effect rate

(1) The test item was GWN-10244 (Extract of *Swinglea glutinosa*; 99.98% purity) in all cases except the algae toxicity test (PMRA No. 3302821), where the study authors extracted dried roots, leaves and stems of *S. glutinosa* in the laboratory for the purposes of their study. The purity of their test item is not reported.

(2) USEPA classification, where applicable

(3) The NOER for onion is reported here for consistency with the ER₂₅ that was used in the risk assessment; however, lettuce had a more sensitive NOER of 944 g a.i./ha with an ER₂₅ of 5513 g a.i./ha.

Table 5 Screening level risk assessment for non-target organisms

Organism	Exposure	EEC	Endpoint	UF	Effects metric	RQ	LOC	LOC exceeded?
Terrestrial organisms								
Invertebrates								
Honey bee (<i>Apis mellifera</i> L.)	48-h Contact	5.02 µg a.i./honey bee	LD ₅₀ > 100 µg a.i./honey bee	1	> 100 µg a.i./honey bee	< 0.05	0.4	No
	48-h Oral	59.8 µg a.i./honey bee	LD ₅₀ > 100 µg a.i./honey bee	1	> 100 µg a.i./honey bee	< 0.60	0.4	Yes

Organism	Exposure	EEC	Endpoint	UF	Effects metric	RQ	LOC	LOC exceeded?
	10-d Chronic Oral	59.8 µg a.i./honey bee/d	NOEDD ≥ 131 µg a.i./honey bee/day	1	≥ 131 µg a.i./honey bee/day	≤ 0.46	1	No
Non-target vascular plants								
Non-target terrestrial plants	Seedling emergence (seven species)	20,910 g a.i./ha	ER ₂₅ > 7490 g a.i./ha	1	> 7490 g a.i./ha	< 2.79	1	Yes
	Vegetative vigour (onion, dry weight)	5398 g a.i./ha	ER ₂₅ = 4329 g a.i./ha	1	4329 g a.i./ha	1.25	1	Yes
Freshwater organisms								
<i>Daphnia magna</i>	48-h Acute	2.614 mg a.i./L	EC ₅₀ = 695 mg a.i./L	2	347.5 mg a.i./L	0.008	1	No
Fathead minnow (<i>Pimephales promelas</i>)	96-h Acute	2.614 mg a.i./L	LC ₅₀ > 106 mg a.i./L	10	> 10.6 mg a.i./L	< 0.25	1	No
Amphibians	96-h Acute (fathead minnow surrogate)	13.94 mg a.i./L	LC ₅₀ > 106 mg a.i./L	10	> 10.6 mg a.i./L	< 1.32	1	Yes
Freshwater algae (<i>Raphidocelis subcapitata</i>)	96-h Acute	2.614 mg a.i./L	EC ₅₀ > 73.4 mg a.i./L	2	> 37.7 mg a.i./L	< 0.07	1	No
Vascular plants (<i>Lemna gibba</i>)	7-d	2.614 mg a.i./L	EC ₅₀ > 93.9 mg a.i./L	2	> 46.95	< 0.06	1	No
Bold indicates that the RQ exceeds the LOC.								

Table 6 Screening level risk assessment for birds and mammals

Organism	Effects metric (mg a.i./kg bw/d) ⁽¹⁾	Feeding guild (food item)	EDE (mg a.i./kg bw) ⁽²⁾	RQ ⁽³⁾	LOC	LOC exceeded ?
Small bird (0.02 kg)						
Acute	>225	Insectivore	611	< 1.95	1	Yes

Organism	Effects metric (mg a.i./kg bw/d) ⁽¹⁾	Feeding guild (food item)	EDE (mg a.i./kg bw) ⁽²⁾	RQ ⁽³⁾	LOC	LOC exceeded ?
Medium-sized bird (0.1 kg)						
Acute	>225	Insectivore	477	< 1.52	1	Yes
Large-sized bird (1 kg)						
Acute	>225	Herbivore (short grass)	308	< 0.98	1	No
Small Mammal (0.015 kg)						
Acute	>500	Insectivore	253	< 0.51	1	No
Medium-sized Mammal (0.035 kg)						
Acute	>500	Herbivore (short grass)	490	< 0.98	1	No
Large-sized Mammal (1 kg)						
Acute	>500	Herbivore (short grass)	262	< 0.52	1	No
<p>Bold and shaded indicates that the RQ exceeds the LOC.</p> <p>(1) An uncertainty factor of 10 was applied to the acute oral and reproduction endpoints, respectively.</p> <p>(2) EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/bw) × EEC, where:</p> <p>FIR: Food Ingestion Rate (Nagy, 1987). 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:</p> <p>Passerine Equation (body weight < or =200 g): $FIR (g \text{ dry weight/day}) = 0.398 (bw \text{ in g})^{0.850}$</p> <p>All birds Equation (body weight > 200 g): $FIR (g \text{ dry weight/day}) = 0.648 (bw \text{ in g})^{0.651}$.</p> <p>For mammals, the “all mammals” equation was used: $FIR (g \text{ dry weight/day}) = 0.235 (bw \text{ in g})^{0.822}$</p> <p>EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.</p> <p>The EECs for birds and mammals were calculated based on 10 × 2091 g a.i./ha with a 7-day re-application interval and a default foliar half-life of 10 days.</p> <p>(3) RQs were calculated using Microsoft Excel. Values in this table have been rounded for presentation which may result in minor discrepancies in RQs calculated based on the values presented in this table.</p>						

Table 7 Refined risk assessment for non-target organisms

Organism	Exposure	EEC	Endpoint	UF	Effects metric	RQ	LOC	LOC Exceeded?
On-field: Maximum single application rate								
Non-target terrestrial plants	Seedling emergence	2091 g a.i./ha	ER ₂₅ > 7490 g a.i./ha	1	7490 g a.i./ha	<0.28	1	No

Organism	Exposure	EEC	Endpoint	UF	Effects metric	RQ	LOC	LOC Exceeded?
	(ten species)							
	Vegetative vigour (onion, dry weight)	2091 g a.i./ha	ER ₂₅ = 4329 g a.i./ha	1	4329 g a.i./ha	0.48	1	No
Amphibian	96h-Acute (fathead minnow surrogate)	1.39 mg a.i./L	LC ₅₀ > 106 mg a.i./L	10	10.6 mg a.i./L	<0.13	1	No
Off-field: 11% spray drift (field sprayer application); cumulative application rate								
Non-target terrestrial plants	Seedling emergence (ten species)	1255 g a.i./ha	ER ₂₅ > 7490 g a.i./ha	1	7490 g a.i./ha	<0.31	1	No
	Vegetative vigour (onion, dry weight)	324 g a.i./ha	ER ₂₅ = 4329 g a.i./ha	1	4329 g a.i./ha	0.14	1	No
Amphibian	96h-Acute (fathead minnow surrogate)	0.84 mg a.i./L	LC ₅₀ > 106 mg a.i./L	10	10.6 mg a.i./L	<0.15	1	No

Table 8 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active ingredient endpoints	Transformation products endpoints
CEPA toxic or CEPA toxic equivalent ¹	Yes		Yes	Extract of <i>Swinglea glutinosa</i> is a plant extract that is expected to rapidly biodegrade. Its transformation products are also expected to rapidly biodegrade in the environment.
Predominantly anthropogenic ²	Yes		Yes. The active is derived from plants; however, it does not exist in its extracted and purified form in the Canadian environment.	
Persistence ³ :	Soil	Half-life ≥ 182 days	Not available; however, Extract of Swinglea glutinosa is a plant extract that is	

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active ingredient endpoints	Transformation products endpoints
			expected to rapidly biodegrade in the environment.	
	Water	Half-life ≥ 182 days	Not available; however, Extract of <i>Swinglea glutinosa</i> was stable for up to three days in the aquatic vascular plant toxicity test (PMRA No. 3302824), after which, concentrations in the test system decreased. These results were confirmed by the algal toxicity study (PMRA No. 3302820), which showed significant decreases in the measured concentration in the test system 72 and 96 hours after treatment.	
	Sediment	Half-life ≥ 365 days	Not available; however, Extract of <i>Swinglea glutinosa</i> is a plant extract that is expected to rapidly biodegrade in the environment.	
	Air	Half-life ≥ 2 days or evidence of long range transport		
Bioaccumulation ⁴	Log $K_{ow} \geq 5$		No. Data are not available; however, the active is very water soluble (>1000 mg/L). It is not expected to bioaccumulate.	
	BCF ≥ 5000		Not available	
	BAF ≥ 5000		Not available	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	

¹ All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Active ingredient endpoints	Transformation products endpoints
<p>initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).</p> <p>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.</p> <p>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.</p> <p>⁴ When required based on the chemical’s properties, 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}).</p>			

Table 9 List of supported uses for EcoSwing Botanical Fungicide

Supported use claim
<p>Crop: Highbush blueberry, field-grown</p> <p>Disease: Mummy Berry (<i>Monilinia vaccini-corymbosi</i>)</p> <p>Application rate: 1.75–2.35 L/ha</p> <p>Application method: Ground equipment</p> <p>Spray volume: minimum 100 L/ha ground</p> <p>Maximum number of applications per year: 10</p> <p>Re-application interval (days): 7–14</p> <p>Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.</p>
<p>Crop Group: Crop Group 13-07 (Berries and Small Fruits) – field-grown</p> <p>Blackberry; blueberry, highbush; currant; gooseberry; huckleberry; loganberry; cranberry; elderberry; grape; kiwifruit, fuzzy; mulberry; raspberry (black and red); strawberry; and cultivars, varieties, and/or hybrids of these.</p> <p>Disease: Grey mould/bunch rot (<i>Botrytis cinerea</i>) (partial suppression).</p> <p>Application rate: 1.75–2.35 L/ha</p> <p>Application method: Ground equipment</p> <p>Spray volume: Minimum 100 L/ha ground.</p> <p>Maximum number of applications per year: 10</p> <p>Re-application interval (days): 7–14</p> <p>Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.</p>

Supported use claim

Crop Group: Crop Group 13-07 (Berries and Small Fruits) – greenhouse

Blackberry; blueberry, highbush; currant; gooseberry; huckleberry; loganberry; cranberry; elderberry; grape; kiwifruit, fuzzy; mulberry; raspberry (black and red); strawberry; and cultivars, varieties, and/or hybrids of these.

Disease: Grey mould/bunch rot (*Botrytis cinerea*) (partial suppression)

Application rate: 1.88–2.5 mL/L

Application method: Ground equipment

Spray volume: minimum 100 L/ha ground

Maximum number of applications per crop cycle: 10

Re-application interval (days): 7–14

Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.

Crops: Apple, crabapple, loquat, mayhaw, quince

Disease: Apple Scab (*Venturia inaequalis*) (suppression)

Application rate: 1.75–2.35 L/ha

Application method: Ground equipment

Spray volume: minimum 100 L/ha ground

Maximum number of applications per year: 10

Re-application interval (days): 7–14

Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.

Crop Group: Crop Group 9 (Cucurbit Vegetables) – field-grown

Chayote, Chinese wax gourd, Citron melon, Cucumber, Gherkin, Gourd (edible), Muskmelon, Pumpkin, Squash (summer and winter), Watermelon

Disease: Grey mould (*Botrytis cinerea*) (partial suppression)

Application rate: 1.75–2.35 L/ha

Application method: Ground equipment

Spray volume: minimum 100 L/ha ground

Maximum number of applications per crop cycle: 10

Re-application interval (days): 7–14

Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.

Supported use claim
<p>Crop Group: Crop Group 9 (Cucurbit Vegetables) – greenhouse Chayote, Chinese wax gourd, Citron melon, Cucumber, Gherkin, Gourd (edible), Muskmelon, Pumpkin, Squash (summer and winter), Watermelon</p> <p>Disease: Grey mould (<i>Botrytis cinerea</i>) (partial suppression), powdery mildew (<i>Golovinomyces orontii</i>)</p> <p>Application rate: 1.88–2.5 mL/L</p> <p>Application method: Ground equipment</p> <p>Maximum number of applications per crop cycle: 10</p> <p>Re-application interval (days): 7–14</p> <p>Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.</p> <p>Spray volume: minimum 100 L/ha ground</p>
<p>Crop Group: Crop Group 12-09 (Stone Fruits): apricot, cherry (sweet and tart), nectarine, peach, plum (Chickasaw, damson, Japanese), plumcot, prune – field-grown</p> <p>Disease: Brown Rot / Blossom Blight (<i>Monilinia fructicola</i> / <i>Monilinia laxa</i>) (suppression), grey mould/bunch rot (<i>Botrytis cinerea</i>) (partial suppression)</p> <p>Application rate: 1.75–2.35 L/ha</p> <p>Application method: Ground equipment</p> <p>Spray volume: minimum 100 L/ha ground</p> <p>Maximum number of applications per year: 10</p> <p>Re-application interval (days): 7–14</p> <p>Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.</p>
<p>Crop Group: Crop Group 12-09 (Stone Fruits): apricot, cherry (sweet and tart), nectarine, peach, plum (Chickasaw, damson, Japanese), plumcot, prune – greenhouse</p> <p>Disease: Grey mould/bunch rot (<i>Botrytis cinerea</i>) (partial suppression)</p> <p>Application rate: 1.88–2.5 mL/L</p> <p>Application method: Ground equipment</p> <p>Spray volume: Minimum 100 L/ha ground</p> <p>Maximum number of applications per crop cycle: 10</p> <p>Re-application interval (days): 7–14</p> <p>Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.</p>

Supported use claim

Crop Group: Greenhouse Ornamentals: ornamental plants, shrubs, and trees such as amaranthus, ash, aster, azalea, birch, caladium, carnation, cedar, chrysanthemum, cypress, dahlia, daisy, dogwood, elm, ferns, ficus, fuchsia, gardenia, impatiens, iris, ivy, jasmine, juniper, lilac, lilies, maple, marigold, oak, philodendron, pine, poinsettia, rose, spruce, zinnia

Disease: Grey mould (*Botrytis cinerea*) (partial suppression)

Application rate: 1.88–2.5 mL/L

Application method: Ground equipment

Spray volume: Minimum 100 L/ha ground, ensure thorough coverage

Maximum number of applications per crop cycle: 10

Re-application interval (days): 7–14

Application timing: Preventative. Repeat application if measurable rain occurs within two to three hours of spraying.

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