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Proposed Registration Decision

PRD2021-08

Oriental Mustard Seed Meal and MustGrow Crop Biofumigant

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Table of Contents

Overview	1
Proposed registration decision for oriental mustard seed meal	1
What does Health Canada consider when making a registration decision?	1
What is Oriental Mustard Seed Meal?.....	2
Health considerations	2
Environmental considerations	4
Value considerations.....	5
Measures to minimize risk.....	5
Next steps	6
Other information	6
Science Evaluation.....	7
1.0 The Active Ingredient, Its Properties and Uses	7
1.1 Identity of the Active Ingredient	7
1.2 Physical and chemical properties of the active ingredient and end-use product	7
1.3 Directions for use.....	8
1.4 Mode of action.....	9
2.0 Methods of analysis	9
2.1 Methods for analysis of the active ingredient.....	9
2.2 Method for formulation analysis	9
2.3 Methods for residue analysis	9
3.0 Impact on human and animal health	9
3.1 Toxicology summary.....	9
3.2 Occupational, residential and bystander exposure and risk assessment	9
3.2.1 Dermal absorption.....	9
3.2.2 Use description.....	10
3.2.3 Mixer, loader, and applicator exposure and risk.....	10
3.2.4 Postapplication exposure and risk.....	11
3.2.5 Residential and bystander exposure and risk	11
3.3 Food residue exposure assessment	11
3.3.1 Food	11
3.3.2 Drinking water	11
3.3.3 Acute and chronic dietary risks for sensitive subpopulations.....	12
3.3.4 Aggregate exposure and risk.....	12
3.3.5 Cumulative exposure and risk.....	12
3.3.6 Maximum residue limits	13
3.4 Health incident reports.....	13
4.0 Impact on the environment	13
4.1 Fate and behaviour in the environment	13
4.2 Environmental risk characterization.....	13
4.3 Environmental incident reports	14
5.0 Value	14

6.0	Pest control product policy considerations	14
6.1	Toxic Substances Management Policy considerations	14
6.2	Formulants and contaminants of health or environmental concern.....	15
7.0	Proposed regulatory decision	16
	List of Abbreviations	17
Appendix I	Tables and Figures	18
Table 1	List of supported uses	18
	References	19

Overview

Proposed registration decision for oriental mustard seed meal

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 MPT Mustard Seed Meal Technical and MustGrow Crop Biofumigant, containing the technical grade active ingredient oriental mustard seed meal, to suppress soil-borne *Pythium* spp., soil-borne *Fusarium* spp., verticillium wilt, and root knot nematodes on cannabis and industrial hemp grown outdoors, in greenhouses, indoors or in high tunnels.

Oriental Mustard Seed Meal is currently registered to suppress certain nematodes and soil-borne fungi on various field crops and outdoor ornamentals. For details, see Proposed Registration Decision PRD2011-23, *Oriental Mustard Seed Meal*, and Registration Decision RD2012-03, *Oriental Mustard Seed Meal*.

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 oriental mustard seed meal and MustGrow Crop Biofumigant.

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 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 special 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) as well as 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 the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the [Pesticides section](#) of Canada.ca.

Before making a final registration decision on oriental mustard seed meal and MustGrow Crop Biofumigant, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on oriental mustard seed meal and MustGrow Crop Biofumigant, 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 Oriental Mustard Seed Meal?

Oriental mustard seed meal is the remainder of the seed tissue of oriental mustard seed (*Brassica juncea*) extracted for mustard oil. Oriental mustard seed meal contains high levels of glucosinolates, which hydrolyze into isothiocyanates. Oriental mustard seed meal is the active ingredient in the end-use product, MustGrow Crop Biofumigant, which is registered to suppress certain nematodes and soil-borne fungi on various field crops and outdoor ornamentals.

Health considerations

Can approved uses of Oriental Mustard Seed Meal affect human health?

Oriental Mustard Seed Meal is unlikely to affect human health when it is used according to label directions.

Potential exposure to oriental mustard seed meal may occur when handling and applying the product. Postapplication exposure to the pesticidal active component, allyl isothiocyanate (AITC), is possible while the treated soil is being watered and before it degrades or volatilizes from the soil. 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.

MPT Mustard Seed Meal Technical, containing oriental mustard seed meal, is considered to be of low acute toxicity by the oral and dermal routes, mildly irritating to the eyes and slightly irritating to the skin. It is a potential respiratory irritant and a skin sensitizer. Mustard is also considered to be a priority allergen by Health Canada.

Publicly available literature indicates that the degradation product, AITC, is highly acutely toxic by the oral, dermal and inhalation routes. It is considered to be a severe eye and skin irritant, and some studies have shown skin sensitization potential.

MustGrow Crop Biofumigant is considered to be toxicologically equivalent to MPT Mustard Seed Meal Technical and is considered to be of low acute toxicity by the oral and dermal routes, mildly irritating to the eyes and slightly irritating to the skin. It is a potential respiratory irritant and a skin sensitizer.

Residues in water and food

Dietary risks from food and water are acceptable.

Mustard is used for culinary purposes worldwide. MustGrow Crop Biofumigant is not applied directly to crops, and both oriental mustard seed meal and AITC are expected to rapidly degrade in the soil environment. Consumer exposure to oriental mustard seed meal and AITC is not expected based on the proposed use pattern. In addition, the likelihood of oriental mustard seed meal and AITC residues in drinking water will be low. Consequently, health risks 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.

MustGrow Crop Biofumigant is registered for use on food crops and proposed for use on cannabis and industrial hemp (for cannabinoid/cannabidiol (CBD) extraction), grown outdoors, in greenhouses, indoors or in high tunnels. The product label will include measures to reduce bystander exposure such as preventing access to the soil for 24 hours after watering and keeping unprotected persons out of the treated areas for 14 days in order to mitigate risks associated with exposure to the end-use product and AITC. Residential and non-occupational exposure to MustGrow Crop Biofumigant is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Occupational risks from handling mustgrow crop biofumigant

Occupational risks are acceptable when MustGrow Crop Biofumigant is used according to the label directions, which include protective measures.

Workers handling MustGrow Crop Biofumigant can come into direct contact with oriental mustard seed meal and AITC on the skin or by inhalation. Soil is treated 14 days before planting activities. To protect workers from exposure to MustGrow Crop Biofumigant during loading and application of product to the soil, the label requires workers performing these activities to wear long sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, and NIOSH approved respirator with any N-95 filter or a NIOSH approved powered air-purifying respirator with an HE filter for biological products. Immediately after application, treated soil is watered. If present during watering, the applicator is required to wear long sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, protective eyewear (goggles or face shield) and a full-face respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides. There is a restricted-entry interval (REI) of 24 hours after watering and unprotected persons must be kept out of the treated areas for 14 days. Soil intended for cultivation of cannabis and industrial hemp (for cannabinoid/CBD extraction), grown in greenhouses, indoors or in high tunnels, must be treated in an isolated outdoor area and the applicator is required to verbally warn workers of the application and post notification signs around the treatment area to prevent access for 14 days.

The occupational risks are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when Oriental Mustard Seed Meal is introduced into the environment?

When MustGrow Crop Biofumigant, containing oriental mustard seed, is used according to the label, the risks to the environment are acceptable.

Oriental mustard seed meal and the associated secondary compound allyl isothiocyanate are derived from a naturally occurring substance. Oriental mustard seed meal and allyl isothiocyanate are not expected to build-up in the environment, and exposure to non-target organisms is expected to be low. When used as a soil fumigant as per the label directions, the product MustGrow Crop Biofumigant is expected to pose acceptable risks to the environment.

Value considerations

What is the value of MustGrow Crop Biofumigant?

MustGrow Crop Biofumigant suppresses the listed soil-borne pathogens and nematodes on cannabis and industrial hemp grown outdoors, in greenhouses, indoors or in high tunnels.

MustGrow Crop Biofumigant is a biological product that will provide cannabis and hemp growers with an alternative fungicide product to manage certain soil-borne pests and root knot nematodes.

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 MPT Mustard Seed Meal Technical and MustGrow Crop Biofumigant to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The signal words “CAUTION – EYE IRRITANT”, “POTENTIAL SKIN SENSITIZER” and “WARNING: Contains the allergen mustard” are required on the principal display panels of the labels for MPT Mustard Seed Meal Technical and MustGrow Crop Biofumigant. Standard hazard and precautionary statements are also required on the technical grade active ingredient label and the end-use product label to inform workers of the potential for eye, skin and respiratory irritation, and skin sensitization of the product.

Workers handling and applying MustGrow Crop Biofumigant, will be required to wear standard personal protective equipment (PPE) including long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, protective eyewear (goggles or face shield) and a NIOSH approved respirator with any N-95 filter or a NIOSH approved powered air-purifying respirator with an HE filter for biological products. If present during watering, the applicator is required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, protective eyewear (goggles or face shield) and a full-face respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides. There is a restricted-entry interval of 24 hours after applying water to the treated soil.

Soil intended for cannabis and industrial hemp (for cannabinoid/CBD extraction), grown in greenhouses, indoors or in high tunnels, must be treated in an isolated outdoor area. The applicator is required to verbally warn workers of the application and post notification signs around the treatment area to prevent access for 14 days.

Unprotected persons must be kept out of the treated areas for 14 days after watering for all uses.

Environment

A precautionary label statement related to greenhouse effluent is required.

Next steps

Before making a final registration decision on oriental mustard seed meal and MustGrow Crop Biofumigant, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada 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). 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 the Health Canada makes its registration decision, it will publish a Registration Decision on oriental mustard seed meal and MustGrow Crop Biofumigant (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.

Science Evaluation

Oriental Mustard Seed Meal and MustGrow Crop Biofumigant

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Oriental mustard seed meal (<i>Brassica juncea</i>)
Function	Fungicide, Nematicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable. The product is a mixture of complex components
2. Chemical Abstracts Service (CAS)	Not applicable. The product is a mixture of complex components
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—MPT Mustard Seed Meal Technical

Property	Result
Colour and physical state	Yellow brown, solid
Odour	Mild mustardy odour
Melting range	Not applicable
Boiling point or range	Not applicable
Specific gravity	0.62
Vapour pressure at 20°C	Not applicable
Henry's law constant at 20°C	Not applicable

Property	Result
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	Not applicable
Solubility in organic solvents at 20°C (g/100 mL)	Not applicable
<i>n</i> -Octanol-water partition coefficient (K_{OW})	Not applicable
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	The product is stable, provided it is not exposed to water, an open flame, electrical or static sparks, sparks from welding equipment and strong oxidizers.

End-use product—MustGrow Crop Biofumigant

Property	Result
Colour	Yellow brown
Odour	Slightly pungent mustard odour
Physical state	Solid
Formulation type	Pellet (PE)
Guarantee	100%
Container material and description	High density polyethylene (HDPE) Plastic bags or jugs, 4 kg – 500 kg
Specific gravity	0.63
pH of 10% dispersion in water	4.81
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is expected to be stable for 12 months when stored in original commercial packaging as per label directions.
Corrosion characteristics	The product is not corrosive when stored in the original commercial container as per label directions.
Explosibility	The product does not contain potentially explosive components.

1.3 Directions for use

MustGrow Crop Biofumigant will be used to treat outdoor cannabis and hemp fields or for planting media used in greenhouses or indoor production. The product is applied to fields at rates between 1121–2240 kg product/ha via a calibrated spreader 14 days prior to planting.

For greenhouse or indoor use, MustGrow Crop Biofumigant is applied to loose planting mix or soil at rates between 2.21–4.42 kg product per m³. The product must be applied to planting media outdoors, after which the media is quarantined for 14 days before being moved into indoor areas and prepared for planting of seeds or transplants.

1.4 Mode of action

Oriental mustard seed meal contains high levels of glucosinolates, which hydrolyze into isothiocyanates. Isothiocyanates are compounds which are thought to affect nematodes or certain fungi by modifying the soil microbial community, interfering with nematode reproductive cycles, inhibiting growth or resulting in direct toxicity.

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

Not applicable for this type of product.

2.2 Method for formulation analysis

Not applicable for this type of product.

2.3 Methods for residue analysis

No methods are required to quantify residues of oriental mustard seed meal and AITC because there is no direct application to the crops.

3.0 Impact on human and animal health

3.1 Toxicology summary

No additional studies or scientific information were submitted in support of the technical grade active ingredient, pesticidal active component, or end-use product for the proposed use expansion of MustGrow Crop Biofumigant. For details on the previously submitted toxicological studies and scientific information in support of this technical grade active ingredient and end-use product, see PRD2011-23, *Oriental Mustard Seed Meal*.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Dermal absorption

No information on the dermal absorption of oriental mustard seed meal from MustGrow Crop Biofumigant was submitted, but limited information on dermal absorption of AITC was provided. Based on the water solubility of AITC of 2000 mg/L at 20°C, the dermal absorption of AITC is expected to be moderate to high. However, dermal absorption of oriental mustard seed meal and AITC are expected to be limited when the precautionary statements on the label are

observed and directions for use instructions followed. Additionally, while oriental mustard seed meal is a solid meal and AITC is a gas, both are expected to rapidly degrade in the soil environment.

3.2.2 Use description

MustGrow Crop Biofumigant is a commercial end-use product currently registered as a fungicide and netamicide pre-plant soil application for food crops and as a fall soil treatment before spring planting for outdoor ornamentals. The proposed expansion of use would add the pre-plant treatment of soil intended for the cultivation of cannabis and industrial hemp (for cannabinoid/CBD extraction), grown outdoors, in greenhouses, indoors or in high tunnels, for the suppression of soil-borne *Pythium* spp., soil-borne *Fusarium* spp., and verticillium wilt and root knot nematode to the end-use product label. One application is made per season, 14 days prior to seeding or transplanting at a rate of 2240 kg end-use product/ha or 4.42 kg end-use product/m³ for *Pythium* spp., *Fusarium* spp., and verticillium wilt or 1121–2240 kg end-use product/ha or 2.21–4.42 kg/m³ for root knot nematodes.

MustGrow Crop Biofumigant must be incorporated dry into dry soil, 14 days before seeding or planting activities. For outdoor use in fields or planting beds, the end-use product, measured by weight, is added to a calibrated spreader and applied directly to soil at the appropriate rate and incorporated into the soil to a depth of 10–15 cm by raking or tilling using a disc, rotary hoe or other cultivation equipment. For greenhouses, indoors or high tunnel use (beds, containers or pots), the end-use product is added at the appropriate rate and mixed thoroughly in with dry planting mix or soil, in an isolated outdoor area.

Postapplication activities involve the immediate uniform application of water to the treated soil in order to AITC. For outdoor use in fields and planting beds, water should be applied to the treated soil until a soil depth of 10–15 cm is well moistened. For soil or potting mix intended for greenhouses, indoors or in high tunnels, the treated soil should be thoroughly watered. Soil must be left undisturbed for 14 days.

3.2.3 Mixer, loader, and applicator exposure and risk

When MustGrow Crop Biofumigant is used according to label directions, occupational exposure is characterized as short-term in duration and is primarily by the dermal and inhalation routes during loading, applying and handling (including clean-up). To protect workers from exposure to MustGrow Crop Biofumigant during loading, applying and handling, workers are required to wear a long sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, protective eyewear (goggles or face shield) and a NIOSH approved respirator with any N-95 filter or a NIOSH approved powered air-purifying respirator with an HE filter for biological products. Precautionary statements on the end-use product label, such as the wearing of 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.

3.2.4 Postapplication exposure and risk

Postapplication activities include watering the treated soil to AITC. Given the nature of the postapplication activities inhalation is the primary route of exposure with dermal exposure being possible. If present during watering, the applicator is required to wear a long sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, protective eyewear (goggles or face shield) and a full-face respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides.

All soil handling and plant cultivation activities will occur 14 days after watering.

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.

3.2.5 Residential and bystander exposure and risk

Expanding the use of MustGrow Crop Biofumigant as a pre-plant soil biofumigant for cannabis and industrial hemp (for cannabinoid/CBD extraction), grown outdoors, in greenhouses, indoors or in high tunnels is not anticipated to result in any significant residential exposure. The MustGrow Crop Biofumigant label specifies that unprotected persons must be kept out of treated areas for 14 days after watering. Adhering to label instructions will ensure that exposure to bystanders and individuals in residential areas is low. Consequently, the health risks to individuals in residential areas and bystanders are acceptable.

3.3 Food residue exposure assessment

3.3.1 Food

The proposed use pattern is not expected to result in consumer exposure since the product will not be applied directly to the consumed portions of the plants, and oriental mustard seed meal and AITC are expected to rapidly degrade in the soil environment. Therefore, 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, or domestic animals.

3.3.2 Drinking water

Oriental mustard seed meal and AITC, are expected to rapidly degrade in the soil environment. Exposure to oriental mustard seed meal and AITC from drinking water is expected to be negligible and health risks from residues in drinking water are acceptable following application of MustGrow Crop Biofumigant. The label also has the necessary mitigative measures to limit contamination of drinking water based on the proposed uses of MustGrow Crop Biofumigant.

3.3.3 Acute and chronic dietary risks for sensitive subpopulations

Calculations of acute reference doses and acceptable daily intakes are not required for oriental mustard seed meal or AITC. Based on all the available information and hazard data, oriental mustard seed meal is considered to be of low toxicity and oriental mustard seed meal and AITC are expected to rapidly degrade in the soil environment. Thus there are no threshold effects of concern. As a result, there is no need to apply uncertainty factors to account for intra- and interspecies variability, or have a margin of exposure required. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of oriental mustard seed meal or AITC including developmental effects from pre- or post-natal exposures, and cumulative effects on infants and children of this active ingredient and other registered products containing it, does not apply to this active ingredient. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of oriental mustard seed meal or AITC to human health.

3.3.4 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.

Oriental mustard seed meal is considered to be of low acute toxicity by the oral and dermal routes, is mildly irritating to the eyes and slightly irritating to the skin. It is a potential respiratory irritant and a skin sensitizer. AITC, the pesticidal active component, is highly acutely toxic by the oral, dermal and inhalation routes, is a severe eye and skin irritant, and some studies have shown skin sensitization potential. However, oriental mustard seed meal and AITC are expected to rapidly degrade in the soil environment, and are not applied directly to crops or near drinking water. Based on the relevant information, there is reasonable certainty that no harm will result from aggregate exposure of residues of oriental mustard seed meal and AITC to the general Canadian population, including infants and children, when MustGrow Crop Biofumigant is used as labelled. This includes all anticipated dietary (food and drinking water) and consumer exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.3.5 Cumulative exposure and risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Oriental mustard seed meal and the pesticidal active component, AITC, are expected to rapidly degrade in the soil environment.

Given the proposed use pattern of oriental mustard seed, and that dietary or residential exposure to oriental mustard seed meal and AITC is not expected under the proposed conditions of use, there is no requirement for a cumulative risk assessment at this time.

3.3.6 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Oriental mustard seed meal and AITC are not applied directly to the plant and both components are expected to rapidly degrade in the soil environment. Therefore, based on proposed use pattern, residues of oriental mustard seed meal and AITC are not expected to be present in the soil at the time of planting or on the crops. Consequently, the specification of an MRL under the *Pest Control Products Act* is not required.

3.4 Health incident reports

As of 15 April 2021, no human or domestic animal incident reports involving mustard seed meal had been submitted to the PMRA.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

When oriental mustard seed meal is exposed to water, the secondary compound AITC is formed, which imparts pesticidal activity. Neither oriental mustard seed meal nor AITC are expected to build up in the environment. Both compounds are expected to dissipate to negligible levels within 14 days. Further details on the environmental fate and behavior of oriental mustard seed meal can be found in PRD2011-23, *Oriental Mustard Seed Meal* and RD2012-13, *Oriental Mustard Seed Meal*.

4.2 Environmental risk characterization

The registered use pattern for oriental mustard seed meal, including soil incorporation and watering into soil, in addition to the rapid dissipation of oriental mustard seed meal and AITC, results in minimal exposure and risk to non-target organisms in the environment. Refer to PRD2011-23, *Oriental Mustard Seed Meal* for further details. Since the use on cannabis and industrial hemp as an outdoor soil fumigant is at the same application rate and frequency as the registered outdoor uses (1121–2240 kg product/ha, once per season), environmental risk is expected to remain acceptable with the outdoor uses on cannabis and industrial hemp.

The uses on cannabis and industrial hemp also include application at the same rate range to soil intended for use in greenhouses, indoors or in high tunnels; however, application to soil must still be made outdoors followed by a 14-day outdoor quarantine period prior to moving the treated soil indoors or to high tunnels for planting of seeds or transplants. The 14-day quarantine period is the same length as the registered waiting period required between application and seeding or transplanting for registered outdoor uses.

Since there is no change to the registered application rate and patterns (1121–2240 kg product/ha, once per season), and the dissipation of mustard seed meal and its secondary compound in field soils is rapid, the environmental risk posed by the cannabis and industrial hemp uses is encompassed by the registered uses. A precautionary label statement for greenhouse/indoor uses is required. The risk to non-target organisms in the environment is expected to remain acceptable.

4.3 Environmental incident reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the United States Environmental Protection Agency (USEPA) Ecological Incident Information System. Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at the [Report a Pesticide Incident](#) page on Canada.ca.

As of 12 April 2021, no environmental incident reports involving oriental mustard seed meal have been submitted to the PMRA.

5.0 Value

MustGrow Crop Biofumigant provides an alternative product for cannabis and hemp growers to preventatively manage nematodes and certain soil-borne fungi in an integrated pest management program. Data from efficacy trials and scientific rationales supported the claims of suppression of soil-borne *Pythium* spp., soil-borne *Fusarium* spp., verticillium wilt, and root knot nematodes on cannabis and industrial hemp grown outdoors, in greenhouses, indoors or in high tunnels. The supported use claims are summarized in Appendix I, Table 1.

6.0 Pest control product policy considerations

6.1 Toxic Substances Management Policy considerations

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

Canadian Environmental Protection Act. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, oriental mustard seed meal 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 oriental mustard seed meal, AITC and its transformation products do not meet all of the Track 1 criteria. Please refer to PRD2011-23, *Oriental Mustard Seed Meal* for further details on the TSMP assessment.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the technical 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 Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations, including the *Toxic Substances Management Policy*¹ and *Formulants Policy*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 conclusions:

- Technical grade oriental mustard seed meal and its end-use product MustGrow Crop Biofumigant, 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. Please refer to PRD2011-23, *Oriental Mustard Seed Meal* for further details on the assessment of formulants and contaminants.

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

⁶ SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁷ PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

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

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 MPT Mustard Seed Meal Technical and MustGrow Crop Biofumigant, containing the technical grade active ingredient oriental mustard seed meal, to suppress soil-borne *Pythium* spp., soil-borne *Fusarium* spp., verticillium wilt, and root knot nematodes on cannabis and industrial hemp grown outdoors, in greenhouses, indoors or in high tunnels.

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.

List of abbreviations

°C	degree Celsius
AITC	allyl isothiocyanate
CAS	Chemical Abstracts Service
CBD	cannabidiol
cm	centimetres
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol-water partition coefficient
L	litre
m ³	metre(s) cubed
mg	milligram
mL	millilitre
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
p <i>K</i> _a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRD	Proposed Registration Decision
RD	Registration Decision
REI	restricted-entry interval
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 List of supported uses

Supported use claim
<p>Crop: Cannabis and hemp, grown outdoors, in greenhouses, indoors or in high tunnels</p> <p>Disease or Pathogen: suppression of soil-borne <i>Pythium</i> spp., soil-borne <i>Fusarium</i> spp., and verticillium wilt (<i>Verticillium dahlia</i>)</p> <p>Application method: pre-plant application via a calibrated spreader or incorporation into the loose planting mix</p> <p>Rates: Field application: 2240 kg product/ha (or equivalent rates) applied 14 days prior to seeding or transplanting.</p> <p>Planting media: mix dry granular product with loose planting mix or soil at a rate of 4.42 kg per cubic metre of loose planting mix or soil in an outdoor space, and quarantine for 14 days before the soil is moved into indoors areas.</p>
<p>Crop: Cannabis and hemp, grown outdoors, in greenhouses, indoors or in high tunnels</p> <p>Nematode: suppression of root knot nematode (<i>Meloidogyne</i> spp.)</p> <p>Application method: pre-plant application via a calibrated spreader or incorporation into the loose planting mix.</p> <p>Rates: Field application: 1121–2240 kg product/ha (or equivalent rates) applied 14 days prior to seeding or transplanting.</p> <p>Planting media: mix dry granular product with loose planting mix or soil at a rate of 2.21-4.42 kg per cubic metre of loose planting mix or soil in an outdoor space, and quarantine for 14 days before the soil is moved into indoors areas.</p>

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

None

2.0 Human and Animal Health

PMRA Document Number

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1804921	2009, CBI Response for 12.7 Comprehensive Data Summary, DACO: 12.7 CBI
2421725	2009, CBI Response for 12.7 Comprehensive Data Summary, DACO: 12.7 CBI
3058032	2019, Updated Use Description, DACO: 5.2
3154856	2020, Clarification response, DACO: 5.2
3156310	2020, 2019-5875 DACO 5.2 clarification Sept 28, DACO: 5.2
3193534	2021, Response letter, DACO: 5.2
2421725	Borek, V. et al., 1995, Transformation of the glucosinolate-derived allelochemicals allyl isothiocyanate and allylnitrile in soil, Journal of Agricultural Food Chemistry 43:1935-40, DACO: 7.1
2421728	Gimsing AL, Kirkegaard JA., 2009, Glucosinolates and biofumigation: fate of glucosinolates and their hydrolysis products in soil, Phytochem Rev 8:299-310, DACO: 7.1
3043923	2019, Residue, DACO: 7.1

3.0 Environment

None

4.0 Value

PMRA Document Number

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3097154	2013, INPRAS 2012 NOTL AND SIMCOE, DACO: 10.2.3.3
3097155	2011, MPT 1101 TOMATO, DACO: 10.2.3.3
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3097158	2011, MPT 1115, DACO: 10.2.3.3

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3097181 2013, MPT 1353, DACO: 10.2.3.3