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Registration Decision

RD2012-13

Oriental Mustard Seed Meal

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Registration Decision for Oriental Mustard Seed Meal

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of MPT Mustard Seed Meal Technical and MPT Crop Biofumigant, containing the technical grade active ingredient oriental mustard seed meal, to suppress soil-borne nematodes and fungal pathogens on strawberries and caneberries.

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

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2011-23, *Oriental Mustard Seed Meal*. This Registration Decision² describes this stage of the PMRA's regulatory process for oriental mustard seed meal and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-23. This decision is consistent with the proposed registration decision stated in PRD2011-23.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-23, *Oriental Mustard Seed Meal* that contains a detailed evaluation of the information submitted in support of this registration.

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 acceptable³ 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 conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* " the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

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

What is Oriental Mustard Seed Meal?

Seed meal derived from oriental mustard (*Brassica juncea*) is the leftover seed tissue resulting from the extraction of mustard oil. Oriental mustard seed meal contains high levels of glucosinolates, which hydrolyze into isothiocyanates, volatile compounds chemically related to the active ingredients found in fumigants such as metam sodium (methyl isothiocyanate). Oriental mustard seed meal is the technical grade active ingredient present in MPT Crop Biofumigant, which is used to suppress soil-borne nematodes and fungal pathogens on strawberries and caneberries.

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.

Exposure to oriental mustard seed meal may occur when handling and applying the end-use product, which has an agricultural use as a biofumigant to suppress soil-borne nematodes and fungi pre-planting and post-planting for strawberries and caneberries. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, oriental mustard seed meal, is 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. Mustard is also considered to be a priority allergen by Health Canada. Cautionary statements alerting users to the potential for eye and respiratory irritation, skin sensitization and allergenicity are required on product labels.

Dermal and inhalation exposure is possible for occupational workers handling or applying the end-use product, MPT Crop Biofumigant, and for post-application workers. Therefore, personal protective equipment is required on the end-use product label to mitigate such exposure concerns. A restricted-entry interval is also required on the label, restricting access to the treated fields for bystanders and workers for 24 hours after application. Bystander exposure will also be

mitigated by keeping unprotected individuals out of the treatment areas for the duration of the treatment period.

Waivers and additional information obtained from the public domain were deemed adequate to address the potential for short-term toxicity, prenatal developmental toxicity, and genotoxicity.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Mustard is used for culinary purposes worldwide, and its degradation product allyl isothiocyanate (AITC) is used as a food additive as a flavouring agent, and as an antispoilage agent. The end-use product, MPT Crop Biofumigant, is not applied directly to food crops, and both oriental mustard seed meal and AITC are expected to rapidly degrade in the soil environment. Therefore, exposure from residues in food is likely to be minimal. Correspondingly, the presence of oriental mustard seed meal and AITC in drinking water is also expected to be negligible. In turn, the PMRA has determined that the establishment of a maximum residue limit is not required for oriental mustard seed meal.

Occupational Risks From Handling MPT Crop Biofumigant

Occupational risks are not of concern when MPT Crop Biofumigant is used according to label directions, which include protective measures.

Occupational exposure to individuals loading or applying MPT Crop Biofumigant is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Oriental Mustard Seed Meal And The Associated End-use Product MPT Crop Bio Fumigant Is Introduced Into the Environment?

Oriental mustard seed meal and the associated secondary compound AITC are derived from a naturally occurring substance. Based on our knowledge of oriental mustard seed meal and AITC, they are not expected to build-up in the environment. When used as per the label directions, as a soil fumigant, the product is expected to pose a minimal risk to non-target organisms.

Value Considerations

What Is the Value of MPT Crop Biofumigant?

MPT Crop Biofumigant is a non-conventional biofumigant that suppresses economically important nematodes and fungal pathogens on strawberries and caneberries.

Fungal diseases suppressed by MPT Crop Biofumigant include red stele (*Phytophthora fragariae*) on strawberries and phytophthora root rot (*Phytophthora rubi*) on caneberries. Root lesion nematodes (*Pratylenchus penetrans*) will also be suppressed on both strawberries and caneberries. MPT Crop Biofumigant represents a non-conventional alternative that may improve disease management while reducing the reliance on conventional chemistries.

Measures to Minimize Risk

Registered pesticide product labels 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 on the label of MPT 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 panel of both the technical and end-use product labels. The statements “May irritate eyes”, “May cause respiratory irritation”, “Potential skin sensitizer”, and “Contains the allergen mustard” are required on the secondary display panel of the technical and end-use product labels.

The personal protective equipment for all applications required on the end-use product label include a long sleeved shirt, chemical-resistant gloves, long pants, shoes and socks, and a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products.

To avoid bystander exposure, the MPT Crop Biofumigant label states that unprotected persons should be kept out of the treated areas for the duration of the treatment period and for 24 hours after watering. To prevent post-application worker exposure to the degradation product AITC, the MPT Crop Biofumigant label requires a restricted-entry interval of 24 hours after watering the product into the soil.

To further reduce the risk of direct application to food crops, directions for use will be revised to state that the incorporation of MPT Crop Biofumigant into the soil layer to a depth of 10 – 15 cm is a necessary step in the application.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-23 — *Oriental Mustard Seed Meal*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/public-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.