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Registration Decision

RD2014-17

Penthiopyrad

(publié aussi en français)

4 July 2014

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

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Canada 

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2014-17E (print version)
H113-25/2014-17E-PDF (PDF version)

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Registration Decision for Penthiopyrad

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 Penthiopyrad Technical Fungicide and DuPont Penthiopyrad 250 FS Fungicide Seed Treatment containing the technical grade active ingredient penthiopyrad, for use as a seed treatment on canola, rapeseed, mustard (oil and condiment types), corn and soybean to control or suppress various soil-borne and seed-borne fungal diseases.

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 PRD2014-01, *Penthiopyrad*. This Registration Decision² describes this stage of the PMRA's regulatory process for Penthiopyrad and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2014-01. This decision is consistent with the proposed registration decision stated in PRD2014-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-01, *Penthiopyrad* 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 Penthiopyrad?

Penthiopyrad is a systemic fungicide that can be applied as a seed treatment to control or suppress various soil-borne and seed-borne fungal diseases on canola, rapeseed, oil and condiment varieties of mustards, corn and soybean. This active ingredient is currently registered for use in other products applied as foliar or in-furrow treatments.

Health Considerations

Can Approved Uses of Penthiopyrad Affect Human Health?

Product containing penthiopyrad is unlikely to affect your health when used according to label directions

Potential exposure to Penthiopyrad Technical Fungicide may occur through the diet (food and water), or when handling and applying the product or when entering treated sites. 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.

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

In laboratory animals, the acute toxicity of the active ingredient penthiopyrad was low via the oral, dermal and inhalation routes of exposure. Penthiopyrad was minimally irritating to the eyes, non-irritating to the skin and did not cause an allergic skin reaction.

The acute toxicity of the end-use product DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and did not cause an allergic skin reaction. DuPont Penthiopyrad 250 FS Fungicide Seed Treatment was mildly irritating to the eyes; consequently, the hazard signal words "CAUTION – EYE IRRITANT" are required on the label.

Health effects in animals given repeated doses of penthiopyrad included changes in the liver, thyroid, adrenals and kidneys. Penthiopyrad did not cause birth defects in animals and there were no effects on the ability to reproduce. When penthiopyrad was given to pregnant or nursing animals, effects on the developing fetus and juvenile animal (reduced survival, pup and litter weights, body size, thymus weight, altered thymus development and/or delayed sexual development) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to penthiopyrad than the adult animal. Penthiopyrad caused temporary functional effects, possibly related to the nervous system; however, there was no indication that penthiopyrad caused damage to the nervous system. There was no evidence to suggest that penthiopyrad damaged genetic material. Penthiopyrad did, however, cause thyroid tumours in rats. There was also evidence of an effect on the immune system at high doses.

The risk assessment protects against the effects of penthiopyrad by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation that would ingest the most penthiopyrad relative to body weight, are expected to be exposed to less than 19% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from penthiopyrad is not of health concern for all population subgroups. There were no cancer risks of concern.

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 6% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was infants less than one year old.

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

MRLs to cover residues of penthiopyrad in/on rapeseeds (canola), mustard seeds (oilseed type), soybean, field corn, sweet corn cobs plus kernels with husks removed, and popcorn grain have been established based on residue data generated following foliar applications. The seed treatment use of penthiopyrad on these crops is not expected to result in residues exceeding the established MRLs. The MRL for this active ingredient on mustard seeds (condiment type) can be found in the Science Evaluation of PRD2014-01.

Occupational Risks From Handling DuPont Penthiopyrad 250 FS Fungicide Seed Treatment

Occupational risks are not of concern when DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is used according to the proposed label directions, which include protective measures.

Workers treating seed with DuPont Penthiopyrad 250 FS Fungicide Seed Treatment in commercial seed treatment facilities and workers planting treated seed can come into direct contact with penthiopyrad residues on the skin and through inhalation. Therefore, the label specifies that workers treating and handling treated seed must wear the following personal protective equipment (PPE). In commercial seed treatment facilities, workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment in commercial seed treatment facilities must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Closed transfer is required for treating seeds in commercial seed treatment facilities and a closed cab tractor is required when planting treated seed. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

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

Environmental Considerations

What Happens When Penthiopyrad Is Introduced Into the Environment?

When used as a seed treatment for canola, rapeseed, mustard, corn and soybeans to control plant diseases, penthiopyrad is not likely to move a great distance downward into soil and contaminate groundwater. Once in soil, studies show that penthiopyrad breaks down quickly. It is unlikely to evaporate from the seeds after the seeds are planted.

Birds and small mammals will not be at risk if they happen to eat the seeds that are treated with penthiopyrad. Similarly, earthworms and insects will not be at risk if they come into contact with penthiopyrad in the soil or come into contact with the treated seed.

Value Considerations

What Is the Value of DuPont Penthiopyrad 250 FS Fungicide Seed Treatment?

DuPont Penthiopyrad 250 FS Fungicide Seed Treatment is a flowable suspension (FS) product for soil-borne and seed-borne disease management in canola, rapeseed, mustard, corn and soybean seeds.

Penthiopyrad has demonstrated efficacy against diseases with potentially severe economic impact on major Canadian field crops. Seed treatments are an effective and targeted means of early disease control requiring a single application in a closed environment and relatively small amounts of active ingredients compared to soil or foliar applications in the field.

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 DuPont Penthiopyrad 250 FS Fungicide Seed Treatment to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with penthiopyrad on the skin or through inhalation of spray mists, anyone mixing, loading and applying DuPont Penthiopyrad 250 FS Fungicide Seed Treatment must wear the following PPE: In commercial seed treatment facilities, workers mixing, loading, calibrating, treating, bagging, sewing, stacking, and forklifting treated seed must wear a long-sleeved shirt and long pants and chemical-resistant gloves. In addition, workers cleaning treatment equipment in commercial seed treatment facilities must wear coveralls over a long-sleeved shirt and long pants and chemical-resistant gloves. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Closed transfer is required for treating seeds in commercial seed treatment facilities and a closed cab tractor is required when planting treated seed.

Environment

As the environmental risks are very small with the planting of seeds treated with penthiopyrad, no additional precautions or risk-reduction measures are required that are not already indicated on the product label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-01, *Penthiopyrad*) 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) or contact the PMRA's Pest Management Information Service.

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