Registration Decision RD2014-23

Fenamidone

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Registration Decision for Fenamidone

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 Fenamidone Technical Fungicide and Reason 500SC Fungicide, containing the technical grade active ingredient fenamidone, to control seed-borne late blight on potato.

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 document[1] Proposed Registration Decision PRD2014-03,*Fenamidone*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for fenamidone and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-03. This decision is consistent with the proposed registration decision stated in PRD2014-03.

For more details on the information presented in this Registration Decision, please refer to PRD2014-03, which 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 acceptable[3] 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 value[4] 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 Fenamidone?

Fenamidone is the active ingredient contained in Reason 500SC Fungicide (500 g a.i./L). It is a member of the imidazolinone chemical group. The mode of action of fenamidone is the inhibition of mitochondrial respiration in susceptible fungi.

Health Considerations

Can Approved Uses of Fenamidone Affect Human Health?

Reason 500SC Fungicide, containing fenamidone, is unlikely to affect your health when used according to the label directions.

Potential exposure to fenamidone 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 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 pesticide products are used according to label directions.

In laboratory animals, the acute toxicity of the end-use product Reason 500SC Fungicide was low by the oral and dermal routes of exposure. It was slightly acutely toxic via the inhalation route of exposure. It was mildly irritating to the eyes and slightly irritating to the skin. It did not cause an allergic skin reaction. The hazard signal words "CAUTION – EYE IRRITANT" are required on the label.

Health effects in animals given repeated doses of fenamidone included effects on the liver and the thyroid. Fenamidone did not cause cancer in animals and did not damage genetic material. There was no indication that fenamidone caused damage to the nervous system or immune system. When fenamidone was given to pregnant animals, effects (reduced weight gain, delayed

bone ossification) in the developing fetus were observed at doses that were toxic to the mother indicating that the young do not appear to be more sensitive to fenamidone than the adult animal. Reduced body weight gain was also observed in the offspring of animals exposed to fenamidone through pregnancy and lactation; however, this may have been the result of a direct consumption of treated diet by the young animals.

The risk assessment protects against the effects of fenamidone 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

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

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most fenamidone relative to body weight, are expected to be exposed to less than 20% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fenamidone is not of health concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of fenamidone is not likely to cause acute health effects in the general population (including infants and children).

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.

An MRL to cover residues of fenamidone in/on potatoes has been established based on residue data generated following foliar applications. The seed treatment use of fenamidone on this crop is not expected to result in residues exceeding the established MRL.

Occupational Risks From Handling Reason 500SC Fungicide

Occupational risks are not of concern when Reason 500SC Fungicide is used according to the proposed label directions, which include protective measures.

Workers treating potato seed pieces with Reason 500SC Fungicide on-farm and in commercial treating facilities can come into direct contact with fenamidone residues on the skin and through inhalation. Therefore, the label specifies that workers treating and handling treated potato seed pieces wear long-sleeved shirt, long pants, shoes plus socks and chemical resistant gloves. Taking into consideration these label statements, 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 Fenamidone Is Introduced Into the Environment?

Fenamidone is introduced into the environment when used as a fungicide treatment for potato seed pieces.

Fenamidone is non-persistent in soil, while its major transformation products are expected to be moderately persistent to persistent in soil. Although the use pattern of this product does not include direct application to water, the possibility that aquatic systems will be exposed to fenamidone, directly or indirectly, cannot be ruled out. In an aquatic environment, fenamidone readily partitions from water to sediments, where it persists. Laboratory studies of mobility indicated that fenamidone and its major transformation products have moderate to high mobility in soils and sediment; however, no leaching of these compounds was observed below the 15 centimetre depth under field conditions. Based on its low volatility, fenamidone residues are not expected in the air. The *n*-octanol–water partition coefficient of fenamidone and its major transformation products indicate that these compounds have limited potential for bioaccumulation/bioconcentration in biological organisms.

Treatment of potato seed pieces is not expected to significantly increase environmental exposure of fenamidone. The environmental risks to non-target organisms have been previously assessed for expected environmental concentrations exceeding those from the additional treatment of potato seedlings (Regulatory Note REG2003-11, *Fenamidone Technical Fungicide, Reason 500SC Fungicide*). Existing environmental label statements are expected to mitigate known risks.

Value Considerations

What Is the Value of Reason 500SC Fungicide?

Reason 500SC Fungicide is a water-based suspension concentrate fungicide that controls seed-borne late blight when applied as a seed treatment.

It is the first seed treatment registered in Canada for this use, increases stand emergence in late blight-infected potato seeds, and may prevent the spreading of late blight spores during seed piece handling and planting operations. Reason 500SC Fungicide may also be tank-mixed with Titan Insecticide (Registration Number 27449) and/or Emesto Silver (Registration Number 30361) to increase the spectrum of controlled diseases from a single seed treatment application.

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 are required by law to be followed.

The key risk-reduction measures on the label of Reason 500SC Fungicide 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 Reason 500SC Fungicide on the skin or through inhalation of spray mists, anyone applying Reason 500SC Fungicide to potato seed pieces or planting treated potato seed pieces must wear a long-sleeved shirt, long plants, shoes plus socks and chemical resistant gloves.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-03 — *Fenamidone)* 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 objection[5] 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, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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