Registration Decision RD2013-13

Mandipropamid

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Registration Decision for Mandipropamid

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 Mandipropamid Technical Fungicide and Revus Fungicide, containing the technical grade active ingredient mandipropamid, for control or suppression of various foliar diseases in Brassica vegetables, bulb vegetables, cucurbits, peppers, tomatoes, leafy vegetables and grapes.

Mandipropamid Technical Fungicide (Registration Number 29073) and Revus Fungicide (Registration Number 29074) were conditionally registered in Canada. The detailed review for Mandipropamid Technical Fungicide and Revus Fungicide can be found in Evaluation Report ERC2009-01, *Mandipropamid Technical Fungicide*. The current applications were submitted to convert Mandipropamid Technical Fungicide and Revus Fungicide from conditional registration to full registration.

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 full registration in the consultation document[1] PRD2012-23, *Mandipropamid*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for mandipropamid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-23. This decision is consistent with the proposed registration decision stated in PRD2012-23.

For more details on the information presented in this Registration Decision, please refer to PRD2012-23, *Mandipropamid* 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 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

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 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 (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 Mandipropamid?

Mandipropamid is a Group 40 fungicide active ingredient and is classified as a carboxylic acid amide. It has a mode of action that inhibits phospholipid biosynthesis, and interferes with cell wall division. It is rated as having a low to medium risk for resistance development in pathogen populations. It is the active ingredient in the end-use product Revus Fungicide for control or suppression of various foliar diseases in Brassica vegetables, bulb vegetables, cucurbits, peppers, tomatoes, leafy vegetables and grapes.

Health Considerations

Can Approved Uses of Mandipropamid Affect Human Health?

Mandipropamid is unlikely to affect your health when used according to the label directions.

Potential exposure to mandipropamid may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which 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 group (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 at which 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 mandipropamid products are used according to the label directions.

Mandipropamid Technical Fungicide and the end-use product, Revus Fungicide, are not acutely toxic.

Mandipropamid did not cause cancer in animals and was not genotoxic. There was also no indication that mandipropamid caused damage to the nervous system and there were no effects on reproduction or fetal development. The first signs of toxicity in animals given daily doses of mandipropamid over longer periods of time were decreases in bodyweight gain and liver effects. The risk assessment protects against these effects 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 water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1–2 years old, the subpopulation that would ingest the most mandipropamid relative to body weight, are expected to be exposed to less than 6% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from mandipropamid is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of mandipropamid 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. Pesticide maximum residue limits 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 residue limits does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using mandipropamid on Brassica vegetables, cucurbits, dry bulb and green onion, fruiting vegetables, grapes, leafy vegetables and potato were acceptable. Residue trials conducted in Europe using mandipropamid on greenhouse vegetables (cucumber, lettuce and tomato) were acceptable. The maximum residue limits for this active ingredient can be found in ERC2009-01, *Mandipropamid Technical Fungicide*.

Occupational Risks From Handling Revus Fungicide

Occupational risks are not of concern when Revus Fungicide is used according to the label directions, which include risk reduction measures.

Farmers and custom applicators who mix, load or apply Revus Fungicide, as well as field workers re-entering freshly treated fields, nurseries and greenhouses, can come in direct contact with mandipropamid residues on the skin. Therefore, the label specifies that anyone mixing, loading and applying Revus Fungicide must wear a long-sleeved shirt, long pants, and shoes plus socks. Additionally, workers must wear chemical-resistant gloves during mixing and loading. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications, and the exposure duration for handlers and workers, risk to these workers is not of 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 Mandipropamid Is Introduced Into the Environment?

When used according to the label directions, which include precautionary statements, mandipropamid does not pose a risk to the environment.

Mandipropamid is slightly to moderately persistent in soil with the main route of dissipation being biotransformation. Mandipropamid is not expected to volatilize nor leach significantly. No major transformation products of mandipropamid were identified in the soil laboratory studies.

Mandipropamid can enter the aquatic environment through spray drift and runoff from the treatment area. Based on the environmental fate characteristics, limited runoff of mandipropamid and its transformation products is expected. Mandipropamid dissipates rapidly from the water layer mainly via partitioning to the sediments, but phototransformation will also contribute to this dissipation in the photic zone. Biotransformation is the main route of dissipation for mandipropamid in sediments. Mandipropamid is stable to hydrolysis and is not expected to volatilize; therefore, these two processes will not affect the dissipation of mandipropamid from the aquatic environment. In the total aquatic system, mandipropamid is classified as non-persistent to slightly persistent depending on the system and conditions present.

Major transformation products of mandipropamid were identified in the aquatic fate studies. These transformation products will only form in significant levels in the aquatic environment if large quantities of mandipropamid enter the aquatic environment as they are not expected to be present in runoff. Further discussion regarding these transformation products occurs in ERC2009-01, *Mandipropamid Technical Fungicide*.

Risk to non-target species is considered negligible based on the uses of mandipropamid.

Value Considerations

What Is the Value of Revus Fungicide?

Revus Fungicide controls or suppresses downy mildew, late blight and phytophthora blight on various field and greenhouse-grown crops.

Revus Fungicide is a reduced-risk product for use on leafy vegetables, grapes, tomatoes, cucurbits, bulb vegetables, and Brassica head and stem crops. It is currently the only fungicide registered in Canada for suppression of phytophthora blight on field peppers. Revus Fungicide can be tank mixed with Bravo 500 Agricultural Fungicide (registration number 15723) for resistance management, or to increase the disease spectrum on crops that are registered on both product labels. In addition, Revus Fungicide can be applied by ground and aerial application equipment.

Sensitivity monitoring studies have suggested that populations of *Phytophthora infestans*, the causative pathogen of potato late blight, have not developed resistance to mandipropamid. However, certain isolates of *Plasmopara viticola*, the causative pathogen for downy mildew of grape, have been found to be simultaneously resistant to all Group 40 active ingredients. Therefore, resistance management practices are required when using Revus Fungicide on grapes for control of downy mildew and are highly recommended when using Revus Fungicide on other labelled crops.

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 on the label of Revus Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Given there is a concern with users coming into direct contact with Revus Fungicide on their skin or through inhalation of spray mists, anyone mixing, loading or applying Revus Fungicide must wear a long-sleeved shirt, long pants, and shoes plus socks. Additionally, workers must wear chemical-resistant gloves during mixing/loading. In addition, standard label statements to protect against drift during application have been added to the label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-23, *Mandipropamid)* 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 Pesticide 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/publi-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.*