Registration Decision RD2015-29

Oxathiapiprolin

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Registration Decision for Oxathiapiprolin

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 DuPont Zorvec Technical Fungicide, Dupont Zorvec Enicade Fungicide, Dupont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide, containing the technical grade active ingredient oxathiapiprolin, for use against selective oomycete diseases on bulb vegetables, brassica (cole) leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, succulent shelled and edible-podded peas, and potatoes.

Dupont Zorvec Enicade Fungicide and Orondis Fungicide are oil dispersion (OD) formulations applied to soil or as a foliar spray to control downy mildew and phytophthora diseases. Dupont Zorvec Epicaltrin Fungicide and OXTP 200SC Fungicide are suspension concentrate (SC) formulations that are for use as soil applied products to control certain phytophthora 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 document[1] Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for oxathiapiprolin and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2015-22. This decision is consistent with the proposed registration decision stated in PRD2015-22.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin* 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.

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.*

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.

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 Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Oxathiapiprolin?

Oxathiapiprolin is a new conventional fungicide active ingredient that prevents spore initiation and inhibits growth in susceptible fungi. It represents a new mode of action not previously available to Canadian growers.

Health Considerations

Can Approved Uses of Oxathiapiprolin Affect Human Health?

Products containing oxathiapiprolin are unlikely to affect your health when used according to label directions.

Potential exposure to oxathiapiprolin may occur through the diet (food and water) or when handling and applying the products. 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.

[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".

In laboratory animals, the technical grade active ingredient (oxathiapiprolin) was of low acute toxicity by the oral, dermal and inhalation routes. It was non-irritating to skin, minimally irritating to eyes and did not cause an allergic skin reaction.

The acute toxicity of the oil dispersion (OD) end-use products, Orondis Fungicide and Dupont Zorvec Enicade Fungicide, was low via the oral, dermal and inhalation routes of exposure. The products were non-irritating to the eyes and moderately irritating to the skin. They caused allergic skin reactions; consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on their labels.

The acute toxicity of the suspension concentrate (SC) end-use products, OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide, was low via the oral, dermal and inhalation routes of exposure. They were non-irritating to the eyes and skin and did not cause an allergic skin reaction.

Short- and long-term (lifetime) animal toxicity tests were assessed for the potential of oxathiapiprolin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were decreased body weight and body-weight gain and delayed sexual maturation in males. There was an indication that the young were more sensitive than the adult animal. The risk assessment protects against the findings noted above as well as any other potential effects by ensuring that the level of exposure to humans 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 infants less than one year old, the subpopulation which would ingest the most oxathiapiprolin relative to body weight, are expected to be exposed to less than or equal to 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from oxathiapiprolin is not of health concern for all population subgroups.

Oxathiapiprolin is not carcinogenic; therefore, a cancer dietary risk assessment is not required. Animal studies revealed no relevant health effects for acute dietary risk assessment. Consequently, a single dose of oxathiapiprolin 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 The *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.

Residue trials conducted throughout Canada and the United States using oxathiapiprolin on potatoes, dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, broccoli, cabbage, cauliflower, tomatoes, peppers, cucumbers, summer squash, cantaloupe, succulent peas and ginseng are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational Risks From Handling DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide are not of health concern when used according to the label directions, which include protective measures.

Workers, who mix, load or apply DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, or OXTP 200SC Fungicide, can come in direct skin contact with oxathiapiprolin residues or through inhaling spray mists during mixing/loading and application. Furthermore, workers re-entering freshly treated fields and greenhouses can come in direct skin contact with DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide residues from the treated foliage. Therefore, the OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. The Orondis Fungicide and Dupont Zorvec Enicade Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves, and chemical-resistant footwear plus socks. The labels also require that no one can enter treated areas for 12 hours after application.

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 Oxathiapiprolin Is Introduced into the Environment?

When used according to label directions, oxathiapiprolin is not expected to pose an unacceptable risk to the environment.

Oxathiapiprolin can enter the environment when it is used as a fungicide for the control of oomycete diseases in a variety of field vegetable crops. It can be applied directly to plants as a foliar spray or as a soil drench, but not as both on the same crop. Oxathiapiprolin can enter into plant tissues and be distributed throughout the plant because it is systemic.

In the terrestrial environment in Canada, oxathiapiprolin can persist in the environment and has a potential to carryover to the following growing season. Breakdown of the molecule is predominantly by soil microbes which produce three major transformation products which can persist in soil.

Oxathiapiprolin does not readily break down by reacting with water or sunlight. Oxathiapiprolin and two of the three major transformation products have limited potential to move through the soil to enter groundwater. One transformation product has the potential to move through soil, but was not found beyond 70 cm in depth in North American field studies. Oxathiapiprolin is not volatile and is unlikely to enter the atmosphere.

In the aquatic environment, oxathiapiprolin breaks down primarily in the presence of microbes. It does not react with water and has a limited potential to break down by reacting with sunlight in water. In water, oxathiapiprolin will move to sediments where it will be broken down by microbes. Several major transformation products were observed in water and sediments. In general, once oxathiapiprolin enters the aquatic environment it will begin to breakdown and is unlikely to be persistent in water and sediments.

Oxathiapiprolin is not expected to accumulate in fish tissues.

Overall, oxathiapiprolin and its major transformation products are not expected to pose a risk to soil-dwelling invertebrates, birds, mammals, terrestrial and aquatic plants, algae, aquatic invertebrates and fish (freshwater and marine). Plant-dwelling invertebrates within treated fields may be at risk from oxathiapiprolin at rates greater than 200 g a.i./ha. Oxathiapiprolin may present a slight risk to amphibians living in shallow water. In order to minimize the potential risk of oxathiapiprolin to terrestrial and aquatic organisms, precautionary label statements as well as mitigation measures are specified on the labels of the end use products (refer to Measures to Minimize Risk). When oxathiapiprolin is used in accordance with the label and the mitigation measures have been applied, the reduced environmental exposure is deemed adequate and the risk is considered to be acceptable.

Value Considerations

What Is the Value of DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide?

These oxathiapiprolin products provide a new mode of action for growers to manage downy mildew and diseases caused by *Phytophthora* species on multiple field and greenhouse crops. The registration of oxathiapiprolin will address several priority diseases identified by Canadian growers. As a new mode of action fungicide that is effective against difficult to control oomycete fungi, oxathiapiprolin will contribute to protecting the quality of labelled crops and reducing the development of resistance in susceptible fungi while allowing alternation with other products currently registered for the same use.

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 on the label of DuPont Zorvec Technical Fungicide, DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC 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 skin contact with DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide or through inhalation of spray mists, the OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. The Orondis Fungicide and Dupont Zorvec Enicade Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves, and chemical-resistant footwear plus socks. The labels also require that no one can enter treated areas for 12 hours after application.

Environment

- Environmental hazard statements are required to indicate toxicity to aquatic organisms
- Dupont Zorvec Enicade Fungicide and Orondis Fungicide labels require a hazard statement indicating that the product contains an aromatic petroleum distillate which is toxic to aquatic organisms.
- To mitigate potential exposure of amphibians through spray drift, spray buffer zones of 1 to 2 metres are required to protect sensitive aquatic habitats for foliar applications and must be specified on the labels of DuPont Zorvec Enicade Fungicide and Orondis Fungicide.
- Instructions for reducing run-off are required on the labels of all the end use products.
- Environmental hazard statements to indicate potential harm to beneficial invertebrates in fields receiving foliar applications at rates over 200 g a.i./ha are required.
- To minimize the potential of oxathiapiprolin to be carried over to the following growing season, a label statement informing the users of the carry-over potential of this chemical is to be specified on the labels of the end use products.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-22, *Oxathiapiprolin* 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) or contact the PMRA's Pest Management Information Service.

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