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Registration Decision

RD2015-25

Fluopicolide

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Registration Decision for Fluopicolide

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 Fluopicolide Technical and the end-use products, Fluopicolide 4 SC Fungicide and Presidio Fungicide, containing the technical grade active ingredient fluopicolide, to suppress or control important fungal diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers).

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.

The current decision will result in the conversion of the conditional registration of Fluopicolide Technical (Registration Number 30049), Presidio Fungicide (Registration Number 30051), and Fluopicolide 4 SC Fungicide (Registration Number 30050) to full registration.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2015-18, *Fluopicolide*. This Registration Decision² describes this stage of the PMRA's regulatory process for fluopicolide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-18. This decision is consistent with the proposed registration decision stated in PRD2015-18, *Fluopicolide*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-18, 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 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. 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 Fluopicolide?

Fluopicolide is the active ingredient present in the end-use products Presidio Fungicide and Fluopicolide 4 SC Fungicide, which belong to a new chemical class (Group 43). Fluopicolide causes rapid destabilization of fungal cell structures. It is a systemic and protectant fungicide applied as a foliar or a drench treatment that is used to control some important diseases on plants.

Health Considerations

Can Approved Uses of Fluopicolide Affect Human Health?

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

Potential exposure to fluopicolide 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 fluopicolide products are used according to label directions.

Fluopicolide is of low acute toxicity by oral, dermal and inhalation routes in the rat. It is non-irritating to the skin and minimally irritating to the eyes of rabbits and it is not a dermal sensitizer in guinea pigs. Consequently, no signal words are required on the label. The end-use products Presidio Fungicide and Fluopicolide 4 SC Fungicide are of low acute toxicity by the oral and dermal routes of exposure and slightly toxic by the inhalation route in the rat. They are minimally irritating to the skin and mildly irritating to the eyes of rabbits and are not dermal sensitizer in guinea pigs. The signal words "CAUTION POISON - EYE IRRITANT" are required on the label for the end-use products.

No treatment-related toxicity was observed in rats after repeated exposure with high dose levels of fluopicolide via the dermal route.

Fluopicolide is not genotoxic and is not likely to pose a carcinogenic risk to humans. There was no indication that fluopicolide caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of fluopicolide over long periods of time were decreases in body weight and body weight gain and changes to the kidney, liver and adrenal glands. When fluopicolide was given to pregnant animals, malformations (rats) and abortions (rabbits) were observed at doses that were also toxic to the dams. Due to the nature of these endpoints and their potential implications on the health of the foetus, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to fluopicolide.

The risk assessment was conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children, nursing mothers and women of child bearing age). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Risks in Residential Environments

Postapplication risks for individuals contacting outdoor ornamentals (bedding plants and cut flowers) treated with Fluopicolide 4 SC Fungicide or Presidio Fungicide are not of concern.

There is potential for dermal exposure for individuals through contact with dislodgeable residues following commercial application of fluopicolide on outdoor ornamentals (bedding plants and cut flowers) sold in nurseries for residential areas.

Postapplication risk estimates for individuals contacting treated outdoor ornamentals (bedding plants and cut flowers) are not of concern. Therefore, contact with foliage of treated ornamentals is acceptable once residues have dried.

Occupational Risks From Handling Fluopicolide 4 SC Fungicide or Presidio Fungicide

Occupational risks are not of concern when Fluopicolide 4 SC Fungicide or Presidio Fungicide is used according to the label directions, which include protective measures.

Farmers, custom applicators, or ornamental nursery operators who mix, load or apply Fluopicolide 4 SC Fungicide or Presidio Fungicide, as well as field workers re-entering treated fields and nurseries, can come in direct contact with fluopicolide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Fluopicolide 4 SC Fungicide or Presidio Fungicide must wear a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes. The label also requires that workers do not enter treated fields or other treated sites for specific activities in some crops for 1 to 16 days after application. For all other uses, a restricted-entry interval of 12 hours is specified.

Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to workers handling Fluopicolide 4 SC Fungicide or Presidio Fungicide 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.

Residues in Water and Food

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

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that may ingest the most fluopicolide relative to body weight, are expected to be exposed to less than 37% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fluopicolide is not of concern for all population sub-groups.

The acute aggregate (food and water) dietary intake estimate for women aged 13-49 years was less than 16% of the reference dose, which is not a health concern.

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. The fluopicolide MRLs specified under the *Pest Control Products Act* may be found at Health Canada's MRL Database.

Environmental Considerations

What Happens When Fluopicolide Is Introduced Into the Environment?

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

When fluopicolide is released into the environment some of it can be found in soil and surface water. In the terrestrial environment, fluopicolide is expected to be persistent and residues may carry over into the following growing season. Fluopicolide is shown to bind weakly to soils, however, there is evidence that adsorption to soil may increase over time as the product is used. The major transformation product, 2,6-dichlorobenzamide (BAM), is expected to be mobile in soils. Both fluopicolide and BAM are expected to leach through soil and have the potential to reach groundwater.

In aquatic environments, fluopicolide is expected to be persistent and to partition from the water phase to the sediment; BAM has been shown to partition mainly into the water phase. Fluopicolide residues are not expected in the air because of its low volatility and it has a low potential for bioaccumulation in biota. BAM is not expected to be a concern to terrestrial and aquatic life.

Fluopicolide may pose a potential risk to aquatic organisms. In order to minimize the potential exposure of aquatic organisms to fluopicolide, an unsprayed area (spray buffer zone) is needed between the sprayer and downwind sensitive habitats. The width of these spray buffer zones is specified on the product label.

Value Considerations

What Is the Value of Fluopicolide 4 SC Fungicide and Presidio Fungicide?

Fluopicolide, the active ingredient in Fluopicolide 4 SC Fungicide and Presidio Fungicide, controls or suppresses economically important diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers).

Presidio Fungicide and Fluopicolide 4 SC Fungicide are products formulated as a foliar or a drench treatment against important diseases on vegetable crops and outdoor ornamentals (bedding plants and cut flowers). Presidio Fungicide and Fluopicolide 4 SC Fungicide are active against certain pathogens by affecting the normal cell division cycle. They have systemic and curative properties and offer additional tools for disease and resistance management, particularly for the control of downy mildew on various vegetable crops as well as late blight on potato and tomato. Presidio Fungicide and Fluopicolide 4 SC Fungicide are most effective when applied in a regularly scheduled spray program and are to be used as a tank-mix with other registered fungicides with a different mode of action.

Additional value information was submitted and deemed sufficient to fulfill the value conditions for Fluopicolide 4 SC Fungicide and Presidio Fungicide.

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 proposed on the label of Fluopicolide 4 SC Fungicide and Presidio 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 fluopicolide on the skin, anyone mixing, loading, applying, and involved in clean-up or repair activities with Fluopicolide 4 SC Fungicide or Presidio Fungicide must wear the recommended personal protective equipment. In addition, standard label statements to protect against drift during application are included on the label. The label also requires restricted-entry intervals of 8 days for hand pruning, thinning, tying and leaf pulling in grapes, 16 days for cane turning and girdling in table grapes, and 1 day for hand pruning and irrigation in brassica vegetables. A 12-hour restricted-entry interval is required for all other re-entry activities.

Environment

Precautionary statements and spray buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment. To reduce the potential for runoff of fluopicolide to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. Fluopicolide residues could have a high leaching potential, therefore, a label statement is required advising that use may result in contamination of groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow. Fluopicolide is persistent and may carry over into the following growing season, therefore a label statement is required advising that products containing fluopicolide should not be used in areas treated with fluopicolide during the previous season.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-18) 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*.