Registration Decision RD2012-19

Mono- and Di-Potassium Salts of Phosphorous Acid

(publié aussi en français)

7 December 2012

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

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

Catalogue number: H113-25/2012-19E (print version)
H113-25/2012-19E-PDF (PDF version)

Registration Decision for Mono- and Di-Potassium Salts of Phosphorous Acid

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 Mono- and Di-Potassium Salts of Phosphorous Acid and Confine, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, for suppression of late blight and pink rot on harvested potato tubers.

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 detailed review of Mono- and Di-Potassium Salts of Phosphorous Acid and Confine can be found in Evaluation Report ERC2010-09, *Mono- and Di-Potassium Salts of Phosphorous Acid*. These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-03, *Mono- and Di-Potassium Salts of Phosphorous Acid*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for mono- and di-potassium salts of phosphorous acid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-03. This decision is consistent with the proposed registration decision stated in PRD2012-03.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-03, *Mono- and Di-Potassium Salts of Phosphorous Acid* and Evaluation Report ERC2010-09, *Mono- and Di-Potassium Salts of Phosphorous Acid* which contain 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.

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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 Mono- and Di-potassium Salts of Phosphorous Acid?

Mono- and di-potassium salts of phosphorous acid, or phosphorous acid, is a fungicide active ingredient belonging to Group 33 and is classified as a phosphonate. The mode of action of phosphorous acid is both direct and indirect. Mono- and di-potassium salts of phosphorous acid is the active ingredient in the fungicide Confine, which is registered for suppression of late blight and pink rot on harvested potato tubers.

Health Considerations

Can Approved Uses of Mono- and Di-Potassium Salts of Phosphorous Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur 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.

Mono- and di-potassium salts of phosphorous acid is of low toxicity by the oral, dermal and inhalation routes, and only minimally irritating to the eyes. The precautionary label statement indicating that contact with eyes must be avoided, and the personal protective equipment statement that applicators and other handlers must wear protective eyewear are effective mitigative measures to reduce the risk associated with the use of this chemical.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Mono- and di-potassium salts of phosphorous acid is of low acute toxicity by the oral, dermal and inhalation routes. It is minimally irritating to the eyes, non-irritating to the skin and is not a skin sensitizer. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects.

Dietary risk to humans is considered negligible based on the intended use, method of application, low application rate, and low toxicity of the end-use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the proposed use of mono- and di-potassium salts of phosphorous acid in Canada on stored potatoes will not pose a risk to any segment of the population, including infants, children, adults and seniors, when potatoes are subjected to the normal process of washing, peeling and cooking for human consumption. In the United States, phosphorous acid has been designated Generally Regarded As Safe (GRAS) and the potassium salts of phosphoric acid have been exempted from the requirement of tolerance in and on all food commodities when used as an agricultural fungicide on food crops. The United States Environmental Protection Agency (USEPA) introduced an initiative whereby an exemption from the requirement of a tolerance were established for ammonium, sodium, and potassium salts of phosphorous acid on all food commodities to permit post-harvest application to stored potatoes at 35 600 ppm or less of phosphorous acid.

This end-use product will be used in a contained treatment area and will not be applied to water. No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Mono- and Di-Potassium Salts of Phosphorous Acid

Occupational risks are not of concern when mono- and di-potassium salts of phosphorous acid is used according to label directions, which include protective measures.

Occupational exposure to mono- and di-potassium salts of phosphorous acid is expected to be minimal as application is done by automated enclosed spray chamber, which sprays newly-harvested potatoes when they pass along a conveyor belt towards storage bins. Precautionary statements on the label (for example, wearing of personal protective equipment and clothing) are considered adequate to protect individuals from any unnecessary risk due to exposure. Given the method of application and low toxicity of the end-use product, bystander exposure risk is anticipated to be negligible.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorous Acid Is Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid is used in the formulation of Confine for the suppression of late blight and pink rot storage infection on harvested potato tubers. Since the end-use product will be used indoors on post-harvest potatoes, the risk to non-target organisms is considered to be negligible, when used according to the label. Because of the use pattern, Confine is unlikely to be introduced to the environment.

Value Considerations

What Is the Value of Confine?

Confine is a non-conventional and systemic fungicide to be used for post-harvest suppression of late blight and pink rot in potato tubers.

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 Confine to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because mono- and di-potassium salts of phosphorous acid is used for formulating a commercial product, the statement on the technical label: "prevent access by unauthorized personnel" in the precaution section of the technical label will help mitigate the inappropriate use of the product, and help avoid accidental exposure. Other precautionary statements on the technical and end-use product labels, such as: "avoid breathing vapours or spray mist, avoid contact with eyes; remove contaminated clothing and wash clothing before use; applicators and other handlers must wear protective eyewear, long pants and long sleeved shirt, waterproof gloves, and shoes plus socks," should be effective in minimizing the potential for exposure.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-03, *Mono- and Di-Potassium Salts of Phosphorous Acid* and ERC2010-09, *Mono- and Di-Potassium Salts of Phosphorous Acid)* 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, 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.*