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RVD2008-13

Re-evaluation Decision

2-Phenylphenol and Salts

(publié aussi en français)

7 April 2008

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

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ISBN: 978-0-662-48439-4 (978-0-662-48440-0)
Catalogue number: H113-28/2008-13E (H113-28/2008-13E-PDF)

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Overview

Re-evaluation Decision

After a re-evaluation of the antimicrobials 2-phenylphenol and its two sodium salts (sodium-o-phenylphenate and tetrahydrate), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, is granting continued registration of products containing 2-phenylphenol and salts for sale and use in Canada.

An evaluation of available scientific information found that products containing 2-phenylphenol and salts do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of 2-phenylphenol and salts, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of 2-phenylphenol and salts was first presented in Proposed Re-evaluation Decision document [PRVD2008-04, 2-Phenylphenol and Salts](#), a consultation document.¹ This Re-evaluation Decision document² describes this stage of PMRA's regulatory process for the re-evaluation of 2-phenylphenol and salts, as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-04. To comply with this decision, registrants of products containing 2-phenylphenol and salts will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive [DIR2001-03, PMRA Re-evaluation Program](#), presents the details of the re-evaluation activities and program structure.

2-Phenylphenol and salts have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

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*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a regulatory decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy (TSMP)).

The USEPA re-evaluated 2-phenylphenol and salts and published its conclusions in a 2006 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation section of the related Proposed Re-evaluation Decision PRVD2008-04, *2-Phenylphenol and Salts*.

What Are 2-Phenylphenol and Salts?

2-Phenylphenol and its two sodium salts, sodium-o-phenylphenate and tetrahydrate, are antimicrobials that control microorganisms, including fungi, bacteria, mould and yeast. They are material preservative agents and are also used in the post-harvest treatment of fruits and vegetables. In Canada, 2-phenylphenol and salts (classified as use-site categories 12 and 18) are applied by dipping, fogging, flooding or spraying for post-harvest treatment of fruits and vegetables; painted on by brush, roller or airless sprayer; or added (open pour) as a material preservative (the products are used in items such as ceramic glazes, felt gaskets, paper dyes, laundry starch, concrete additives, adhesives, paints, leather, textiles, metalworking fluids, fire extinguisher solutions, floor wax emulsions, chemical toilets, construction materials and polyvinyl alcohol).

All current uses were supported by the registrants, except for the post-harvest application on certain fruits and vegetables (i.e. apples, cantaloupes, cherries, peaches, plums, carrots, cucumbers, peppers and tomatoes). Only use on pears will remain on the Canadian label and was included in the assessment.

Health Considerations

Can Approved Uses of 2-Phenylphenol and Salts Affect Human Health?

2-Phenylphenol and salts are unlikely to affect your health when used according to the revised label directions.

Exposure to 2-phenylphenol and salts may occur through consumption of food and water, working as a mixer/loader/applicator, or by entering treated sites. 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 (e.g. children and nursing

mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that 2-phenylphenol and salts were unlikely to affect human health, provided that risk-reduction measures were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

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*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

2-Phenylphenol and salts are currently registered in Canada for use on pears, apples, cantaloupes, cherries, peaches, plums, carrots, cucumbers, peppers, sweet potatoes and tomatoes. 2-Phenylphenol and salts may be used on other crops in other countries that are imported into Canada. The Canadian MRLs established for 2-phenylphenol and salts are 10 ppm for citrus and 25 ppm for pears. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document [DIS2006-01](#), *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When 2-Phenylphenol and Salts Are Introduced Into the Environment?

Additional risk-reduction measures are required on the labels of products containing 2-phenylphenol and salts. 2-Phenylphenol and salts are unlikely to affect non-target organisms when used according to revised label directions.

The USEPA did not conduct a quantitative risk assessment. In toxicity studies, 2-phenylphenol and salts demonstrated low toxicity to birds, and moderate toxicity to mammals, freshwater fish, freshwater invertebrates, and algae. Based on environmental fate of 2-phenylphenol and salts, the USEPA believes that environmental exposure from use of 2-phenylphenol and salts is likely to be low. No data were required for an environmental quantitative assessment.

The USEPA concluded that the reregistration of 2-phenylphenol and salts was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions were considered to be applicable to the Canadian situation, and equivalent risk-reduction measures are required.

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. As a result of the re-evaluation of 2-phenylphenol and salts, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- to protect mixer/loader/applicators: additional protective equipment
- to protect consumers from postapplication exposure to textiles: additional advisory label statement

Environment

- to reduce potential surface water contamination: additional advisory label statement

Appendix I lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection³ regarding this decision on 2-phenylphenol and salts within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing 2-Phenylphenol and Salts

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment:

- I) The following statement must be included in the **PRECAUTIONS** section, in addition to the PPE currently listed on each label.
- Wear a long-sleeved shirt, long pants and chemical-resistant gloves when handling product.
- II) For the label with textile use (PCP #27862), the following statement must be included in the **DIRECTIONS FOR USE** section.
- All preserved textiles must be washed before manufacturing clothing.
- III) The following statement must be included in the **ENVIRONMENTAL HAZARDS** section.
- DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.
- IV) Delete the following uses from the labels:
- Post-harvest treatment on fruits, including apples, cantaloupes, cherries, peaches, plums, carrots, cucumbers, peppers, sweet potatoes and tomatoes.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.