RVD2008-12

Re-evaluation Decision

Oxirane Derivatives

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Overview

Re-evaluation Decision

After a re-evaluation of the antimicrobial oxirane derivatives, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing oxirane derivatives.

An evaluation of available scientific information found that products containing oxirane derivatives do not present unacceptable risks to human health or the environment under their conditions of use. As a condition of the continued registration of oxirane derivatives uses, new risk-reduction measures must be included on the labels of products containing oxirane derivatives.

The regulatory approach for the re-evaluation of oxirane derivatives was first presented in Proposed Re-evaluation Decision document PRVD2008-02, *Oxirane Derivatives*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of oxirane derivatives 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 PRVD2008-02. To comply with this decision, registrants of products containing oxirane derivatives 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.

[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*.

Oxirane derivatives, one of the active ingredients in the current re-evaluation cycle, has 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;
- 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 oxirane derivatives and published its conclusions in a 2005 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 PRVD2008-02, *Oxirane Derivatives*.

What Are Oxirane Derivatives?

Oxirane derivatives are an equilibrium mixture of three components. This antimicrobial is used as a material preservative in adhesives, caulks and sealants, latex emulsion, ink, latex paint, pigment dispersion and slurry, and paper coatings and printing colours. It is handled by professional workers during introduction of the active ingredient as a materials preservative through liquid pour or pump application during manufacture of the material. Homeowners can use household products that already contain this active ingredient.

Health Considerations

Can Approved Uses of Oxirane Derivatives Affect Human Health?

Oxirane derivatives are unlikely to affect your health when used according to the revised label directions.

People could be exposed to oxirane derivatives while working with treated materials during their manufacture or through residential exposure (i.e. homeowners may be exposed during application of the treated product or postapplication to the treated materials (e.g. paint). The PMRA considers two key factors when assessing health risks: 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 uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that oxirane derivatives are unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Oxirane Derivatives Are Introduced Into the Environment?

Oxirane derivatives are unlikely to affect non-target organisms when used according to the revised label directions.

Based on a qualitative risk assessment, the USEPA determined that indoor uses of oxirane derivatives were not likely to result in unacceptable ecological risk to non-target organisms based on minimal exposure potential and low to slight toxicity.

The USEPA concluded that oxirane derivatives were unlikely to affect non-target organisms provided that risk-reduction measures to further protect the environment were implemented. These conclusions apply 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 oxirane derivatives, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Updated protective equipment statement to protect workers
- Addition of signal words “potential skin sensitizer” to protect workers
- Reduction in concentration added to paint (maximum 0.20% by weight) to protect homeowners

Environment

- Additional advisory label statement to reduce potential water contamination

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

Other Information

Any person may file a notice of objection[3] regarding this decision on oxirane derivatives 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 Oxirane Derivatives

The label amendments presented below 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.

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 PMRA requires that the label be modified so that oxirane derivatives is added to paint at a maximum concentration of 0.2% a.i. by weight (i.e. 0.4% product by weight).

II) The following statement must be removed from the section entitled **DIRECTIONS FOR USE.**

> **Food Contact Application**: NUOSEPT 95 Preservative cannot be used in direct or indirect food contact applications unless the Bureau of Chemical Safety of Health Canada has issued an opinion indicating that it has no objection to the use of NUOSEPT 95 Preservative in such applications.

And the following statement must be included in the section entitled **DIRECTIONS FOR USE**.

> **NOT** for use in the production of paper or paperboard that will come into contact with food.

III) The following statements must be included in a section entitled **PRECAUTIONS**.

> Wear goggles or face shield, long pants, long-sleeved shirt, shoes plus socks, chemical-resistant gloves and a respirator during mixing, loading, clean-up and repair.
>
> POTENTIAL DERMAL SENSITIZER

IV) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

References[4]

Studies/Information Provided by Applicant/Registrant

PMRA 1448390 Nuosept 95 Part 2 Product Chemistry Submission Number: 79-0984.

PMRA 1448375 Part 2- Product Chemistry. 2.1-2.11. Vol. 1 of 2. February 26, 1992.

PMRA 1448382 Nuosept 95 Preservative. Part 2- Product Chemistry. 2.12-2.16 Vol. 2 of 2. February 26, 1992.

Additional Information

PMRA 1448372 Nuosept 95 Preservative. Product Description
www.ispcorp.com/products/biocides/content/products/products/nuosept/95.html

[4] These references are in relation to the chemistry section of PRVD2008-02. They are included in this document because the PMRA reference numbers were not yet available at the time of publication of PRVD2008-02.