Re-evaluation Decision RVD2010-10

Sodium Fluoride

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Re-evaluation Decision

After a re-evaluation of the antimicrobial sodium fluoride, 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 sodium fluoride for sale and use in Canada.

An evaluation of available scientific information found that products containing sodium fluoride 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 sodium fluoride uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of sodium fluoride was first presented in Proposed Re-evaluation Decision document PRVD2010-08, *Sodium Fluoride,* a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of sodium fluoride 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 PRVD2010-08. To comply with this decision, registrants of products containing sodium fluoride will be informed of the specific requirements affecting their product registration(s).

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.

Sodium fluoride, 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.

[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*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of sodium fluoride. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the Federal Toxic Substances Management Policy).

The USEPA re-evaluated sodium fluoride and published its conclusions in a 2007 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-08, *Sodium Fluoride*.

What Is Sodium Fluoride?

Sodium fluoride is an antimicrobial that is used as a remedial wood preservative on industrial posts, poles, timbers and crossties. Sodium fluoride is formulated as a paste, an impregnated fabric, or a solid cartridge. It is applied by professional applicators using a grease gun or pressurized applicator for interior pole treatments, or using a brush or fabric wrapping for exterior pole treatments.

Health Considerations

Can Approved Uses of Sodium Fluoride Affect Human Health?

Sodium fluoride is unlikely to affect your health when used according to the revised label directions.

People could be exposed to sodium fluoride by working as a handler or by contacting treated wood. 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 (for example, 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 sodium fluoride was 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 Sodium Fluoride Is Introduced Into the Environment?

Sodium fluoride is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that the reregistration of sodium fluoride was acceptable provided 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 sodium fluoride, the PMRA requires further risk-reduction measures for product labels.

- Certification of handlers.
- Additional protective equipment for handlers.
- Requirement for the use of brushes with elongated handles for paste applications.
- Additional advisory label statements prohibiting use on children's playground equipment, picnic tables, or other products with food/feed contact surface areas.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on sodium fluoride 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 section of Health Canada'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 (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca)

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

Appendix I Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of sodium fluoride are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrants of the technical grade active ingredients by the PMRA.

- DACO 4.3.4 Short-term Dermal (90-day) Study

This study must be conducted with the Canadian technical grade active ingredient or a product with equivalent formulation and guarantee and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organization for Economic Co-operation and Development guidelines.

- DACO 5.4 Mixer/Loader/Applicator: Passive Dosimetry Data.

This study must be conducted with a relevant end-use product and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organization for Economic Co-operation and Development guidelines.