Re-evaluation Decision RVD2010-13

Diodofon

(publié aussi en français)

19 October 2010

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

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100537

ISBN: 978-1-100-16950-7 (978-1-100-16951-4)
Catalogue number: H113-28/2010-13E (H113-28/2010-13E-PDF)

Re-evaluation Decision

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

An evaluation of available scientific information found that products containing diodofon 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 diodofon uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of diodofon was first presented in Proposed Re-evaluation Decision document PRVD2010-04, *Diodofon*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of diodofon as well as summarizes the Agency's decision and the reasons for it. A comment received during the consultation process resulted in some revisions to the proposed label statements as described in the PRVD. Appendix I summarizes the comment and provides the PMRA's response. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-04. To comply with this decision, registrants of products containing diodofon 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.

Diodofon, 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 diodofon. In this decision, the PMRA took into account the Canadian use pattern and issues (such as the federal Toxic Substances Management Policy).

The USEPA re-evaluated diodofon and published its conclusions in a 2008 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 PRVD2010-04, *Diodofon*.

What Is Diodofon?

Diodofon is an antimicrobial used as a material preservative in latex paints, pigment dispersions, coatings, latex caulks and adhesives, leather tanning and paper production (wet lap and sheet pulp). Diodofon is handled by professional workers and is added during the manufacturing process of treated articles and materials using open pour or closed systems. Homeowners can use household products which already contain this active ingredient.

Health Considerations

Can Approved Uses of Diodofon Affect Human Health?

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

People could be exposed to diodofon while working with treated materials during their manufacture or through residential exposure (such as homeowners who may be exposed during application of the treated product or postapplication to the treated materials; for example, 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 (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 diodofon 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 Diodofon Is Introduced Into the Environment?

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

The USEPA concluded that the reregistration of diodofon 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 diodofon, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment for handlers
- Removal of uses from wettable powder labels
- Additional advisory label statements indicating that end-use products intended for leather preservation are limited to leather tanning drums only
- Rate reduction for products used in the preservation of exterior latex paints
- Additional advisory label statements prohibiting use in toys or finger paint
- Additional advisory label statements indicating use is for carpet backing only

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination

Appendix II lists all required label amendments.

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 III lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on diodofon 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), 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 Comments and Responses

1.0 Comment on the limitations of wettable powder and dust/powder formulations

In PRVD2010-04, *Diodofon*, it is proposed that all diodofon end-use products formulated as wettable powders or dusts/powders be limited to leather tanning drum use only, and that all other uses must be removed from product labels. The limitation to leather tanning should apply to wettable powder formulations only as per conclusions from the USEPA RED. Dust/powder formulations should continue to be used for the other registered scenarios (for example, paints, pigment dispersions, caulks, etc.).

Response

The PMRA assumed from the USEPA RED, that the voluntary discontinuation of uses applied to both wettable powders and dusts/powders, when in fact the voluntary discontinuation of these uses was for wettable powder formulations only. Therefore, based on the USEPA RED, the PMRA will revise the re-evaluation decision to specify that end-use products formulated as wettable powders be limited to leather tanning drum use only. As described in PRVD2010-04, occupational exposures and risks were not of concern for dust/powder diodofon formulations used in the following scenarios: leather tanning, preservation of latex paints, pigment dispersions, latex caulks and adhesives, provided that appropriate personal protective equipment are used. On this basis, the PMRA will revise the re-evaluation decision to include continued registration of powder and dust formulations in these scenarios.

Appendix II Label Amendments for Products Containing Diodofon

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 label statements below.

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 labels of end-use products formulated as a wettable powder must state on the primary display panel that this product is only to be used for leather tanning drums. All other uses must be removed from product labels.

II) The **DIRECTIONS FOR USE** of the end-use products formulated as suspensions and registered for exterior latex paints must include a maximum application rate of 0.3% (3000 ppm) of active ingredient by weight for all exterior paint uses.

III) The **DIRECTIONS FOR USE** of all end-use product labels must bear clear application rates, for example, concentrations must indicate if expressed as active ingredient or product concentrations.

IV) The **DIRECTIONS FOR USE** of the labels of all end-use products registered for paint uses must include:

> **DO NOT** use this product in toys or finger paint.

V) Add to **PRECAUTIONS**:

For end-use products formulated as a wettable powder or dust/powder:

> Wear coveralls over long pants, a long-sleeved shirt, chemical-resistant gloves and footwear, and a full face respirator or a half face respirator plus goggles while cleaning equipment and handling product.

For all other end-use product formulations:

> Wear coveralls over long pants, a long-sleeved shirt, chemical-resistant gloves and footwear, and a face-shield or goggles while cleaning equipment and handling product.

VI) For end-use products registered for exterior latex paints (registration numbers 15321 and 25848), add to the **DIRECTIONS FOR USE**:

> Wear long pants, a long-sleeved shirt and chemical-resistant gloves when applying paint with airless sprayers.
>
> It is suggested that the formulator perform field trials within the label rates to determine the best rate for preservation of their paint.
>
> It is recommended to prevent paint chips or dust caused by removing paint from entering water. DO NOT place the painted parts in water after painting until the paint is fully cured.

VII) For adhesives used in carpet treatment, add to the **DIRECTIONS FOR USE**:

> Use only to treat carpet-backing. **DO NOT** use in carpet fibers.

VIII) For all end-use products, add to the **ENVIRONMENTAL HAZARDS**:

> **TOXIC** to aquatic organisms. **DO NOT** discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

Appendix III 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 diodofon 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 active ingredients by the PMRA.

- DACO 4.3.5 Short-term Dermal (21/28-day)
- DACO 4.3.6 Short-term Inhalation (90-day)

These studies 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 OECD guidelines.

- DACO 5.2 Use Description/Scenario
- DACO 5.4 Mixer/Loader/Applicator: Passive Dosimetry Data, OR
- DACO 5.11 Glove/Clothing Penetration Data
- DACO 5.9 Dislodgeable/Transferrable Residue

These studies must be conducted with relevant end-use products and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or OECD guidelines.