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RVD2008-02

Re-evaluation Decision

Naptalam

(publié aussi en français)

28 January 2008

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

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ISBN: 978-0-662-47714-3 (978-0-662-47715-0)

Catalogue number: H113-28/2008-2E (H113-28/2008-2E-PDF)

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Re-evaluation Decision

After a re-evaluation of the herbicide naptalam, under the authority of the [Pest Control Products Act](#) and Regulations, Health Canada's Pest Management Regulatory Agency (PMRA) is granting continued registration for the sale and use of a product containing naptalam in Canada.

An evaluation of available scientific information found that the naptalam end-use product does not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of naptalam uses, new risk-reduction measures must be included on the label of the end-use product. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of naptalam was first presented in Proposed Re-evaluation Decision Document [PRVD2007-11](#), *Re-evaluation of Naptalam*, a consultation document.¹ This Re-evaluation Decision² describes this stage of PMRA's regulatory process for the re-evaluation of naptalam, the Agency's decision and the reasons for it. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-11. To comply with the decision, registrants of products containing naptalam 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.

Naptalam, 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 re-evaluation 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*.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation 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)).

What Is Naptalam?

Naptalam is a herbicide that is used to control weeds in cucumber, melon, squash and pumpkin. Naptalam is applied using groundboom equipment by farm workers and professional applicators.

Appendix I lists all naptalam products that are registered as of 28 February 2007 under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Naptalam Affect Human Health?

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

People could be exposed to naptalam by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. 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 naptalam 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.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of 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.

Naptalam is currently registered in Canada for use on cucumbers, melons, squash and pumpkins, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for naptalam in Canada. 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 Naptalam Is Introduced Into the Environment?

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

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to naptalam in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of naptalam 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. Furthermore, the PMRA will require Tier II data for terrestrial plants and aquatic plants to be submitted to calculate buffer zones.

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 naptalam, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional use directions and environmental hazard statements

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

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 objection³ regarding this decision on naptalam 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 Current Canadian Registered Products Containing Naptalam as
of 28 February 2007**

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
16244	Commercial	Chemtura Canada Co./cie	ALANAP 3 Liquid Herbicide	Solution	240 g/L

Appendix II Label Amendments for Products Containing Naptalam

The Canadian end-use product label must be amended to include the following statements to further protect workers and the environment.

- I) The following statement should be included on the **PRIMARY DISPLAY PANEL**:

POTENTIAL SKIN SENSITIZER

- II) The following statements must be included in the **PRECAUTIONS** section:

May cause skin sensitization. Avoid contact with skin, eyes and clothing.

Wear long-sleeved shirt, long pants, shoes and socks when handling this product. In addition, wear chemical-resistant gloves during mixing, loading, or clean-up and repair activities.

DO NOT apply this product in a way that it will contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

DO NOT enter or allow worker entry into treated areas for 48 hours following application.

- III) The following hygiene recommendations must be included on the label in the **DIRECTIONS FOR USE** section:

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Users should remove clothing/personal protective equipment immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing before reuse.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

IV) The following statements must be included in the **DIRECTIONS FOR USE** section:

DO NOT apply through any type of irrigation system.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

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

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty.

DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium or coarse classification.

DO NOT apply by air.

Not for use in greenhouses.

Release spray no more than 4 feet (1.2 m) above the ground.

V) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted, fine-textured or low in organic matter such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

VI) The label of the end-use product must be amended to reflect the following information:

- Naptalam may be applied to cucumbers and melons 1–2 times per year (one pre-emergence and/or one post-emergence to the crop) with a maximum single application rate of 4.48 kg a.i./ha, and to squash and pumpkins only once per year (pre-emergence to the crop) with a maximum single application rate of 4.48 kg a.i./ha.

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 this active ingredient are required to provide these data or an acceptable scientific rationale:

- Part 2 chemistry data as described in Regulatory Directive [DIR98-04](#), *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, must be submitted to register the technical grade active ingredient.
- For the PMRA to determine an appropriate buffer zone, the registrant of naptalam is required to provide Tier II data for effects of naptalam on terrestrial plants (10 crop species) and aquatic plants (four algae and one vascular plant).

These studies must be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) guidelines.