Re-evaluation Decision RVD2010-04

Naphthalene

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What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the insecticidal uses of naphthalene, 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 naphthalene for sale and use in Canada.

An evaluation of available scientific information found that pest control products containing naphthalene 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 naphthalene uses, new risk-reduction measures must be implemented for all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of naphthalene was first presented in a Proposed Re-evaluation Decision document PRVD2009-16, Naphthalene, a consultation document.[1] This Re-evaluation Decision document describes this stage of PMRA's regulatory process for the re-evaluation of naphthalene 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 PRVD2009-16. To comply with this decision, registrants of products containing naphthalene will be informed of the specific requirements affecting their product registration(s).

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

Naphthalene, as a pest control product, is part of the PMRA's current pesticide re-evaluation program. This 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.

Naphthalene is also used as an intermediate in industrial processes in larger volumes than those used in pesticides, and has been identified as high priority for action by Health Canada and Environment Canada under the Chemicals Management Plan. Naphthalene is included in Batch 1 of the Chemicals Management Plan and a Screening Assessment as well as a Proposed Risk Management Approach were published in July 2008. The Proposed Risk Management Approach states that pesticide uses of naphthalene will be re-evaluated by the PMRA based on currently available information including the Chemicals Management Plan Screening Assessment. In the United States, pesticide uses of naphthalene have undergone re-evaluation as part of the United States Environmental Protection Agency (USEPA) Reregistration Program, and a Reregistration Eligibility document (RED) was published in September 2008. Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that naphthalene was eligible for reregistration provided risk-reduction measures were adopted.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

The USEPA RED was found to cover the science areas that are necessary for the Canadian re-evaluation of naphthalene pest control uses, and to address all formulation types and uses of naphthalene registered in Canada.

The USEPA RED, the Canadian Chemicals Management Plan Screening Assessment and Proposed Risk Management Approach, as well as a Risk Assessment Report on naphthalene generated by the European Union in 2003 were used as a basis for the proposed Canadian re-evaluation decision.

In this decision, the PMRA has also taken into consideration the Canadian specific chemistry of registered pest control products as well as the federal Toxic Substances Management Policy (TSMP).

For more details on the information presented in this Overview, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2009-16.

What Is Naphthalene?

When used as a pest control product, naphthalene is an insecticide in the form of mothballs or flakes for control of moth and larvae which are destructive to textiles made of natural fibres. Moth balls or flakes are to be placed by hand by home owners in airtight containers (trunk or chest) where clothing is stored. Joints or holes are to be sealed with adhesive tape to prevent loss of vapour and entry of insects. Naphthalene vapours build up to levels toxic to the adult or larvae forms of the moth.

Health Considerations

Can Approved Pest Control Uses of Naphthalene Affect Human Health? Naphthalene is unlikely to affect your health when used according to the revised pest control product label directions.

Exposure to naphthalene could occur during placement of mothballs or flakes by homeowners, after placement from inhabiting indoor areas treated with naphthalene, and from accidental ingestion of mothballs by toddlers.

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).

The 2008 USEPA RED covers the aspects of human health risk assessment that are necessary for the Canadian re-evaluation of naphthalene pesticidal uses, and it addresses all naphthalene formulation types and uses registered in Canada. The USEPA concluded that naphthalene 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.

The Canadian Chemicals Management Plan Screening Assessment estimated the potential risk to the Canadian population from exposure to naphthalene based on measured concentrations in homes in Canada. Although this assessment cannot be directly related to the use of pest control products since there are multiple sources of naphthalene in homes, the overall conclusion was taken into consideration in this re-evaluation. The Screening Assessment has concluded that naphthalene may be entering the environment in a quantity that may constitute a danger to human life or health and that preventive or control actions should be developed to protect the health of Canadians and their environment from the potential effects of exposure to this substance. Additional mitigation measures are required in view of this conclusion.

The European Union has looked at the potential risk from use of naphthalene for the control of moths indoors and has concluded that "there is a need for limiting the risk". The carcinogenic and non-carcinogenic potential of naphthalene resulting from inhalation exposure is currently being reassessed by the USEPA Integrated Risk Information System (IRIS) program. There is also research being conducted by industry on the pharmacokinetics of naphthalene. The PMRA may revisit the naphthalene re-evaluation assessment when the IRIS assessment and research on pharmacokinetics are completed.

Environmental Considerations

According to label directions, mothballs and flakes are to be placed exclusively indoors and no environmental exposure is expected to result from the use of naphthalene as a pest control product.

Measures to Minimize Risk

As a result of the re-evaluation of naphthalene, the PMRA is requiring further risk-reduction measures.

Human Health

- Modification of packaging to reduce the potential for accidental ingestion by toddlers.
- Reduction of application rate and modification of packaging to reduce potential release of
- naphthalene vapours inside homes.
- Addition of the statement "For indoor use only" on all labels to clarify that outdoor uses are not registered in Canada.
- Addition of label language to provide clearer use directions.

Appendix I lists required mitigation measures including 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 II lists all data requirements.

Other Information

Any person may file a notice of objection[2] regarding this decision on naphthalene 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, http://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).

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

Appendix I Additional Mitigation Measures Required for Products Containing Naphthalene

1) Packaging Amendments

A) Registrants are required to modify the packaging of end-use products to mitigate the risk of accidental ingestion of loose mothballs by children. Registrants are required to submit a proposal for packaging/formulation options which would discourage children from eating the product (for example, naphthalene formulated as blocks or cakes, packaged individually in sachets). Additional label language is required to ensure that naphthalene products are not applied loose to areas accessible to children.

B) Registrants are required to modify the packaging of mothballs and flakes to minimize the release of vapours while naphthalene products are in storage. A proposal for packaging options must be submitted, this may include use of a re-sealable hermetically closed container, and reduction of the number of mothballs/amount of flakes per product.

2) Rate Reduction

In the United States, according to the USEPA RED, naphthalene is applied indoor at a maximum rate of 330 to 494 g a.i./m^3. This is less than the Canadian maximum application rate of 1667 g a.i./m^3. The Canadian maximum application rate for mothballs and flakes must be reduced to match that of the American rate.

3) Label Amendments

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 mentioned below.

The labels of end-use products in Canada must be amended as follows to further protect human health.

a) The following statement must be included on the primary panel of all labels.

“For indoor use only”

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

“For use in airtight containers only. Do not use as an animal repellent.”

“Apply product at the following rates:

Number of mothballs:	Enclosed space:
ADD NUMBER	Large Trunk (add volume HERE)
according to new application rate	Small drawer (add volume HERE)
	Large drawer (add volume HERE)

“The volume of the storage container to be treated can be calculated bymultiplying the height, width, and depth of the space.”

“Open in a well ventilated area and reseal carefully after application”

“Store in a dry place, inaccessible to children and pets.”

Appendix II Additional Data Requirements

1) Additional chemistry data required

DACO	1.0
Title:	Label
Required Data:	A label revised to the nominal guarantee if this value is different from the current minimum.

DACO:	2.12.2
Title:	Statement of Product Specification Form (SPSF)
Required Data:	An SPSF which includes the nominal concentration (NC), lower and upper certified limits (LCL and UCL) for the active ingredient, and the NC and UCL for all the impurities present in the product above 0.1%.

DACO:	2.13.3
Title:	Batch Data
Required Data:	The registrant is requested to provide analytical data from five recent batches of the TGAI to 0.1% as per Section 2.13.3 of Regulatory Directive Dir98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*.

2) Other data required

The USEPA is requiring a confirmatory study to determine levels of naphthalene in the air resulting from use of mothballs at the maximum rate. This is to refine estimates of intermediate and long-term postapplication inhalation exposure to naphthalene in residential indoor settings. This study is also required by the PMRA as a condition of continued registration under section12 of the *Pest Control Products Act*.

DACO 5.6: Postapplication – Passive dosimetry data