Re-evaluation Decision

Santé

Canada

RVD2023-05

Formic Acid and Its **Associated End-use Products**

Final Decision

(publié aussi en français)

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Re-evaluation decision for formic acid and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental standards and continue to have value. The re-evaluation considers information from various sources such as data and information from pesticide manufacturers and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as risk management approaches and policies.

Formic acid is a miticide registered in Canada for the control of tracheal and varroa mites and used for the treatment of honeybee colonies. Treatment of a hive with formic acid results in the diffusion of vapours through the hive, which target and suffocate mites. The commercial end-use product is applied as a liquid formulation poured onto absorbent materials (such as paper and wood pulp), or pads are pre-soaked and placed into honeybee hives. Domestic end-use products are applied to hives as a liquid formulation poured onto absorbent materials/applicator pads, or as pre-formulated slow-release pads/gel strips. Currently registered products containing formic acid can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2022-15, *Formic Acid and its Associated End-use Products*¹ containing the evaluation of formic acid and proposed decision, underwent a 90-day consultation period ending on 12 October 2022. PRVD2022-15 proposed continued registration of formic acid products in Canada, with label updates to meet current labelling standards (Appendix IV).

Health Canada received one comment relating to the labels of two products containing formic acid. Commenters are listed in Appendix II. The comment is summarized in Appendix III along with the response by Health Canada. The comment and new information did not result in revisions to the value and risk assessments and did not result in changes to the proposed re-evaluation decision as described in PRVD2022-15. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2022-15.

This document presents the final re-evaluation decision² for the re-evaluation of formic acid, including the label updates required to meet the current labelling standards. All products containing formic acid that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for formic acid

Health Canada has completed the re-evaluation of formic acid. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing formic acid is acceptable with label updates (Appendix IV). An evaluation of

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*.

available scientific information found that uses of formic acid products meet current standards for protection of human health and the environment and have acceptable value under the current conditions of use.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required updated label statements as a result of the re-evaluation of formic acid, are summarized below. Refer to Appendix IV for details.

Label improvements to meet current standards:

Human health

• Update to standard label statements (wording related to personal protective equipment and health precautions).

Environment

• Updates to standard label statements (disposal and storage).

Next steps

To comply with this decision, the required label amendments must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available in the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection³ regarding this decision on formic acid and its associated end-use products 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 Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-15) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

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

Appendix I Registered products containing formic acid in Canada¹

Table 1 Products containing formic acid requiring (label) amendments

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%, g/L)
27834	Т	NOD Apiary Products Ltd.	NOD 95% Formic Acid	Liquid	95%
30107	Т	Univar Solutions Canada Ltd.	Formic Acid 85%	Liquid	85%
30106	С	NOD Apiary Products Ltd.	Tracheal Mite Treatment	Liquid	65%
30108	D	Canadian Honey Council	Formic Acid 65%	Liquid	65%
30324	D	NOD Apiary Products Ltd.	Mite Away Quick Strips	Slow-Release Generator	46.7%
31315	D	MiteGone Enterprices Int.	Formic Acid 65% For Use With MiteGone Ready To Fill And Use Kits - Pads And Method	Solution	65%
33321	D	NOD Apiary Products Ltd.	Formic Pro	Slow-Release Generator	42.25%

¹as of 29 November 2022, excluding discontinued products or products with a submission for discontinuation

Appendix II

List of commenters to PRVD2022-15

List of commenters' affiliations for comments submitted in response to PRVD2022-15.

Category	Commenter		
Registrant	NOD Apiary Products Ltd.		

Appendix III Comment and response

Health Canada received one written comment during the public consultation for the formic acid proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. The comment was considered during the final decision phase of this re-evaluation. The summarized comment and Health Canada's response is provided below.

1.0 Comment related to the formic acid product labels

1.1 Comment

A comment related to product labels was received from a registrant stating that the PMRA's label search webpage only provided the primary panel for Formic Acid 65% (Reg. No. 30108), whereas the directions for use on the package leaflet was missing. Additionally, the label for Formic Acid 85% (Reg No. 30107) was not available on the PMRA's label website.

Health Canada response

The labels have been updated accordingly and are now available on the <u>PMRA's Product Label</u> website and in the PMRA's <u>Public Registry</u>.

Appendix IV Label amendments for products containing formic acid

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Label updates for technical grade active ingredients (Reg. Nos. 27834, 30107)

I. Under the DISPOSAL section MODIFY the following label statement as follows:

"Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or and provincial regulations. For additional details and clean up of spills, contact the manufacturer or and the provincial regulatory agency."

Label Updates for commercial and domestic class end-use products (Reg. Nos. 30106, 30108, 30324, 31315, 33321)

II. Under PRECAUTIONS section MODIFY the personal protective equipment as follows:

"Handlers are required to wear a long-sleeved shirt, long pants or coveralls, chemical-resistant gloves, and boots; protective eyewear (goggles or face shield) is also required for liquid/solution products."

III. Under the STORAGE section ADD the following statement:

"Store this product away from food or feed."

For commercial class end-use products (Reg. No. 30106)

IV. Under the DISPOSAL section REPLACE the following label statements:

"Absorbent pads containing formic acid should be disposed of according to provincial instructions. For information on the disposal of unused, unwanted or damaged product and the cleanup of spills, contact the regional office of Environmental Protection, Environment Canada. Follow provincial instructions for any required cleaning of the formic acid container prior to its disposal. Dispose of the container in accordance with provincial requirements."

WITH:

"Follow provincial instructions for any required cleaning of the container prior to its disposal. Dispose of the containers and absorbent pads in accordance with provincial requirements. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.