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Proposed Re-evaluation Decision

PRVD2022-15

# Formic Acid and Its Associated End-use Products

*Consultation Document*

*(publié aussi en français)*

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## Proposed re-evaluation decision

Under 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 safety standards and continue to have value. The re-evaluation considers data and information from various sources such as information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

This document presents the proposed regulatory decision for the re-evaluation of formic acid, including any proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based.

Formic acid is a miticide registered in Canada for the control of tracheal and varroa mites and used for the treatment of honey bee 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 honey bee 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 are listed in Appendix I.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. When the current label directions are followed, these products were shown to have value in providing a pest management solution, and potential risks to human health (occupational, dietary, residential and bystander) and the environment are considered to be acceptable. As a result of the re-evaluation of formic acid, label updates are proposed to meet the current labelling standards (Appendix II).

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing formic acid (Appendix I) are being proposed for continued registration in Canada with proposed label updates.

All products containing formic acid registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,<sup>1</sup> during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration the comments and information received during the consultation period.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

## **Next steps**

The public, including the registrants and stakeholders, are encouraged to submit written comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document<sup>2</sup>, which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it, and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

## **Other information**

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on formic acid (based on the Science Evaluation of PRVD2022-15). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

## **Additional scientific information**

Additional scientific data are not required at this time.

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<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

# Science evaluation

## 1.0 Human health

Formic acid is a naturally-occurring substance found in animals (for example, venom of ants and bees), and in plants (for example, stinging nettles). Synthetic formic acid is used world-wide for a variety of commercial uses, such as a preservative and antibacterial agent in livestock feed, a chemical intermediate in the production of various pharmaceuticals, in the tanning process for leather, and as an ingredient in commercial cleaning products.

Formic acid is considered to be moderately acutely toxic via the oral route. As a volatile acid with a pH of 2, formic acid is extremely corrosive; therefore, it is considered to be highly acutely toxic via the dermal and inhalation routes of exposure. It is also considered to be corrosive to the skin and eyes, and is a potential skin sensitizer (Canada, 2016a).

Occupational and residential handler exposure to formic acid is expected during the application of commercial and domestic liquid products containing formic acid, which handlers pour onto absorbent materials (such as paper and wood pulp), while placing pre-soaked pads into honey bee hives, and during the removal of used materials from hives. Residential handler exposure to formic acid can also occur during the application of solution products, which handlers pour onto applicator pads, and during the placement of pre-formulated slow release pads/gel strips into hives.

Potential occupational and residential handler exposure is expected to be short-term and to occur via dermal and inhalation routes. To mitigate dermal exposure, current domestic and commercial product labels require handlers to wear personal protective equipment. However, label statements for commercial and domestic products are proposed to be updated to reflect current standards; handlers are required to wear a long-sleeved shirt, long pants or coveralls, chemical-resistant gloves, and boots. Protective eyewear (goggles or face shield) are also required when handling liquid/solution products (commercial and domestic).

Inhalation exposure to temporarily high formic acid concentrations is possible during application, for brief periods. Exposure to vapours of formic acid affect the respiratory tract consistent with the corrosive nature of the acid. However, vapours of formic acid are easily detectable at low levels due to its very pungent odour, thus allowing users to avoid prolonged exposure (Canada, 2004). In addition, the atmospheric formic acid level in air is expected to be much lower than that found in the treated hives due to natural aeration with fresh air. Precautionary label statements on commercial and domestic products include: avoid inhaling the vapour; known respiratory irritant; and handle product in a well ventilated area.

Post-application exposure is expected to be minimal as it only involves the removal of used materials from beehives for disposal. Formic acid concentration in used materials is expected to be low due to the high vapour pressure of formic acid resulting in dissipation of the active ingredient (Canada, 2004). Potential risk from post application activities is considered acceptable under the current conditions of use.

Bystander exposure is expected to be negligible since products are intended to be applied directly into beehives. The amount released into the air would be very low (Canada, 2004).

Precautionary and hygiene statements on the product labels are considered adequate to protect occupational and residential handlers, from potential exposure to formic acid. No additional mitigation measures are required, but label updates are proposed to meet current standards.

Formic acid is naturally present in honey. Maximum residue limits (MRLs) are not required for formic acid. Current restrictions include that products are to be used outside of honey flow when no honey supers are present, and the pre-harvest interval of two weeks for liquid products and 0 days for slow release generators (which contain lower concentrations of formic acid than liquid products). See PRDD2004-05 and previous assessments for details (Canada, 2004 and 2015). The potential for residues of formic acid to be present in wax or comb honey is expected to be negligible and the application of formic acid to beehives is not anticipated to result in exposures to sources of drinking water. See PRDD2004-05 and previous assessments for details (Canada, 2004 and 2016b). The general population and potentially sensitive subpopulations, including infants and children, are not expected to be exposed to formic acid residues above levels found naturally in honey and foods (in the form of a food additive). The dietary risk is considered to be acceptable when products containing formic acid are used according to label directions. No additional mitigation measures are proposed.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). Dietary (food and drinking water) exposure is expected to be negligible and residential exposure is not expected to contribute significantly to overall exposure under current conditions of use. On this basis, the potential aggregate risk is considered acceptable when products are used according to label directions.

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, PMRA did not identify any information indicating that formic acid shared a common mechanism of toxicity with other pest control products. The currently registered products containing formic acid also have limited use patterns. Therefore, a cumulative assessment is not required at this time.

As of 21 February 2022, no human or domestic animal incident reports involving formic acid have been reported to the PMRA.

## **2.0 Environment**

Formic acid is freely soluble in water, a moderately strong acid, very highly volatile, and bioconcentration is unlikely to occur. Carbon monoxide is the major transformation product. The use of formic acid in the treatment of honey bee colonies is unlikely to result in significant exposure to the environment. As a result, environmental toxicology, chemistry, and fate data have been waived for the registered use pattern. See PRDD2004-05 for details (Canada, 2004).

Formic acid is not considered a Track 1 substance as it does not meet all Track 1 criteria as per the Toxic Substances Management Policy. Potential risk to the environment from the current use of formic acid is considered acceptable under the current conditions of use.

### **3.0 Value**

Honey bees (*Apis mellifera*) are susceptible to parasitic mites, which can impact the health of a honey bee colony with effects ranging from minor stress to the death of the colony. Uncontrolled mite infestations will kill the entire colony and spread to other hives. Formic acid controls both varroa mites and tracheal mites. It is the only active ingredient registered to manage tracheal mites. Due to its mode of action, mites are not expected to develop resistance to formic acid (Canada, 2004).

As of 21 February 2022, there were seven incident reports submitted to the PMRA involving formic acid. All incidents occurred in 2012 and involved the death of honey bees or honey bee queens from the application of a product which had been newly registered at that time, Mite Away Quick Strips, Registration Number 30324. These are pre-soaked polysaccharide gel strips with a guarantee of 46.7% formic acid that are placed in sealed hives. No incidents have been reported in subsequent years. Formic acid is known to impact honey bees and entire colonies, especially at high temperatures or in weakened colonies from either the mite infestation or another cause (for example, poor overwintering) (Canada, 2012 and 2015).

Label statements are present on all end-use products that warn of potential honey bee deaths, and additional guidance statements to mitigate the risk are present (for example, the liquid domestic product recommends to use a smoker to drive bees from the bottom board, or to drive bees away from the top bars for upper hive placement. The solution product cautions against applications at temperatures above 30°C, and to apply pads in late summer when the queen reduces laying to protect the winter brood. Slow release generator labels caution against applications at temperatures above 29.5°C). Additionally, honey bee and colony deaths caused by mites are a bigger problem than potential injury to the colony caused by formic acid.

No additional mitigation measures are required.

## Appendix I Registered products containing formic acid in Canada

**Table 1 Registered products containing formic acid in Canada<sup>1</sup>**

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
27834	T	NOD Apiary Products Ltd. (NOK)	NOD 95% Formic Acid	Liquid	95%
30107	T	Univar Canada Ltd. (UVN)	Formic Acid 85%	Liquid	85%
30106	C	NOD Apiary Products Ltd. (NOK)	Tracheal Mite Treatment	Liquid	65%
30108	D	Canadian Honey Council (HCA)	Formic Acid 65%	Liquid	65%
30324	D	NOD Apiary Products Ltd. (NOK)	Mite Away Quick Strips	Slow Release Generator	46.7%
31315	D	MiteGone Enterprises Int. (MTU)	Formic Acid 65% For Use With MiteGone Ready To Fill And Use Kits - Pads And Method	Solution	65%
33321	D	NOD Apiary Products Ltd. (NOK)	Formic Pro	Slow Release Generator	42.25%

<sup>1</sup> As of 14 April 2022, excluding discontinued products or products with a submission for discontinuation.  
T – technical, C – commercial, D – domestic



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## Appendix II      Label updates for products containing formic acid

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

### Label Updates for TGAI (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 EP (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 EP (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.”

## References

### Published information

PMRA number	Reference
2541503	Canada, 2016a. Evaluation Report for Category B, Subcategory 1.2 Application. Application Number: 2011-0927. Formic Acid. Registration Number: 30107.
903898	Canada, 2004. Proposed Regulatory Decision Document. <i>Formic Acid/NOD Formic Acid Pad and Mite-Away II™ Formic Acid Pad</i> . PRDD2004-05. 5 November 2004.
2541505	Canada, 2016b. Evaluation Report for Category B, Subcategory 2.1 Application. Application Number: 2011-0943. Formic Acid. Registration Number: 30108.
2135924	Canada, 2012. Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.5, 3.4 Application. Application Number: 2011-2775. Formic Acid. Registration Number: 30324.
2319718	Canada, 2015. Evaluation Report for Category B, Subcategory 3.3, 3.6, 4.6 Application. Application Number: 2013-2327. Formic Acid. Registration Number: 30324.
1032430	Canada, 2005. Regulatory Decision Document. <i>Formic Acid/NOD Formic Acid Pad and Mite-Away II™ Formic Acid Pad</i> . RDD2005-02. 20 April 2005.