

Formic Acid (214900) Biopesticide Registration Eligibility Document

I. Executive Summary

A. Identity

Formic acid (CAS # 64-18-6), is a low molecular weight carboxylic acid. Food grade formic acid is used to formulate the end-use product.

B. Use/Usage

FOR-MITE is a gel formulation of formic acid in a vented plastic pouch that controls the honeybee tracheal mite and aids in the suppression of verroa mite through the volatilization of formic acid. FOR-MITE is not recommended for suppression of the verroa mite in tropical climates or in areas where there is no broodless period for the honeybee. The product is not to be used when honey supers are in place, in order to prevent contamination of marketable honey or wax. It is to be used when there is no surplus honey flow and daytime temperatures are expected to reach at least 50 degrees F., but not to exceed 85 degrees F. For two-story colonies (8-20 full-size Langstroth frames or equivalent), one pouch is to be used and left in place for 30 days. The FOR-MITE pouch must be removed at least 6 weeks prior to harvesting the honey to prevent contamination of marketable honey. Use of formic acid may disturb colony activities and may result in slightly increased bee mortality or queen rejection, especially at temperatures above 90 degrees F. If colonies are treated during hot weather or during honey flow, the bees may be repelled from the hive and honey production reduced.

C. Risk Assessment

There is reasonable certainty that no harm will result from aggregate exposure to formic acid residues in the diet. Formic acid is naturally occurring in honey and other foods and cleared as a flavoring agent (GRAS) by the FDA. The proposed use pattern is not expected to add measurably to background levels naturally occurring in honey and beeswax. As such, the EPA has found the tolerance exemption safe under Section 408(c)(2)(A)(i) of the [Food Quality Protection Act of 1996](#) (FQPA) (Public Law 104-170). While the corrosive nature of formic acid places it in Toxicity Category I with respect to eye, skin, and mucosal irritation potential, the gel-pack method of delivery of formic acid, plus the use of label-required personal protective equipment (PPE), is expected to result in negligible exposure to the applicator.

Use within beehives is considered an indoor use, and as such, no environmental residues or significant non-target organism exposure is expected to result from this use.

1. Human Health Risk Assessment

Formic acid is mildly acutely toxic via the oral and inhalation routes (Tox. Cat. III), a severe eye irritant (Tox. Cat. I), corrosive to the skin (Tox. Cat. I) and highly irritating to the respiratory tract. Published results of Ames tests for mutagenic potential are negative.

2. Ecological Risk Assessment

No environmental residues are expected to occur from use of formic acid in honeybee hives.

D. Data Gaps

There are no data gaps.

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II. Overview

A. Pesticide Overview

The following active ingredient is covered by this registration decision

- **Common name** Formic Acid
- **OPP Chemical code** 214900
- **Trade and other names** FOR-MITE™
- **Registrant**
Mann Lake, Ltd.
501 S. 1st Street
Hackensack, MN 56452

B. Use Profile

- **Type of pesticide** Conventional, Reduced Data Set
- **Use Site** Beehives (Indoor Use)
- **Target pests** Control of Honey Bee Tracheal Mite and suppression of Varroa Mite

- **Formulation type**

FOR-MITE is an end-use product formulation containing 65.9% Active Ingredient. This product is a gel formulation of formic acid in a plastic pouch.

- **Method and Rates of Application**

For two-story colonies (bees covering 8-20 full size Langstroth frames or equivalent), one FOR-MITE pouch is used (remove complete adhesive strip from pouch), and left in place for 30 days. For one-story colonies (bees covering 4-10 full-size Langstroth frames or equivalent), remove half of bottom adhesive strip and leave pouch in place for 30 days.

- **Equipment**

None. This product is formulated as a gel-pack which is activated by means of removing all or portions of adhesive strips which cover vents through which formic acid is volatilized.

- **Method** Volatilization of formic acid.

- **Timing**

This product is not to be used when honey supers are in place, in order to prevent the contamination of marketable honey or wax. It should be used when there is no surplus honey flow and daytime temperatures are expected to reach at least 50 degrees F., but not exceed 85 degrees F. The pouch must be removed from the hive at least 6 weeks prior to harvesting the honey.

- **Use practice limitations**

FOR-MITE is not recommended for suppression of the varroa mite in tropical climates or in areas where there is no broodless period for the honeybee. It is not to be used at temperatures above 90EF, or during honey flow. Use of formic acid at high temperatures may result in slightly increased bee mortality, queen rejection, or repel bees from hive resulting in reduced honey production.

C. **Estimated Use of Pesticide**

None officially used in the U.S. since this is the first registered use of formic acid. Formic acid is already registered in Canada and certain parts of Europe for control of tracheal and varroa mites.

D. **Data Requirements**

Product chemistry data requirements for formic acid have been adequately satisfied by the submitted data and public literature citations. Mammalian toxicology requirements have been satisfied by appropriate waiver rationales and references in the published literature. All ecological effects and environmental fate data requirements have been waived because use in beehives is considered an "indoor" use, and no significant environmental residues or non-target organism exposure is expected. The data required for granting this registration under Section 3(c)(5) of the [Federal Insecticide, Fungicide, and Rodenticide Act](#) (FIFRA) EXIT Disclaimer have been reviewed by the EPA. The Agency foresees no unreasonable adverse effects on human health or the environment from this use of formic acid and recommends an unconditional registration for the proposed use.

E. **Regulatory History**

In June, 1996, the Agency received an application from Mann Lake, Ltd. to register the first use of a new active ingredient, and first end-use product containing formic acid.

A [Notice of Receipt](#) (FRL-5389-2) of the application for a new active ingredient was published in the Federal Register on 8/6/96 (61 FR 40841). Nine comments were received in response to the notice. Eight of the commenters urged the Agency to proceed with registration of formic acid. The emergency situation which exists among apiarists nation-wide due to the impacts of tracheal mites on bee survival and honey production was cited in support of the registration action. One commenter expressed concern regarding impacts of formic acid on bee egg hatchability, larval survivability, and bee behavior, noting a lack of studies designed to assess these potential impacts. The Agency is aware of formic acid use in Canada, where dehydrated eggs, dead young larvae, and dead queens were observed when 85% formic acid was applied, or when application occurred at extremely high temperatures. However minimal negative impact was noted when 65% formic acid was applied. Label statements warn of potential queen rejection and a possible slight increase in bee mortality if formic acid is applied above 90EF. Finally, FIFRA Section 6(a)(2) requires the registrant to submit to the Agency any factual information regarding unreasonable adverse effects on the environment that might be caused by a registered pesticide.

A [Notice of New Active Ingredient Approval](#) was published in the Federal Register on 3/31/99.

F. **Food Clearances / Tolerances**

The registration application was accompanied by a petition for an exemption from the requirement of a tolerance. Residue trials are summarized in section III(A)(2). Formic acid is cleared by FDA as a flavoring agent in foods under 21 CFR 172.515. Ethyl formate is classified as generally recognized as safe (GRAS) under 21 CFR 184.1295.

A [Notice of Filing](#) (FRL-5389-1) of a petition from the Interregional Research Project No. 4 (IR-4) on behalf of Mann Lake Ltd., requesting exemption from the requirement of a tolerance for formic acid in or on honey and beeswax, was published on 8/6/96 (61 FR 40841) with a 30-day comment period. Four comments were received in response to the Notice of Filing. Three of the commenters urged the Agency to issue the tolerance exemption, noting that formic acid is currently used in parts of Europe and in Canada, and that tons of European honey are imported into the United States annually. It was also noted that formic acid is naturally occurring in honey to a variable degree, depending upon the source of the nectar.

On February 5, 1997, a [Federal Register Notice](#) (FRL-5584-6) (62 FR 5370) proposing a tolerance exemption under Section 408(e) of the FFDCA, was published following the passage of the Food Quality Protection Act (FQPA) of 1996.

The [Final Rule](#) granting the exemption under 40 CFR 180.1178 was published on February 22, 1999.

Response to Comments

There were twelve comments received in response to the proposal to exempt formic acid from the requirement of a tolerance. Nine of the commenters urged the Agency to proceed with registration and to grant the tolerance exemption for formic acid.

One of these nine commenters expressed concern regarding impacts of formic acid on short and long-term brood survivability, and potential absorption into brood nest wax, which might later be rendered and introduced into the market. It should be noted that in the United States, brood nest honey and wax are generally recycled in the bee colony, and not harvested for sale as either liquid or comb honey. However, if brood nest wax were to be marketed for non-food use, it would likely be heavily processed due to the marked discoloration of brood nest wax, thereby reducing potential formic acid residues. Regarding the brood survivability issue, one commenter submitted a research report entitled *Sublethal Effects of Three Acaricide Treatments on Honey Bee Colony Development and Honey Production*. This study investigated the effects of fluvalinate, menthol and formic acid (2 application methods) on colony development and honey production. Worker bee longevity, colony weight gain, adult bee mortality, brood viability, sealed brood area, returning foragers, pollen load weight and emerged bee weight were not statistically different between fluvalinate- and formic acid-treated colonies, and control colonies. Brood viability, adult bee population, returning foragers and honey production were not statistically different between menthol- and formic acid- treated colonies, and control colonies. Queen behavior patterns and the number of workers attending the queen were not statistically significant before versus after colonies were treated with formic acid. There were, however, small, but statistically significant decreases in bee longevity and sealed brood area in formic acid -treated colonies as compared to fluvalinate-treated colonies and controls. In addition, formic acid-treated colonies experienced slightly lower honey production than either menthol-treated or control colonies. The overall conclusion of the researcher are that formic acid is not detrimental to colony development or surplus honey production, and that the benefits gained from using formic acid to control parasitic bee mites far outweigh the slight decrease in sealed brood.

One commenter urged the use of spearmint oil, which he considers less invasive, and one commenter expressed concern that beekeepers do not monitor the presence or numbers of tracheal mites before or after applying miticides. This same commenter urged the use of menthol as a less invasive alternative. The Agency supports the use of Integrated Pest Management (IPM) wherein pest population levels are monitored before application of a pesticide, and actively promotes the adoption of IPM practices using less environmentally invasive alternatives.

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III. Science Assessment

A. Physical and Chemical Properties Assessment

1. Product Identity

- Formic acid (CH₂O₂) is a low molecular weight (MW 46) carboxylic acid.
- **CAS Registry Number** 64-18-6
- **Structural Formula** OH-C-OH

2. Food Tolerances (Residue Chemistry)

The petitioner, IR-4, on behalf of the Agricultural Experiment Station of Georgia, and the U.S. Department of Agriculture requested the establishment of an exemption from the requirement of a tolerance for the pesticide formic acid in or on honey and beeswax, when used in overwintering beehives for the control of tracheal mite.

Residue trials conducted in the United States and Canada indicate that residues from formic acid treatment are not expected to add appreciably to background levels naturally found in honey. In studies conducted in the U.S., maximum residues ranged from 6.8-11.9 ppm, as compared to untreated control values of 4.66-9.04 ppm. The mean combined levels of formic acid residues in Canadian trials averaged 61 ppm in a total of 29 samples. Background levels ranged from 41 ppm in clover honey to 1178 ppm in chestnut honey.

The scientific literature indicates that formic acid is a natural component of honey with concentrations most often found in the 9-100 ppm range. Concentrations above this range have been found in honey derived from certain sources, such as chestnut (1178 ppm). It is also naturally occurring in a broad variety of plants, such as *Cistus labdanum* and oil of *Artemisia transiliensis*. It has also been identified in strawberry aroma, bitter orange essential oil, petitgrain lemon and peaches.

3. FDA Clearances

Formic acid has been cleared as a flavoring agent in food under 21 CFR 172.515. Examples of concentrations of formic acid in processed foods are:

non-alcoholic beverages:	1.0 ppm
ice cream, ices, etc.	5.0 ppm
candy	5.0-18.0 ppm
baked goods:	5.0-6.1 ppm
processed cheeses:	9.1-28.1 ppm

Ethyl formate has also been cleared as generally recognized as safe (GRAS) under 21 CFR 184.1295. Examples of concentrations of ethyl formate in processed foods are:

non-alcoholic beverages:	9.4 ppm
ice cream, ices, etc.	21 ppm
candy	50 ppm
baked goods:	98 ppm
processed cheeses:	430 ppm

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Table 1. Product Chemistry Data Requirements

Guideline No	Study	Results	MRID No.
151B-10	Product Identity	Formic Acid CAS #64-18-6	43967201
151B-11	Manufacturing Process	Acceptable	43967201
151B-12	Discussion of formulation of unintentional ingredients	n/a - only food grade formic acid used (FDA cleared as GRAS for use as flavoring agent)	
151B-15	Certification of Limits	Limits listed in CSF adequate	
151B-16	Analytical Method	Titration with NaOH to phenolphthalein endpoint	43967202
151-17	Physical/Chemical Properties		43967202
	Color	colorless	
	Physical State	liquid	
	Odor	13.5EC (85%)	
	Boiling Point	106EC (85%)	
	Density	1.19 (85%)	
	Solubility	Infinitely soluble in water	
	Vapor Pressure	27 mm Hg (100%)	
	Dissociation Constant	n/a	
	Octanol/Water Partition Coefficient	n/a - not required for polar molecules	
	pH	2.0	
	Stability	>7 years in unopened container	
	Oxidizing or Reducing	n/a	
	Flammability (Flashpoint)	64EC	
	Explosibility	In bulk quantities may fuse or melt at high temperatures. Application of water during firefighting efforts may explode, causing extensive scattering of molten material.	
	Storage Stability	7 years in unopened container	
Viscosity	1 centipoise at 20EC		
Miscibility	Infinitely soluble in water;		
Corrosion Characteristics	Corrosive		
Dielectric Breakdown voltage	n/a		

B. Human Health Risk Assessment

1. Toxicology Assessment

a. Acute and Subchronic Toxicity (Tier I)

The acute toxicity of formic acid is described in the published literature as well as the Material Safety Data Sheet (MSDS) supplied by the BASF Corporation, the manufacturer and supplier of the technical product (85% formic acid). Formic acid is mildly acutely toxic via the oral and inhalation route, a severe eye irritant, corrosive to the skin and highly irritating to the respiratory tract. The OSHA standard for occupational exposure is 5 ppm. Formic acid was not mutagenic in the Ames/Salmonella assay.

Since the product has a pH of 2.0, testing for dermal toxicity, dermal irritation, and eye irritation was not required. The end-use product is assigned Toxicity Category I on the basis of severe eye and skin irritation potential. A dermal sensitization study was waived because repeated exposure to the skin is not anticipated given its corrosive characteristics and label personal protective equipment requirements. Immunotoxicity and all subchronic studies have been waived because formic acid is permitted by FDA to be used as a flavoring agent in foods, it is naturally occurring in honey, and this use pattern is not anticipated to add measurable residues to naturally occurring background levels.

Table 2. Product Chemistry Data Requirements

Guideline No	Study	Results	MRID No.
TIER 1 - Acute Toxicity Studies			
152-10	Acute oral toxicity	Rat LD ₅₀ > 1100 mg/kg Tox. Cat. III	43967202 and Admin. Vol 6
152-11	Acute dermal toxicity	Not required for products with pH<2 Corrosive to skin	
152-12	Acute inhalation toxicity	Rat 4 hr. LC50 7.4 mg/l Tox. Cat. III	43967202
152-13	Primary eye irritation	Not required for products with pH<2 Corrosive to eye	
152-14	Primary dermal irritation	Not required for products with pH<2 Corrosive to skin	
152-15	Hypersensitivity	Not required. Corrosive to skin	
152-16	Hypersensitivity Incidents	Not required	
152-17	Microbial Mutagenicity (Ames)	Negative	Admin. Vol 6
152-18	Immunotoxicity	Waived	

b. Chronic Toxicity (Tiers II and III)

All Tier II and III tests *i.e.*, those designed to assess mammalian mutagenic potential and impacts on the immune system, chronic feeding studies and carcinogenicity studies, have been waived because formic acid is a naturally occurring substance in honey and other foods, and is cleared under 21 CFR 172.515 as a Direct Food Additive for use as a flavoring agent in a wide range of processed foods (See Section IIIA, Physical and Chemical Properties).

c. Effects on the Immune and Endocrine System

Formic acid and other related organic acids have no known effect on the immune system, and formic acid bears no structural resemblance to known estrogen mimics. In addition, formic acid is naturally occurring in honey, cheeses, and certain fruits, and is cleared as a Direct Food Additive for use as a flavoring agent in processed food.

2. Dose Response Assessment

The identified toxicological endpoints, *i.e.*, the corrosive properties to eyes, skin and mucosa, neither lend themselves to, nor require a dose response assessment.

3. Dietary Exposure and Risk Characterization

The proposed use pattern will result in negligible residues of formic acid when compared to background levels naturally occurring in honey. Natural levels vary considerably, depending upon the source of the nectar. In trials conducted in the U.S. (Alvin, Texas) six colonies of bees were treated with the label rate and 2X label rate, applied in 4 weekly doses. Honey and beeswax samples were harvested one month following treatment. Maximum residues ranged from 6.81-11.0 ppm, as compared to untreated control levels of 4.66-9.04. In Canadian trials, mean combined levels of formic acid in marketable honey (nectar source unspecified) averaged 61 ppm in a total of 29 samples, as compared to 41 ppm in clover honey and up to 1178 ppm in untreated chestnut honey. These studies demonstrate that residues resulting from treatment do not contribute significantly to background levels when treatment occurs in the spring or early fall, before the beginning of surplus honey flow.

Formic acid is listed as GRAS (21 CFR 121.1164), is permitted on hay crop silage (21 CFR 573.480), and is cleared as a flavoring agent in foods (e.g., 5 - 18 ppm in candy). All the above information suggests that no significant increase in dietary exposure is expected to result from the use of formic acid in overwintering bee hives for the control of tracheal mites.

Because of the low oral toxicity (Toxicity Category III) of formic acid, and because of the fact that its presence in the diet is for the most part, as a naturally occurring food ingredient, the Agency does not believe that there is any reason to be concerned about the potential for cumulative effects of formic acid and other substances that have a common mechanism of toxicity. Since essentially no measurable residues result from the proposed pesticidal use, (*i.e.*, no incremental increase in exposure) EPA believes there is minimal dietary risk associated with this use.

4. Occupational, Residential, School and Daycare Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

While the corrosive nature of formic acid places it in Toxicity Category I with respect to eye, skin, and mucosal irritation potential, the gel-pack method of delivery, plus the label-required personal protective equipment (PPE), is expected to result in negligible exposure to the applicator.

b. Residential, School and Daycare Exposure and Risk Characterization

No residential, school or daycare uses appear on the label.

5. Drinking Water Exposure and Risk Characterization

The proposed use of formic acid in beehives is considered an indoor use, and therefore is not expected to result in environmental residues at any significant distance beyond the site of application.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Including Infants and Children

Use of formic acid against bee mites according to label directions is not expected to raise residues above background levels naturally occurring in honey and beeswax, or result in environmental residues of any kind. In addition, there currently exist no other registered pesticidal uses of formic acid. Therefore, exposure of infants and children to formic acid residues above those naturally found in honey and other foods is not expected to occur as a result of this use.

7. Aggregate Exposure

The potential for dietary exposure of the general public to formic acid residues resulting from its use in beehives for the control of tracheal mites and suppression of varroa mites is not expected to raise background levels naturally found in honey and beeswax. Exposure via drinking water is not expected to occur from this use because use in beehives is considered an indoor use and is not expected to result in environmental residues of any sort. Non-occupational, non-dietary (i.e., residential) exposure is not expected to occur as a result of this use because there are no residential or any other uses registered for formic acid.

The general public is exposed to formic acid through its use as a direct food additive (flavoring agent), and by virtue of its natural occurrence in honey and other foods. Given that no additional dietary or residential exposure is expected to occur from this use, the Agency finds that there is a reasonable certainty that no harm will result from aggregate exposure to formic acid residues.

C. Environmental Assessment

All ecological effects and environmental fate studies have been waived because this use of formic acid for the control of tracheal mites in honeybee hives is considered an indoor use and therefore is expected to result in minimal environmental exposure.

D. Efficacy Data

No efficacy data were required because no public health uses are involved.

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IV. Risk Management/Registration Eligibility

A. Determination of Eligibility for Registration

Being the first registered use of formic acid, and having satisfied the requirements of FIFRA Section 3(c)(5), FOR-MITETM is eligible for registration. The eligible use is for control of the honeybee tracheal mite, and suppression of varroa mite.

B. Regulatory Position

1. Conditional/Unconditional Registration

All data requirements are fulfilled and the Agency has granted an unconditional registration of FOR-MITETM Formic Acid.

2. Tolerance Reassessment

This registration was accompanied by a petition for an exemption from the requirement of a tolerance. There were no existing tolerances or tolerance exemptions for formic acid.

3. CODEX Harmonization

There are currently no CODEX tolerances or exemptions for formic acid.

4. Non-Food Registration

There are no non-food uses for formic acid at this time. The honeybee tracheal mite use is the only current registered use.

5. Risk Mitigation

While the corrosive nature of formic acid places it in Toxicity Category I with respect to eye, skin, and mucosal irritation potential, the gel-pack method of delivery of formic acid, plus the use of label-required personal protective equipment (PPE), is expected to result in negligible exposure to the applicator.

6. Endangered Species Statement

The proposed use of formic acid is considered an indoor use and thus expected to have no impact on endangered species.

C. Labeling Rationale

1. Human Health Hazard

a. Worker Protection Standard Coverage

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse, must comply with the labeling requirements specified by the Worker Protection Standard (40 CFR part 170). The use of formic acid for the control of tracheal mites in honey bee hives is, therefore, not subject to the Worker Protection Standard.

b. Worker Protection Standard Non-Coverage

The method of delivery of formic acid (volatilization from vents in a plastic pouch containing a gel formulation of formic acid), plus the label-required personal protective equipment, is expected to result in negligible exposure to the applicator.

c. Precautionary Labeling

Formic acid possesses a pH of approximately 2.0, and is thus placed in Toxicity Category I based on severe eye, skin and mucosal irritation potential, with no need for additional testing. Because formic acid is corrosive, the Agency requires the most stringent precautionary label statements, as well as the following personal protective equipment to be worn by applicators and other handlers.

"DANGER" "Corrosive to eyes and skin by direct contact or exposure to vapors. Causes potentially irreversible eye damage and skin burns. Harmful or fatal if swallowed. Do not get in eyes, on skin, or clothing. Wear goggles, faceshield, or safety glasses, and chemical resistant gloves. Potential skin sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Harmful if inhaled. Avoid breathing vapors. Use only with adequate ventilation."

Personal Protective Equipment Applicators and other Handlers Must Wear:

Safety glasses or goggles or faceshield

Chemical-resistant gloves, such as barrier laminate or butyl rubber, or neoprene rubber,

or polyvinyl chloride (PVC) or viton or nitrile rubber. Long sleeved shirt and long pants

USER SAFETY RECOMMENDATION

Always stand upwind of the use location to avoid strong vinegar odor.

2. Environmental Hazard Labeling

None required, since use in bee hives is considered an indoor use, and there is no equipment to clean, thereby obviating the need for a "washwaters" statement.

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V. Actions Required by Registrants

Registered Use Sites

No additional action is required at this time.

VI. Acceptable Use Sites

Registered Use Sites

Food Use Sites: Bee Hives

Date Registered: 1/28/99