UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: December 10, 2014

SUBJECT: Oxalic Acid. New Use in Bee Hives to control Varroa mites. D424360

PC Code: 009601
Decision No.: 497398
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: 424360
Registration No.: 91266-R
Regulatory Action: New Use
Case No.: NA
CAS No.: NA
40 CFR: NA

FROM: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Meredith Laws, Chief
Invertebrate-Vertebrate Branch 3
Registration Division (7505P)

The U.S. Department of Agriculture has requested a new use of oxalic acid dihydrate (91266-R, oxalic acid dihydrate 100 % w/w a.i.) to control Varroa mites in honey bee hives.

A Reregistration Eligibility Decision (RED) document for Oxalic acid was issued in 1992.

As part of a work share with the U.S. EPA, Canada's Pest Management Regulatory Agency (PMRA) completed an updated review of the toxicity data for oxalic acid, a dietary assessment, and an occupational assessment for the proposed use (Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009). HED concurs with the conclusions drawn by PMRA and reiterates them, in part, below.

Oxalic acid is ubiquitous in the environment being found naturally in many plants and vegetables, as well as in honey. Dietary exposure from the proposed use will be insignificant and indistinguishable from background levels of oxalic acid; the use should be considered a food use without the requirement of a tolerance. Labeled personal protective equipment (PPE) is sufficient to reduce worker exposures to insignificant levels presenting no risk concern. Therefore, HED has no objection to granting this registration.

Toxicity:

Toxicity data for oxalic acid are summarized in the attached review from PMRA (Toxicology Review, Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009).

Proposed Use

Oxalic acid may be applied using two different methods as described below.

SOLUTION METHOD:

NOTE: To completely dissolve Oxalic Acid Dihydrate, use warm syrup.

Dissolve 35 g of Oxalic Acid Dihydrate in 1 liter of 1:1 sugar: water (weight:volume). Smoke bees down from the top bars. With a syringe or an applicator, trickle 5 ml of this solution directly onto the bees in each occupied bee space in each brood box. The maximum dose is 50 ml per colony whether bees are in nucs, single, or multiple brood chambers. Under certain unfavorable conditions (e.g., weak colonies, unfavorable overwintering conditions), this application methods may cause some bee mortality or overwintering bee loss.

VAPORIZER METHOD:

Apply only to outdoor colonies with a restricted lower hive entrance. Seal all upper hive entrances and cracks with tape to avoid escape of Oxalic Acid vapor. Smoke bees up from the bottom board, Place 2.0 g Oxalic Acid Dihydrate powder into vaporizer. Follow the vaporizer manufacturer's directions for use. Insert the vaporizer apparatus through the bottom entrance. Apply heat until all Oxalic Acid has sublimated.

Dietary and Aggregate Exposure:

The following summary is taken from the PMRA dietary exposure review (Dietary Exposure Review, Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009). HED concurs with these conclusions [*information in brackets added by HED*]:

"Oxalic acid occurs naturally in honey with amounts varying with the type of flower pollen is collected from. The applicant is unable to provide a range of values of oxalic acid in Canadian Honey, but submitted information which suggests that European honey contains 1-800 mg/kg, depending on the botanical source of the pollen.

It is anticipated that the amount of oxalic acid present as a food residue after application of the end use product will not likely exceed the naturally occurring background concentration currently found in honey or vegetables (300-17,000 mg/kg for vegetables). It is also expected that a majority of available oxalate anion will bind with calcium (also naturally occurring in honey) on ingestion, resulting in a compound which is poorly absorbed by the gastro-intestinal tract (GI tract). Excretion of calcium oxalate in the faecal matter and urine of rodents was evidenced upon ingestion of oxalic acid in non-fasted animals. Less than 10

% of the administered dose was absorbed through the GI tract.

Distinguishing between endogenous and anthropogenic sources of oxalic acid and enforcing an MRL [*pesticide tolerance in the case of the U.S. registration*] is not possible. As such, promulgation of an MRL [*pesticide tolerance in the case of the U.S. registration*] will not be necessary."

HED concurs with this assessment. Since low level residues in honey are possible as a result of this use but are indistinguishable from endogenous sources, the use should be considered a food use, but a tolerance should not be required.

Since oxalic acid is ubiquitous in the environment and exposures from use in honey bee hives will be minimal, the contribution to aggregate risk from this use will be insignificant relative to the total exposure from other sources.

Worker Exposure:

The following label restrictions are included in the oxalic acid label (EPA Reg. No. 91266-R)

"Hazard avoidance: Do not breathe dust or fumes. Do not get in eyes, on skin, or on clothing. Wear protective clothing, eyewear, and respiratory protection as listed under "Personal Protective Equipment.." Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT:
Handlers and Applicators who apply product by the Solution Method must wear:
- Long-sleeved shirt and long pants
- Socks and shoes
- Waterproof gloves
- Protective eyewear (goggles or face shield)
- Half-face respirator with cartridge and/or particulate filter

Handlers and Applicators who apply product by the Vaporizer Method must wear:
- Long-sleeved shirt and long pants
- Socks and shoes
- Waterproof gloves
- Protective eyewear (goggles or face shield)
- Half-face respirator with cartridge and/or particulate filter

User Safety Requirements:
Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

HED recommends that the label additionally specify that the respirator used when applying this product be used with an acid gas cartridge and a particulate filter.

HED has not selected endpoints related to use of oxalic acid in bee hives, or completed a quantitative risk assessment. However, based on the high level of personal protective equipment (PPE) required by the pesticide label, HED concludes that the label use restrictions will reduce worker exposures to oxalic acid to an insignificant level, unlikely to result in risks of concern.

Attachment: Toxicity Review from Canada's Pest Management Regulatory Agency

Health Canada / Santé Canada

Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

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October 26, 2009

Memorandum To/Note adressée à: Brian Belliveau, Ph.D.
Head, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

From/De: Kevin Arnold
Senior Evaluation Officer, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

Subject/Objet:

Sub. No(s):	1) 2008-4596 2) 2008-4584
Product Name:	1) Oxalic Acid Dihydrate 2) Oxalic Acid Varroa Mite Control Product
Active Ingredient:	Oxalic acid (OXL) / acaricide
Applicant:	Canadian Honey Council (HCA)

ACTION REQUESTED: **Level D, Category A.1.1 Submission Review (HED3) Toxicology**

Submission Information: The Canadian Honey Council has applied for the registration of a new source of the technical grade active ingredient (TGAI), Oxalic Acid Dihydrate (2008-4596), as well as the commercial registration of a new end-use product (EP), Oxalic Acid Varroa Mite Control Product (oxalic acid, 99.6 % w/w a.i.). The EP, a miticide, is proposed for use in the control of varroa mites on honey bees.

According to the U.S. EPA, oxalic acid is commonly used as an analytical reagent, in textile finishing, in metal, wood, or equipment cleaning, in bleaching straw and leather, in removing paint, varnish, rust, or ink stains, in dye manufacturing, in chemical synthesis, in the paper, ceramics, photographic, and rubber industries, *in vitro* as a blood specimen anticoagulant in veterinary medicine, *etc*.

Oxalic Acid Dihydrate and Oxalic Acid Varroa Mite Control Product (oxalic acid, 99.88 % w/w a.i.) were originally submitted for registration in 2005 as submissions 2005-0026 & 2005-0027 but were withdrawn by the applicant in 2006. An interim decision was made by the SMC and a letter notifying the Canadian Honey Council (Aucoin to Clay, October 5, 2005) that permission to use oxalic acid as an unregistered miticide in bee colonies would be granted if conditions and precautions determined by the PMRA were observed and followed. According to the Canadian Honey Council, concerns were raised by their members regarding the legality of using an unregistered pest control product in the colonies. The Canadian Honey Council has since reapproached the PMRA for full registration of the TGAI and associated EP.

Oxalic acid is not registered with the PMRA as a technical grade active ingredient but is present in a number of registered EPs as a formulant (list 3) since 2002. There are currently no active registrants using oxalic acid as active pesticide ingredient registered with the U.S. EPA. The only active submissions within the PMRA, involving oxalic acid as the TGAI, are those submitted by the Canadian Honey Council (2008-4596 & 2008-4584).

Review:

Technical Grade Active Ingredient

Acute Toxicity

Oxalic Acid Dihydrate has an oral LD_{50} of 375 mg/kg bw in female rats, and a dermal $LD_{50} > 20{,}000$ mg/kg bw in female rabbits. The inhalation LC_{50} was not included in the available literature, but the chemical nature of oxalic acid is such that one would expect irritation and mucosal burns to result from oxalic acid dust and/or fumes. The TGAI is classified as highly acutely toxic via the oral route and a low acute toxicity classification via the dermal route.

According to available literature, oxalic acid dihydrate is moderately irritating when applied to the skin and severely irritating to the eyes. The pH of oxalic acid dihydrate is 1.3, which suggests a corrosive compound. In light of the fact that detailed studies were not submitted by the applicant, classification of oxalic acid dihydrate with the skin or the eye will default to corrosive.

Although there was a lack of information with respect to oxalic acid's potential as a dermal sensitizer, the long history of use in a variety of processes and products, coupled with a general lack of medical reports regarding sensitization potential of oxalic acid, suggests that the TGAI is not a dermal sensitizer.

Table 1. Acute toxicity information for oxalic acid dihydrate (99.6 % w/w a.i.).

ACUTE STUDIES			
Oral (gavage)	Rat – Sprague-Dawley (5/sex)	LD_{50} (♀) 375 mg/kg bw LD_{50} (♂) 475 mg/kg bw **Highly acutely toxic.** (Based on the LD_{50} (♀) 375 mg/kg bw)	A NOAEL could not be determined from the available information. The principal display panel should include the statement **DANGER POISON. Fatal or Poisonous if swallowed** should be included on the secondary display panel.
Dermal	Rabbit – New Zealand white (3 females) Dose administered as a 5 % aqueous solution.	LD_{50} (♀) > 20,000 mg/kg bw **Low acute toxicity.**	A NOAEL could not be determined from the available information.
Inhalation	Information regarding acute inhalation was not available for evaluation. It is expected, however, that, due to the caustic nature of oxalic acid, inhaling dusts or fumes should be avoided. There are NIOSH and ACGIH adopted TLVs of 1 mg/m^3 (TWA) and 2 mg/m^3 (STEL).[a] The statements **Avoid inhaling/breathing dust or fumes** and **NIOSH approved mask should be worn** should be included on the secondary display panel.		
Eye Irritation	Rabbit Dose: 250 µg of oxalic acid for 24 hours.	Extreme Irritation when unrinsed after 24 hours. **Severly irritating.**	In another study, corneal injury was resolved within 6 days (30 second exposure to a 5 % solution). Since the pH of oxalic acid dihydrate is 1.3, eye irritation will be categorized as

			corrosive. The principal display panel should include the statement **DANGER – CORROSIVE TO EYES**. The secondary display panel should include **CORROSIVE to the eye** and **DO NOT get in eyes**.
Dermal Irritation	Rabbit Dose: 500 mg of oxalic acid for 24 hours.	**Moderately Irritating.**	The principal display panel should include the statement **DANGER – SKIN IRRITANT**. The secondary display panel should include **Corrosive to skin** and **DO NOT get on skin**.
Dermal Sensitization	Although there appears to be no available information regarding dermal sensitization, the long history of use suggests that oxalic acid is not a potential sensitizer.		

a - TLV - Threshold Limit Value; TWA – Time Weighted Average; STEL – Short-Term Exposure Limit; NIOSH – National Institute for Occupational Safety and Health; ACGIH – American Conference of Government Industrial Hygienists.

Short-term Toxicity

Young adult Long-Evans rats were administered oxalic acid in the diet at 0, 2.5, and 5.0 % (estimated to be 0, 1.98, and 5.3 g/kg bw/day in females; 0, 1.78, and 5.3 g/kg bw/day in males) for 70 days.

There was an statistically significant decrease in term body weight in both the 2.5 and 5.0 % dose groups ($p<0.001$ in males and females. The mortality rate for the 5.0 % dose group was 25 %, whereas the mortality rate for the 2.5 % group was < 10 %. There were no clinical effects apparent in the 2.5 % dose group, but pronounced effects were noted in the 5.0 % dose group, *i.e.*, emaciated, stunted, gaunt with arched backs.

Gross pathology results demonstrated a lack of body fat and a minimal amount of adipose tissue adherent to visceral and endocrine tissue, as well as kidneys which were discoloured, brownish with roughened crinulated surfaces, abnormal notching on the edges and small stones. All pathology findings were observed in male and female rats at 5.0 % oxalic acid. The majority of these findings are consistent with emancipated animals, resulting from a significant loss of body weight in the test animals and not necessarily due to the direct effects of oxalic acid. The kidney pathology may have been due to exposure

from oxalic acid, but insufficient data was available in the literature to verify these findings.

Additional short-term toxicity information was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in short-term toxicological effects.

Prenatal Developmental Toxicity

Information with respect to prenatal developmental toxicity was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in prenatal developmental toxicological effects.

Mutagenicity and Genotoxicity

Anhydrous oxalic acid (99 %), in water as a solvent, was tested for bacterial mutagenicity using the AMES assay, *i.e.*, *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100. The doses tested were 0.0 - 6666.7 Φg/plate, with and without metabolic activation, *i.e.*, rat and hamster liver S-9, Aroclor 1254 induced. Positive controls were also tested concurrently. The positive control chemical 2-aminoanthracene was tested on all strains in the presence of rat and hamster S-9. 4-Nitro-o-phenylenediamine was tested on TA98 without S-9, 9-aminoacridine was tested on TA1537 without S-9, and sodium azide was tested on TA100 and TA1535 without S-9. The number of revertants was used as the endpoint and a positive result was determined to be a result of at least 2x the background count.

All other genotoxicity results were negative, with or without metabolic activation.

Additional information with respect to mutagenicity and genotoxicity was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in mutagenic and/or genotoxic effects.

End Use Product

Acute Toxicity

The end use product is the same as the technical grade active ingredient, therefore, the acute toxicity of the EP will be identical to the TGAI.

The reader is referred to the acute toxicity section of the technical grade active ingredient of this evaluation report.

Label Recommendations:

Technical Grade Active Ingredient

Principal Display panel

Remove the following statements and pictographs:

OXALIC ACID

Varroa Mite Control Product

Agricultural

KEEP OUT OF REACH OF CHILDREN

POISON

CORROSIVE

Add the following statements and pictograph:

OXALIC ACID DIHYDRATE

FOR MANUFACTURING, FORMULATING OR REPACKAGING

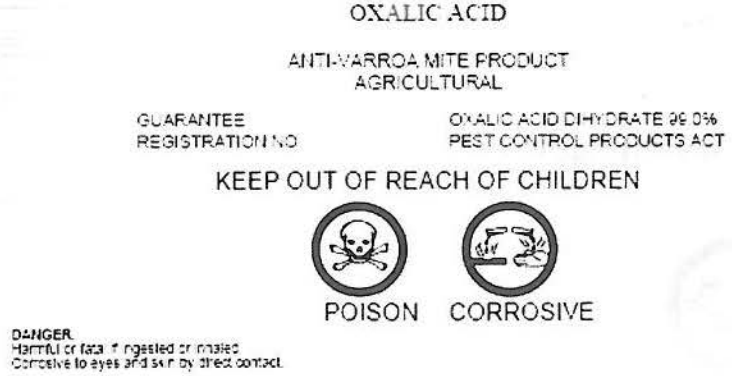
DANGER - POISON

DANGER – CORROSIVE TO EYES

DANGER – SKIN IRRITANT

Secondary Display Panel

Remove the following statements and pictographs from the beginning of the secondary display panel:



Remove the following statements from the **PRECAUTIONS** section:

> **Wear a full mask (or a half mask and goggles) fitted with organic acid filter and chemical resistant gloves when applying oxalic acid.**
>
> **Keep away from food, drink and bee feeds.**

Add the following statements to the **PRECAUTIONS** section:

> **PREVENT ACCESS BY UNAUTHORIZED PERSONNEL.**
>
> **Fatal or Poisonous if swallowed.**
>
> **Avoid inhaling/breathing dust or fumes.**
>
> **CORROSIVE to the eyes.**
> **DO NOT get in eyes.**
>
> **Corrosive to skin.**
> **DO NOT get on skin or clothing.**

Remove the following statements from the **FIRST AID** section:

> **Always carry large amount of clean water to wash skin and eyes immediately if contact with Oxalic Acid Dihydrate occurs.**
> **SKIN: Remove contaminated clothing immediately. Wash affected area with soap or mild detergent and large amounts of water. If chemical burn develops, cover area with a sterile, dry dressing and bandage securely. Contact a physician immediately.**
>
> **EYES: Wash eyes immediately with large amounts of water. Cover with sterile bandages. Contact a physician immediately.**
>
> **INGESTED. Do not induce vomiting. Drink large quantities of water or milk. If vomiting occurs, administer fluids repeatedly. Never give anything by mouth to an unconscious person. Contact a physician or Poison Control Center immediately.**

INHALED. Remove victim to a safe, uncontaminated area. Rest. Keep warm. If breathing is shallow, give oxygen. Get immediate medical attention.

Add the following statements to the **FIRST AID** section:

If swallowed	**Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.**
If on skin or clothing	**Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.**
If inhaled	**Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.**
If in eyes	**Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.**

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

Add the following section and associated statement to the secondary display panel:

TOXICOLOGICAL INFORMATION.

Treat symptomatically.

End Use Product

Principal Display Panel

Remove the following statements and pictographs:

OXALIC ACID

POISON

CORROSIVE

Add the following statements and pictograph:

OXALIC ACID DIHYDRATE

DANGER - POISON

DANGER – CORROSIVE TO EYES

DANGER – SKIN IRRITANT

Secondary Display Panel

Remove the following statements and pictographs from the beginning of the secondary display panel:

Add the following statements to the **PRECAUTIONS** section:

Fatal or Poisonous if swallowed.

Avoid inhaling/breathing dust or fumes.

CORROSIVE to the eyes.
DO NOT get in eyes.

Corrosive to skin.
DO NOT get on skin or clothing.

Remove the following statements from the **FIRST AID** section:

Always carry large amount of clean water to wash skin and eyes immediately if contact with Oxalic Acid Dihydrate occurs.
SKIN: Remove contaminated clothing immediately. Wash affected area with soap or mild detergent and large amounts of water. If chemical burn develops, cover area with a sterile, dry dressing and bandage securely. Contact a physician immediately.

EYES: Wash eyes immediately with large amounts of water. Cover with sterile bandages. Contact a physician immediately.

INGESTED. Do not induce vomiting. Drink large quantities of water or milk. If vomiting occurs, administer fluids repeatedly. Never give anything by mouth to an unconscious person. Contact a physician or Poison Control Center immediately.

INHALED. Remove victim to a safe, uncontaminated area. Rest. Keep warm. If breathing is shallow, give oxygen. Get immediate medical attention.

Add the following statements to the **FIRST AID** section:

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If on skin or clothing	**Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.**
If inhaled	**Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.**
If in eyes	**Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.**

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

Add the following section and associated statement to the secondary display panel:

TOXICOLOGICAL INFORMATION:

Treat symptomatically.

Formulant Toxicology: There were no formulants of toxicological concern. See Appendix 1.

TGAI: (HED3) Toxicology Level D Passed.

EP: (HED3) Toxicology Level D Passed.

Reviewed by:

_____ **Date:**_____
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Peer Reviewed by:

_____ **Date:**_____
Sathish Achuthan
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Approved by:

_____ **Date:**_____
Brian Belliveau, Ph.D.
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1767370 DACO: 0.1.6003

Appendix 1: Product Specifications

Purpose	Acaricide
Formulation Name	Oxalic Acid Dihydrate Varroa Mite Control Product
Technical Active (%)	Oxalic Acid Dihydrate (99.6 %)
PCP / Appl. No.	2008-4584
Use Pattern	USC # 8 – Livestock For Food

Formulant Evaluation

Formulant Ingredient	CAS #	Purpose in Formulation	Percent by Weight	PMRA Formulant List
None.	N/A	N/A	N/A	N/A

PMRA List:
List 1: Contains formulants identified as being of significant concern with respect to their potential adverse effects on health and the environment, meeting defined criteria for carcinogenicity, neurotoxicity, chronic effects, adverse reproductive effects, ecological effects, Track 1 substances as defined under the Toxic Substances Management Policy (TSMP) and substances designated under the Montreal Protocol.

List 2: Contains formulants that are considered potentially toxic, based on either structural similarity to List 1 formulants or data suggestive of toxicity.

List 3: Contains formulants that do not meet the criteria of any of the other lists.

List 4A: Contains formulants that appear on the USEPA Minimum Risk Inerts List, which are generally regarded to be of minimal toxicological concern, as well as substances commonly consumed as foods.

List 4B: Includes formulants, some of which may be toxic, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product [as on specific use pattern listed in the United States Code of Federal Regulations, 40 CFR Protection of Environment, Subpart D 180.000(c)(d)(e)] will not adversely affect public health and the environment.