

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

May 14, 2024

Brian Hogan Agent, KRK Consulting LLC Chemicals Laif S.P.A. Vis Dell' Artigianato, 13 Vigonza, PD, Italy 35010

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Replacing

Primary Name (Throughout Label); Updating EPA Reg # and Company Address

Product Name: Api-Bioxal

EPA Registration Number: 73291-2 Company: Chemicals Laif S.P.A. Application Date: 3/19/2024

Action Code Case Number: 00558542

Dear Mr. Hogan:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The primary brand name - Api-Bioxal – has replaced the previous primary brand name - Oxalic Acid Dihydrate. The new name has been documented in the product's records.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false

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or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions, please contact Chris Pfeifer of my team by phone at (202)-566-1599 or via email at pfeifer.chris@epa.gov.

Sincerely,

James Parker, Team Leader Biochemical Pesticide Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

73291-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/14/2024

Oxalic Acid Dihydrate Api-Bioxal

For Varroa mite control on bees

Active Ingredient:

Oxalic Acid Dihydrate: 97.0% Inert Ingredients 3.0% TOTAL: 100.0%

EPA Reg. No. 91266-173291-2

EPA Est. No.
Net Contents:
Batch Code No.:

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO POISON



FIRST AID		
If swallowed	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. DO NOT INDUCE VOMITING unless told to by the poison control center or doctor. Do not give anything by mouth to an unconscious person 	
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 center or doctor for advice. 	
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for advice. 	
If inhaled	 - Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, if possible. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance, use respiratory medical device. - Call a poison control center or doctor for advice. 	
	HOT LINE NUMBER	

Have the product container or label with you when calling a poison control center, doctor, or going for treatment.

For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Website: www.npic.orst.edu).

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Provide general supportive measures and treat symptomatically. Treatment should be rapidly instituted by giving a dilute solution of calcium lactate, limewater, finely pulverized chalk, plaster, and/or milk to supply large amounts of calcium to inactivate oxalate by forming an insoluble calcium salt in the stomach. Gastric lavage is controversial, since this may compound an already severe corrosive lesion in the esophagus or stomach. However, if used, gastric lavage should be done with limewater (calcium hydroxide). Intravenous gluconate or calcium chloride solutions should be given to prevent hypocalcemic tetany; in severe cases parathyroid extract also has been given. Additionally, acute renal failure should be anticipated, and careful fluid management is necessary. Metabolically its toxicity is believed to be due to the capacity of oxalic acid to immobilize calcium and thus upset the calcium-potassium ratio in critical tissues. Effective therapy against burns from oxalic acid involves replacement of calcium.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER POISON



Fatal if swallowed. Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if absorbed through the skin. May be fatal if inhaled. Do not get on skin, in eyes, or on clothing. Do not breathe vapor or spray mist. Wear protective clothing, eyewear, and respiratory protection as listed under "Personal Protective Equipment."

PERSONAL PROTECTIVE EQUIPMENT:

Handlers and Applicators who apply product by the Solution Method must wear:

- Long-sleeved shirt and long pants
- Socks and shoes
- Chemical resistant gloves (barrier laminate, butyl rubber ≥ 14 mils., nitrile rubber ≥ 14 mils., neoprene rubber ≥ 14 mils., natural rubber ≥ 14 mils., polyethylene, polyvinyl chloride ≥ 14 mils., or viton ≥ 14 mils.)
- Protective eyewear such as goggles
- Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter

Handlers and Applicators who apply product by the Vaporizer Method must wear:

- Long-sleeved shirt and long pants
- Socks and shoes
- Chemical resistant gloves (barrier laminate, butyl rubber ≥14 mils., nitrile rubber ≥ 14 mils., neoprene rubber ≥ 14 mils., natural rubber ≥ 14 mils., polyethylene, polyvinyl chloride ≥ 14 mils., or viton ≥ 14 mils.)
- Protective eyewear (goggles or face shield)
- Wear a minimum of a NIOSH-approved elastomeric half mask respirator with acid gas cartridges and combination N, R, or P filters

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/PPE 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read the entire label. This product must be used strictly in accordance with this label's precautionary statements and use directions, as well as with all applicable State and Federal laws and regulations.

USE RESTRICTIONS:

Oxalic Acid Dihydrate Api-Bioxal applications are for in-hive use only.

DO NOT use in enclosed overwintering areas.

Apply only when monitoring indicates treatment is required. Consult state guidelines and local extension experts for monitoring protocols and thresholds for treatment.

APPLICATION DIRECTIONS:

Use Oxalic Acid Dihydrate Api-Bioxal when little or no brood is present as Oxalic Acid-Dihydrate Api-Bioxal will not control Varroa mites in capped brood and may damage bee brood. Consult state guidelines and local extension experts about best application practices when applying Oxalic Acid Dihydrate Api-Bioxal when capped brood is present because multiple treatments several days apart will be needed to reduce successive cohorts of adult mites.

Oxalic acid can be used when honey supers are on the hive.

Oxalic acid is used to treat colonies during low brood periods, packages, or swarms. This product can also be used as a "clean up" Varroa treatment following the application of a different acaricide where Varroa infestations continue to be problematic.

SOLUTION METHOD:

Only apply Oxalic Acid DihydrateApi-Bioxal as a solution when mixed with sugar-water. IMPORTANT: To completely dissolve Oxalic Acid DihydrateApi-Bioxal, use warm syrup. Dissolve 1.23 oz (35 g) of Oxalic Acid DihydrateApi-Bioxal in 0.26 gal (1 L) of 1:1 sugar: water (weight:volume). Smoke bees down from the top bars. With a syringe or an applicator, trickle 0.03 fl oz (5 ml) of this solution directly onto the bees in each occupied bee space in each brood box. The maximum dose is 1.7 fl oz (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 method may cause some bee mortality or overwintering bee loss.

SPRAYING PACKAGE BEES:

Ensure bees are clustered before applying oxalic acid (for example store in cool dark location 24 hours before application).

Spray broodless package bees with a 1:1 sugar:water solution at least 2 hours before spraying with oxalic acid. This allows bees to fill honey stomachs with sugar water reducing ingestion of oxalic acid. Mix a 2.8% oxalic acid solution by dissolving 1.23 oz (35 g) of Oxalic Acid Dihydrate Api-Bioxal in 0.26 gal (1 L) of 1:1 sugar: water (weight:volume). Evenly apply 0.1 fl oz (3.0 mL) of 2.8% oxalic acid solution per 1,000 bees using a pump sprayer or battery powered sprayer (for example, a typical 2 lb package contains approximately 7,000 bees which requires 0.71 fl oz. (21 mL) of solution). Apply solution evenly on both sides of the package.

Store bees in a cool darkened room for 72 hours before hiving.

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 0.4 oz (1.0 g) per brood chamber of Oxalic Acid Dihydrate Api-Bioxal 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.

RESISTANCE MANAGEMENT: Oxalic acid's mechanism of action is unknown at this time. Any Varroa mite population has the potential to become resistant to acaricides. Resistance development is affected by both the frequency of application and rate/dose of application. Continued reliance on a single class of miticide or single miticide with the same mode of action will select for resistant individuals which may dominate the mite population in subsequent generations. In order to prevent resistance development and to maintain the usefulness of individual insecticides it is important to adopt appropriate resistant management strategies.

To delay resistance:

- When possible, rotate the use of miticides to reduce selection pressure as compared to repeatedly using the same product, mode or action or chemical class. If multiple applications are required, use a different mode of action each time before returning to a previously used one.
- Base miticide use on Integrated Pest Management (IPM). This includes proper pest identification, monitoring for locality specific economic threshold and economic injury levels, record keeping, and utilizing all available control practices (cultural, biological and chemical).
- Maximize efficacy by following all label instructions including dosage and timing of application.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store only in original container, in a dry place inaccessible to children, pets, and domestic animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.

PLASTIC CONTAINER DISPOSAL: Triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available. Otherwise, puncture and dispose of in a sanitary landfill, or, by incineration.

UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL RESEARCH SERVICE, Bee Research Laboratory 10300 Baltimore Avenue, Bldg. 306, Rm. 315 BARC-EAST Beltsville, MD 20705 Chemicals Laif S.P.A. Vis Dell' Artigianato, 13 Vigonza, PD 35010, Italy