



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

August 19, 2024

Rob Jones. Agent for
Vita Bee Health Limited
c/o Delta Analytical Corporation
12510 Prosperity Drive
Suite 160
Silver Spring, Maryland 20904

Subject: Non-PRIA (Pesticide Registration Improvement Act) Label Notification per 98-10 conversion to Labeling Amendment – to add a Storage and Disposal section; graphics and symbols; include illustration of proper product use; and product expiration dates
Product Name: VARROXSAN
EPA Registration Number: 94413-3
EPA Receipt Date: 06/13/2024
Action Case Numbers: 00610791

Dear Mr. Jones:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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 FIFRA and is subject to review by the U.S. Environmental Protection Agency or 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

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EPA Reg. No. 94413-3

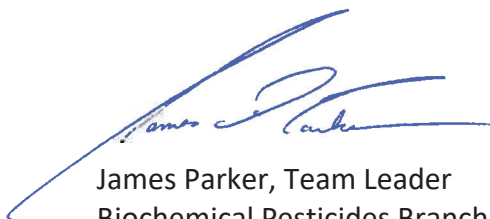
Action Case Nos. 00610791

process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

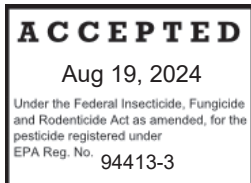
If you have any questions, please contact Cheryl Greene at greene.cheryl@epa.gov or James Parker@parker.james@epa.gov.

Sincerely,



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

Enclosure – Stamped Label



[VARROXSAN™]

EPA REG. NO: 94413-3
EPA Establishment No. 102604-URY-1

- This labeling must be in the possession of the user at the time of application.
- Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the EPA registered label.

SUSTAINED-RELEASE FIBER STRIP FOR CONTROL OF VARROA MITES ON BEES

Active Ingredient: Oxalic Acid Dihydrate:18.42%
 Inert Ingredients: 81.58%
 TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER-PELIGRO

POISON



FIRST AID

If swallowed	<ul style="list-style-type: none"> - 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 to an unconscious person.
If in eyes	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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.

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

Fatal if inhaled. Do not breathe (dust, vapor, or spray mist). Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter. Remove and wash contaminated clothing before reuse. Corrosive. Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin, or on clothing. Wear chemical resistant gloves and protective eyewear (goggles or face shield). May be fatal if swallowed. Harmful if absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

STORAGE AND DISPOSAL	
Do not contaminate water, food or feed by storage or disposal.	
PESTICIDE STORAGE:	Keep strips in original, unopened packaging until ready to use. Store in original packaging only. Store in a cool (below 86°F / 30°C), dry area, out of direct sunlight and heat, and away from other pesticides that may contaminate the strips. Do not freeze. After first opening the immediate packaging, use the strips immediately and do not store.
PESTICIDE DISPOSAL:	Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
CONTAINER HANDLING:	Nonrefillable container. Do not reuse or refill this container. Dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by local regulations .

PERSONAL PROTECTIVE EQUIPMENT:

Handlers and Applicators who apply product 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 particulate filtering facepiece respirator with any N, R, or P 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/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.

VarroxCsan™ is a sustained-release fiber strip designed for use in beehives to control the parasitic mite (Varroa destructor) on honey bees.

EXTENDED-RELEASE METHOD PERMITTED WITH HONEY SUPERS ON.

FOR USE WHEN THE VARROA DESTRUCTOR INFESTATION REACHES A LEVEL THAT WILL AFFECT THE HEALTH OF THE COLONY IF LEFT UNCHECKED. APPLICATION COULD BE SPRING, SUMMER, OR FALL. THE TREATMENT MUST BE SEPARATED BY AT LEAST ONE CHAMBER FROM ANY HONEY TO BE EXTRACTED.

How to determine when treatment is necessary? Use an alcohol wash of about 300 nurse bees collected off of a brood frame and determine the percentage of varroa mite infestation. Treat once the infestation reaches 1-2%.

For varroa treatment -. Use 4 VarroxCsan™ strips per brood chamber (i.e., one strip per 2.5 Frames of Bees - FoB).

# FoB	0 - 2.5	3 – 5	6 - 7.5	8 - 10
# strips	1	2	3	4

Take the appropriate number of strips from the pack, fold in half and hang each strip over one comb frame inside the brood area or the bee cluster, with a minimum distance of 2 frames

between strips, for example, one strip in frames 2, 4, 6, 8. Hang Varroxsan™ strips in the brood chamber in such a way that the bees can walk on the strips, slightly away from the surface of the frames. Leave the strips inside the hive from 42 days to 56 days, and then remove. If, after 42 days bees are not in contact with the strips, reposition the strips closer to the cluster. Strips must be removed after a maximum of 56 days. DO NOT re-use the strips.

Timing:

Hang Varroxsan™ strips in the hives in the spring-summer and/or the Fall if varroa mite infestations have reached treatment threshold.

USE RESTRICTIONS

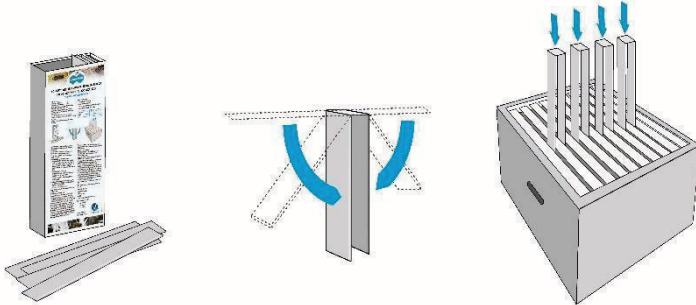
- For in-hive use only. Maximum rate = 4 strips per brood chamber per application (i.e., one strip per 2.5 Frames of Bees - FoB).
- Strips must be removed after a maximum of 56 days.
- Do not re-use strips.

Manufactured For: Vita Bee Health Limited
1 Castlewood Avenue
Rathmines, Dublin 6 D06 H685
Phone: 417-363-0020

Expiration date: 24 months from date of manufacture
Batch number/Date of manufacture: See edge of pack

Made in Uruguay

Image of instruction to user on placement of strips



Company logo

