U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration (under FIFRA, as amended)	EPA Reg. Number: 94413-1	Date of Issuance: 1/29/2020			
	Term of Issuance: Conditional Name of Pesticide Product:				
Name and Address of Registrant (include ZIP Code): Vita Bee Health Limited 1 Castlewood Avenue Rathmines, Dublin 6 006 H685 Ireland	B402 Biological	Larvicide			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.					
On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).					
Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.					
This product is conditionally registered in accordance with FIFRA section $3(c)(7)(B)$ . You must comply with the following conditions:					
1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.					
Signature of Approving Official:	Date:				
SENICH Mon	1/29/2020	0			
Seiichi Murasaki, Senior Regulatory Advisor Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs					

- 2. Be aware that proposed data requirements have been identified in a Final Work Plan. For more information on these proposed data requirements, you may contact the Re-Evaluation Team Leader: <u>https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-biopesticides-and-pollution-prevention</u>.
- 3. Make the following labeling change before you release this product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 94413-1."
- 4. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

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 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 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.

Your release for shipment of this product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

• Basic CSF dated 07/10/2019

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at boukedes,alexandra@epa.gov.

## {Note: Texts in [ ] are optional language. **B402 BIOLOGICAL LARVICIDE** [ABNs: B402 BIOLOGICAL LARVICIDE CERTAN; B402 CERTAN BIOLOGICAL LARVICIDE

For the Prevention and Control of Greater Wax Moth (*Galleria mellonella L.*) Infestation on Bee Hive Frames During Storage

Active Ingredient:				
Bacillus thuringiensis subsp. aizawai strain ABTS-1857 fermentation solids,				
spores, and insecticidal toxins*				
Other Ingredients				
Total:	100.0%			

\*Potency: 2,500 Cabbage Looper Units per mg of product or 1.13 billion Cabbage Looper Units per pound of product.

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

# KEEP OUT OF REACH OF CHILDREN WARNING

## FIRST AID

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 treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15 20 minutes.
- Call a poison control center or doctor for treatment advice.

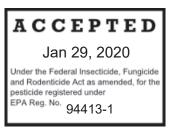
# HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center 1-800-222-1222.

EPA Registration No. 94413-R EPA Est. No. 33762-IA-l

Lot No.: Net Contents: 4 fl oz, 5 fl oz, 8 fl oz, 1 Qt

Manufactured For Vita Bee Health Limited 1 Castlewood Avenue Rathmines, Dublin 6 006 H685 Ireland



## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**Warning.** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin or clothing 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 (PPE)**

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Protective eyewear
- Mixers/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any R or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **User Safety Recommendations**

Users should:

- 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.

#### **Environmental Hazards**

Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

#### **PRODUCT INFORMATION**

Read all directions before using this product.

B402 Biological Larvicide (hereafter B402) is for prevention and control of greater wax moth (*Galleria mellonella L.*) infestation on beehive frames during storage. B402 is a biological product that contains *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, It eliminates larvae of the greater wax moth *Galleria mellonella L.* 

B402 contains living bacterial spores. Store in a cool, dry place inaccessible to children and out of sunlight.

#### MIXING INSTRUCTIONS

- Measure out and mix B402 with water only
- Use 1 part of B402 to 19 parts water (5% spray solution)
- Add water to the mix tank and provide moderate agitation. While agitating, add the required amount of B402. Maintain the suspension with moderate agitation while spraying.
- Use diluted solutions within 3 days.
- [One (1) 4-fluid ounce bottle of B402 can treat 80 Deep Frames, 124 Medium Frames, or 143 Shallow Frames)][One (1) 8-fluid ounce bottle of B402 can treat 160 Deep Frames, 248 Medium Frames, or 286 Shallow Frames)]

#### [Hive Frame Types and Sizes:

Frame Type	Frame Size (inches)	Foundation Size (inches)
Deep	9½ x 17 5/8	8 <sup>1</sup> / <sub>2</sub> x 16 <sup>3</sup> / <sub>4</sub>
Medium	6¼ x 17 5/8	5½ x 16¾
Shallow	5 <sup>3</sup> / <sub>8</sub> x 17 5/8	4 <sup>3</sup> / <sub>4</sub> x 16 <sup>3</sup> / <sub>4</sub>

#### **APPLICATION INSTRUCTIONS**

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- Apply B402 in the Autumn to beehive frames prior to placing combs in storage. Allow treated frames to completely dry prior to storage.
- Spray one (1) fluid ounce of the 5% spray solution on each Deep Frame; 2/3 ounce 5% spray solution on each Medium Frame, <sup>1</sup>/<sub>2</sub>-ounce 5% sprays solution on each Shallow Frame.
- Apply spray solution uniformly to the both sides of the frame, the foundation and wax combs.

	# Frames	Water	B402	Total 5% Spray Solution
Deep Frames	10	9½ fl oz	½ fl oz	10 fl oz
	100	3 Qts	5 fl oz	31/4 Qts
	1000	7½ Gal	1½ Qts	8 Gal
	10	6¼ fl oz	¹∕₃ fl oz	6 2/3 fl oz
Medium Frames	100	2 Qt	3 fl oz	2.1 Qt
	1000	5 Gal	1 Qt	5.2 Gal
	10	5¼ fl oz	1⁄4 fl oz	5.5 fl oz
Shallow Frames	100	1 2/3 Qt	2¾ fl oz	1¾ Qt
	1000	3.6 Gal	0.9 Qt	4.5 Gal

## STORAGE AND DISPOSAL

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

**Storage:** Reclose containers of unused B402. Store in a cool, dry place inaccessible to children and out of sunlight. Keep container closed when not in use.

**Pesticide Disposal:** To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**Container Disposal:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank. Fill the container <sup>1</sup>/<sub>4</sub> full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or dispose of in trash or in a sanitary landfill or by incineration.

## WARRANTY

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Vita Bee Health. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Vita Bee Health makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Vita Bee Health is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Vita Bee Health disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

# [Optional Marketing Claims]

- Biopesticide based on a live bacterium
- Protect combs from Greater Wax Moth
- Made in the USA
- For hobbyist and commercial beekeepers
- Only 1 treatment needed
- Economical
- Innovative
- A Good Choice for Your Comb