



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 13, 2018

Timothy Joseph  
Regulatory Agent  
Vita (Europe) Limited  
c/o Landis International, Inc.  
PO Box 5126  
Valdosta, GA 31603

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Addition of 0.88 oz Sachet Size, Addition of Bee Health Logo and Updates to the Directions for Use  
Product Name: Apiguard  
EPA Registration Number: 79671-1  
Application Date: August 16, 2018  
OPP Decision Number: 543590

Dear Mr. Joseph:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 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 (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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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 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 Gina Burnett by phone at (703) 605-0513 or via email at [burnett.gina@epa.gov](mailto:burnett.gina@epa.gov).

Sincerely,

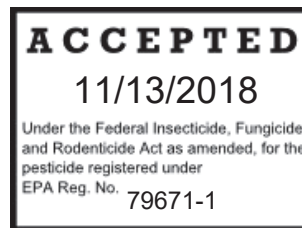
A handwritten signature in black ink, appearing to read "Andrew Bryceland", written over a light blue rectangular background.

Andrew Bryceland, Team Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure

# APIGUARD

For treatment of varroosis due to *Varroa destructor* in honeybees.



**Active Ingredient:**

Thymol (CAS # 89-83-8) .....	25%
Other Ingredients .....	75%
Total:	100%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

<b>FIRST AID</b>	
<b>If In Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call poison control center or doctor for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If On Skin Or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>HOT LINE NUMBER</b></p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact CHEMTREC at 800-424-9300 for emergency medical information (24 hours).</p>	

(See [leaflet inside the box/enclosed/side panels] for [entire label,] precautionary statements and directions before use.)

EPA Reg No. 79671-1

EPA Establishment No. 083118-GBR-001

Batch or Lot Number: \_\_\_\_\_

Net Contents:

**(TUBS) 6.6 lbs. (3 kg)**

**(READY TO USE ALUMINUM TRAYS) 1.1 lbs. (500 g) [10 Trays with 1.76 oz. (50 g) per tray]**

**(SACHETS) 11.02 lbs. (5kg) [200 Sachets x with 0.88 oz. (25g) per Sachet]**

**[0.88 oz. (25 g) Sachet [for individual sale]**

Manufactured For:

**VITA (EUROPE) LIMITED**  
 c/o Landis International, Inc.  
 P.O. Box 5126  
 Valdosta, GA 31603-5126  
 800-526-3471



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**Danger:** Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear chemical resistant gloves. 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 handlers must wear:

- long-sleeved shirt and long pants
- socks and shoes
- chemical resistant gloves
- protective eyewear (goggles, face shield, or safety glasses)

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.

Do not enter or allow personnel to enter into treated areas during the restricted-entry interval (REI) of 48 hours.

#### USER SAFETY RECOMMENDATIONS

##### Users Should:

- 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. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### ENVIRONMENTAL HAZARDS

For terrestrial uses. This product is toxic to aquatic invertebrates. Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

#### PHYSICAL OR CHEMICAL HAZARDS

Do not use, pour, spill or store near heat or open flame. Do not store above 86°F.

## 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 requirement specific to your State or Tribe, consult the State/Tribal agency responsible for pesticide regulation.**

**READ ENTIRE LABEL, USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

[See leaflet (inside the box/enclosed/attached) for entire directions before use.]

## GENERAL INFORMATION

**Failure to follow directions and precautions on this label may result in poor mite control, and/or illegal residues.**

AFIGUARD is a product specifically designed for use in beehives. The unique slow release gel matrix formulation and easy-to-use [tray] [dosing syringe] ensures correct dosage of the active ingredient thymol. AFIGUARD gel regulates the liberation of thymol within the honeybee colony. AFIGUARD has no harmful effect on the honeybee colony, neither on brood nor on adults, when used according to directions.

### For best results:

- Do not use the product when the maximum daily temperature is lower than 60°F or when the colony activity is very low.
- Do not use the product when the maximum daily temperature is above 105°F.
- Combine weak colonies before treatment.
- Make sure the worker bees can access the tray.

### Restrictions:

- Do not treat during honey flow.
- Leave the product in the colony until the trays are empty. In any case remove the product when installing the supers on the colony.
- Remove surplus honey supers before applying treatment.
- Do not enter or allow personnel entry into treated areas during the restricted-entry interval (REI) of 48 hours.

## APPLICATION PROCEDURES

The efficacy of AFIGUARD is maximized if the product is used in late summer after the honey harvest (when the amount of brood present is diminishing). However, in the case of severe infestations, AFIGUARD can also be used during springtime, when temperatures are above 60°F. Efficacy will vary between colonies due to the nature of the application. Therefore, AFIGUARD should be used as one treatment among others within an Integrated Pest Management program, and mite fall regularly monitored. If further significant mite fall is observed during the following winter or spring, use an additional secondary winter or spring treatment for varroa.

**For 200 x 0.88 oz (25g) sachets:** At temperatures above 77°F, a treatment using 2 x 0.88 oz (25g) or 3 x 0.88 oz (25g) Apiguard can be used effectively. A fourth dose of 0.88 oz (25g) gel can be applied at these temperatures, where mite infestations persist.

### METHOD OF ADMINISTRATION:

#### FOR 6.6 lbs (3 kg) TUBS:

Open the hive. Place a piece of wax sheet, cardboard or plastic sheet (approximately 4" x 4"), or the provided dosing tray, centrally on top of the brood frames. **Stir [product] well before each use.** Remove the dosing syringe from its sealed packaging. Insert the syringe nozzle fully into the gel, ensuring no air is drawn into the syringe. Slowly pull the plunger back on the syringe to draw up 51ml (equivalent to 1.76 oz/50g) of Apiguard gel. Remove the syringe from the gel. Gently push the plunger downwards to release the gel within the syringe onto the dosing tray. Flatten out the gel with a hive tool, if necessary. Ensure that there is a free space of at least 1/4 inch between the top of the tray and the hive cover board, for example, by placing an empty super on top of the brood box. Close the hive. After two weeks apply the second dose of 51ml (equivalent to 1.76 oz/50g) Apiguard gel following the same procedure. Leave the product in the colony for a further 2 to 4 weeks until it totally disappears from the tray or until supers are installed, whichever is sooner. Total treatment period should be a minimum of 4 weeks and a maximum of 6 weeks.

At temperatures above 77°F, a lower dosage of 25-26 ml (approximately 0.88 oz/25g) Apiguard gel can be used effectively. At these higher temperatures, only one application of 25-26ml (approximately 0.88 oz/25g) should be applied at any one time. Repeat dose applications may be applied at intervals of 1-2 weeks, as needed for up to 4 applications of

25-26ml (approximately 0.88 oz/25g) where mite infestations persist. Remove any remaining Apiguard gel from the hive before successive applications. Use the dosing syringe as described above to administer the required dose of Apiguard gel.

Small and wintering bee colonies and nuclei require only one dose of 12-13 ml (approximately 0.44 oz/12.5g) to 25-26 ml (approximately 0.88 oz/25g) Apiguard gel (depending on the colony or nucleus size), left in place until the product disappears from the tray. Use the dosing syringe as described above to administer the required dose of Apiguard gel.

#### **FOR 1.76 oz (50g) READY TO USE ALUMINUM TRAYS:**

Open the hive. Peel back the foil lid of the APIGUARD tray leaving one corner of the lid attached to the tray. Place the open tray centrally on top of the brood frames, gel side up. Ensure that there is a free space of at least ¼ inch between the top of the tray and the hive cover board, for example, by placing an empty super on top of the brood box. Close the hive. After two weeks replace the first tray with a new one, according to the same instruction. Leave the product in the colony until the tray is empty. Remove the product when installing the supers on the colony.

At temperatures above 77°F, a lower dosage **consisting** of ½ of the contents of the tray (**half tray =** approximately 0.88 oz/25g) can be used effectively. At these higher temperatures, only one application of approximately 0.88 oz/25g (**a half tray**) should be applied at any one time. To use a half dosage of the tray, peel back the foil lid of the tray then using strong scissors cut the tray in half. Place half of the tray centrally on top of the brood frames, gel side up. Ensure that there is a free space of at least ¼ inch between the top of the tray and the hive cover board, for example, by placing an empty super on top of the brood box. Close the hive. Use the other half of the tray for treating another hive. Repeat dose applications may be applied at intervals of 1-2 weeks, as needed for up to 4 applications of approximately 0.88 oz/25g where mite infestations persist. Remove any remaining Apiguard gel from the hive before successive applications.

#### **FOR 200x 0.88 oz (25g) SACHETS:**

Open the hive. Place the dosing tray provided (approximately 4" x 4") centrally on top of the brood frames. Tear open the Apiguard sachet at the tear notch and squeeze out the sachet contents onto the dosing tray or surface. Ensure that there is a free space of at least ¼ inch between the top of the tray and the hive cover board, for example, by placing an empty super on top of the brood box. Close the hive. After one week replace with a second dose of 0.88 oz (25g) Apiguard gel. One week after the second dose apply a third dose of 0.88 oz (25g) Apiguard, following the same procedure. Where mite infestations are high, a fourth dose of 0.88 oz (25g) Apiguard can be introduced one to two weeks after the third dose. Leave the product in the colony for a further 2 to 4 weeks until it totally disappears from the tray or until supers are installed, whichever is sooner. Total treatment period should be a minimum of 4 weeks and a maximum of 6 weeks. Small and wintering bee colonies and nuclei require one dose of 0.88 oz (25g) gel only, left in place until the product disappears from the tray. At temperatures above 77°F, small or weak colonies can be treated with 0.44 oz (12.5g) Apiguard (half a sachet) only.

#### **Overdose:**

The use of a dose higher than [1.76 oz (50g) (for trays and sachets)/51ml (equivalent to 1.76 oz/50g) (for tubs)] of Apiguard gel per application, corresponding to 0.44 oz (12.5g) thymol, could cause disturbances in the behavior of the colony (agitation, absconding or increased mortality).

**For 200 x 0.88 oz (25g) sachets:** At temperatures above 77°F, the dose can be reduced to 1 x 0.88 oz (25g) (one sachet) per application.

In case of overdose, remove the excess product from the colony.

#### **Withdrawal Period:**

- Surplus honey supers can be installed immediately after the end of treatment and removal of the Apiguard product.
- Honey may be harvested immediately upon accumulation of sufficient surplus in the supers.
- Do not use during honey flow.

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Do not store above 86°F. Do not freeze. Keep unopened in original packaging. Protect from direct sunlight.

**Pesticide Disposal:** Pesticide wastes are acutely 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.

(Tub/Tray:) Triple rinse (or equivalent) promptly after emptying. Then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of container in a sanitary landfill, or by other procedures approved by State and local authorities.

(Sachet:) Place empty sachet in trash or offer for recycling, if available.

(Box for tray and sachet:) Place empty box in trash or offer for recycling, if available.

**WARRANTY AND DISCLAIMER STATEMENT**

VITA (EUROPE) LIMITED, warrants that this product in its unopened package conforms to the chemical description on the label and is reasonably fit for the purposes set forth on the label when used according to directions under normal use conditions to the crops specified. There are no other warranties, expressed or implied, concerning the use of this product other than indicated on the label. This warranty does not extend to the handling or use of this product contrary to label instructions.

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