

79671-1

7/7/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Wm. Ronald Landis, Ph.D
Regulatory Agent
Vita (Europe) Limited
c/o Landis International, Inc.
P.O. Box 5126
Valdosta, GA 31603-5126

JUL 07 2010

Subject: Notification to Update Storage and Disposal Statement per PRN 2007-4
Product Name: Apiguard
EPA Reg. No: 79671-1
Your Submission Dated June 2, 2010

Dear Dr. Landis:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 2007-4, dated above. A screen of the labeling revision request has been conducted for its applicability under PRN 2007-4, and it has been determined that the action request falls within the scope of this document. Our records have been duly noted, and the printed label with this application has been stamped "Notification Accepted" and will be placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Casciano at (703) 605-0513 or via email at casciano.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

2016



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Vita (Europe) Limited/ 79671-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Apiguard	PM# 91 BPPD	Notification Accepted
5. Name and Address of Applicant (Include ZIP Code) Vita (Europe) Limited c/o Landis International, Inc. PO Box 5126 Valdosta, GA 31603-5126 <input type="checkbox"/> Check if this is a new address		
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Reviewer: <u>C. Casciano</u> Date: <u>7/7/10</u> Product Name _____		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Storage and Disposal statements per PR Notice 2007-4. This notification is consistent with the guidance of PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. 50 g	No. per container 10	If "Yes" Package wgt	No. per container	<input checked="" type="checkbox"/> Metal	* Certification must be submitted	
							<input checked="" type="checkbox"/> Plastic		
				<input type="checkbox"/> Glass					
				<input type="checkbox"/> Paper					
				<input type="checkbox"/> Other (Specify) _____					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 3kg and 500g		5. Location of Label Directions <input checked="" type="checkbox"/> on label and leaflet					
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other self-adhesive labels						

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Wm. Ronald Landis, Ph.D.	Title Regulatory Agent	Telephone No. (Include Area Code) 229-247-6472
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Agent	
4. Typed Name Wm. Ronald Landis, Ph.D.	5. Date June 2, 2010	

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Notification Accepted

Date: 7/7/10

Reviewer: G. Casciand

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**

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 further treatment advice.
If Swallowed	§ Call poison control center or doctor for treatment advice. § Do not induce vomiting unless told to do so by the poison control center or doctor. § Have person sip a glass of water if able to swallow. § Do not give anything by mouth to an unconscious person.
In 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 further treatment advice.
If Inhaled	§ Move person to fresh air. § If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. § 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. You may also contact CHEMTREC at 800-424-9300 for emergency medical information (24 hours).	

See side/back panels for additional precautionary statements

EPA Reg No. 79671-1

Net Contents:

EPA Establishment No. 083118-GBR-001

Manufactured By:
VITA (EUROPE) LIMITED
 c/o Landis International, Inc.
 P.O. Box 5126
 Valdosta, GA 31603-5126
 800-526-9417

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. 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)

Do not enter or allow worker entry 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.
- \$ 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.

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.

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 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 worker 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.

METHOD OF ADMINISTRATION:

FOR 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. Using the dosing tools (scoop and spatula), apply the first dose of 50 g gel from the tub onto the tray. Ensure the scoop is full and level off the excess with the spatula. Use the spatula to scrape the gel to an even thickness over the tray area with the spatula. Ensure that there is a free space of at least 3 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 50 g 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. Small and wintering bee colonies and nuclei requires one dose of 25 g gel only, left in place until the product disappears from the tray. Dose out 50 g onto the treatment tray as before and cut in half.

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FOR 50 g 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 3 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.

Overdose:

The use of a dose higher than 50 g gel per application, corresponding to 12.5 g thymol, could cause disturbances in the behavior of the colony (agitation, absconding or increased mortality). 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. 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.

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.