

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Jan Brill Manager, Registrations Bayer Environmental Science 2 T. W. Alexander Drive Research Triangle Park, NC 27709

JUL 25 2008

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4

Dear Mr. Brill:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated June 26, 2008 for:

EPA Registration 432-1385

Premise Granules

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 2007-4 and finds that the label changes requested falls within the scope of PR Notice 2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by nonnotification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-8893.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs



Form Approved, OMB No. 2070-0060 Please read instructions on reverse before completing form. **OPP Identifier Number United States** Registration **Environmental Protection Agency** ☐ Amendment Washington, DC 20460 Other: Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 432-1385 Venus Eagle 4. Company/Product (Name) PM# None Restricted Premise® Granules 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) **Bayer Environmental Science** (b)(I), my product is similar or identical in composition and labeling 2 T.W. Alexander Dr. NOTIFICATION EPA Reg. No. Raleigh, NC 27709 JUL 2 5 2008 Product Name Check if this is a new address Section - II Amendment - Explain below. Final printed labels in response to Agency letter dated _ "Me Too" Application Resubmission in response to Agency letter dated _____ Notification - Explain below. Other - Explain below **Explanation**: Use additional page(s) if necessary. (For Section I and Section II.) Notification of label change per PR Notice 2007-4 This notification is consistent with the guidance in 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 for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to 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: Water Soluble Packaging Type of Container Child-Resistant Packaging Unit Packaging Yes Yes Yes* Metal (foil packet) ⊠ No X No M No Plastic If "Yes" If "Yes" No. per No. per Glass Package wgt. Unit Packaging wgt. container container *Certification must Paper be submitted Other (Specifiy) 3. Location of Net Contents Information 4. Size(s) Retail Container Location of Label Directions 1 through 10 pounds 🛛 On Label Container On labeling accompanying product Other 6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) Name Telephone No: ไม่ยlude Area Manager, Registrations Code) Jan Brill 919/549-2421 Certification Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. If Received acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both (Stamped) under applicable law. 2. Signature 3. Title Manager, Registrations 4. Typed Name 5. Date 26 June 2008 Jan Brill

Bayer Environmental Science



Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN:

Venus Eagle, PM #01

Subject:

Premise® Granules, EPA Reg. No. 432-1385

Notification of Label Change per PR Notice 2007-4

Dear Ms. Eagle,

With this submission, Bayer Environmental Science notifies EPA of Label Changes to bring the subject product into compliance with PR Notice 2007-4, consisting of the following changes to the Container Disposal section of the Storage and Disposal Statement (verbatim from PR Notice);

June 26, 2008

Addition of non-refillable advisory & statement to not re-use or refill container.

Please note that the product is not dilutable, so the PR Notice residue removal statements are not required.

To effect this action, enclosed please find the following;

- EPA Form 8570-1
- 2. 1 copy of final printed labeling for the subject product
- 3. 1 copy of final printed labeling with changes highlighted

Bayer Environmental Science P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Tel. 919 549-2421 Fax. 919-549-3937

I trust that this completes the documentation for this registration action. If you have any questions, or require further information, please contact me either by telephone at 919/549-2421 or email at jan.brill@bayercropscience.com

Sincerely,

Manager, Registration

Email; jan.brill@bayercropscience.com

NOTIFICATION

JUL 25 2008

Premise® Granules

For Pest Management Professionals and Commercial Use Only.

To KILL subterranean termite species of Coptotermes, Heterotermes, Reticulitermes, and Zootermopsis.

This product will kill workers and/or winged reproductive forms of termites present at the time of application only. Application of this product will not provide structural protection nor substitute for mechanical alteration, soil or foundation treatment with termiticide. This product is not to be used as sole protection against termites, as it is not designed to offer structural protection and will not prevent future infestations. A professional inspection is recommended.

ACTIVE INGREDIENT:	
Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine	0.5%
OTHER INGREDIENTS	99.5%
TOTAL	
EPA Reg. No. 432- 1385	EPA Est: 432-xxxx

Net Contents: ___ Pounds

STOP - Read the label before use. KEEP OUT OF REACH OF CHILDREN. CAUTION

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 do so by a poison control center or doctor.	
	Do not give anything by mouth to an unconscious person.	
If on skin or clothing	Take off contaminated clothing.	
	Rinse skin immediately with plenty of water for 15 to 20 minutes.	
· ·	Call a poison control center or doctor for treatment advice.	
If in eyes	 Hold eye open and rinse slowly and gently with water for 15 to 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. 	
	HOT LINE NUMBER	
	er or label with you when calling a poison control center or doctor, or in case of emergency call toll free the Telephone No.1-800-334-7577	
	NOTE TO PHYSICIAN	
No specific	c antidote is available. Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is highly toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when 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.

GENERAL INFORMATION

This product is a ready-to-use formulation of imidacloprid intended to kill subterranean termite species of *Coptotermes, Heterotermes, Reticulitermes, and Zootermopsis.*

This product is formulated on a granulated carrier for perimeter band and/or soil incorporation applications. When applied to soil, precipitation and/or soil moisture cause the active ingredient to release from the granule and establish residues in the top few inches of soil at concentrations that will kill foraging termites which may be present at the time of application. Spot treatments with this product can be made in advance of the date when final treatment of the structure with a conventional soil applied termiticide and/or foundation treatment.

USE SITES

This product can be applied as directed to bare soils, landscaped areas and turfgrass immediately surrounding commercial and residential structures, as well as other wooden constructions subject to termite attack.

Applications should not be made when areas are waterlogged or when the soil is saturated with water. Adequate distribution of the active ingredient into the soil where termites are active cannot be achieved when these conditions exist.

APPLICATION

<u>Perimeter Applications:</u> This product can be used as a perimeter band application 3 to 10 feet wide around and adjacent to the structure foundation in commercial and residential areas. To kill subterranean termites foraging near commercial and residential structures, apply this product at a rate of 1.8 lb. (29 oz.) per 1,000 sq. ft. Irrigation of treated areas (not to the point of run-off) will move the active ingredient through the thatch layer in turf, through ground covering and into the underlying soil where termites forage. Apply this product uniformly over the area being treated with standard granular application equipment; including hand-held spreaders or shaker cans, and wheel-mounted spreaders. Calibrate application equipment prior to use according to the manufacturer's directions. Check frequently to be sure equipment is working properly and distributing granules uniformly and accurately.

Soil Incorporation: Use this product to make spot treatments to kill termites in soil which may be present at the time of application. Incorporate this product in localized areas of soil along the foundation of commercial and residential structures, or in soil adjacent to other threatened wooden constructions. After digging a narrow trench (about 6 inches in width and 6 inches in depth), uniformly incorporate 1/6 lb. (3.0 oz.) of this product per linear foot of trench. Mix this product thoroughly with the soil when backfilling the trench. Alternately, incorporate at a rate of 1/3 lb. (5.0 oz.) of this product per sq. ft. of surface at critical areas such as around plumbing, bath traps, utility services or wells/cisterns, and around poles or posts, fencing and decking materials, landscape timbers and similar non-structural wood-to-soil contacts.

NOTE: 1 level cup is approximately 8.5 oz. of PREMISE Insecticide Granules.

RESTRICTIONS

Avoid runoff or puddling of irrigation water following application. Do not plant for the purpose of consumption, edible plants into the treated areas of soil.

Food utensils such as teaspoons and measuring cups should not be used for food purposes after use with this injecticide. Avoid contamination of public and private water supplies.

Do not apply more than 80 lb. of this product (0.4 lb. of active ingredient) per acre per year.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Handle and open container in a manner as to prevent spillage. If material is spilled for any reason or cause, carefully contain any spilled material to prevent non-target contamination. Do not walk through spilled material and dispose of as directed for pesticides below. Refer to Precautionary Statements on label for hazards associated with the handling of this material. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Environmental Science Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Environmental Science Emergency Response Telephone No. is 1-800-334-7577.

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

Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty container into application equipment. Dispose of empty container in a sanitary landfill, by incineration, or if allowed by the state and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability. **CONDITIONS:** The directions for use of this product are believed to be adequate and should be followed carefully. However, because of manner of use and other factors beyond Bayer CropScience LP's control, it is impossible for Bayer CropScience LP to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE LP 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 Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained therein. Bayer CropScience LP disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

Premise is a registered trademark of Bayer.

Bayer Environmental Science, A Business Group of Bayer Cropscience LP P.O. Box 12014, 2 T. W. Alexander Drive Research Triangle Park, North Carolina 27709

Premise Granules (MASTER) EPA APPROVED 12-19-05 Rev-1, Notification 05/14/08