

432-1368

9-3-2004

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other:

OPP Identifier Number
298815

Application for Pesticide - Section I

1. Company/Product Number 432-1368	2. EPA Product Manager D. Kenny	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Premise Gel Insecticide	PM# 4A	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science, A Business Group of Bayercropscience LP, 95 Chestnut Ridge Road, Montvale, N.J. 07645 <u>PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</u> <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. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application
 Notification - Explain below. Other - Explain below

NOTIFICATION

SEP 03 2004

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

Additional Patent Language added to last page

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
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***Certification must be submitted**

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
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 _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Adrian Krygsman	Title Manager, Registration	Telephone No. (include Area Code) 201-307-3884
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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 or both under applicable law.

6. Date Application Received (Stamped)

2. Signature 	3. Title Manager, Registration
4. Typed Name Adrian Krygsman	5. Date 8/19/04

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Bayer Environmental Science

Notification of Label Revision per PR Notice 98-10:

Premise Gel Insecticide
EPA Reg. No. 432-1368

NOTIFICATION

SEP 03 2004

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and 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 EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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.



Adrian Krygsmán
Manager, Registration

8/19/04
Date

Bayer Environmental Science

95 Chestnut Ridge Road
Montvale, NJ 07645
Tel. (201) 307-9700
Fax (201) 307-3438

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NOTIFICATION

SEP 03 2004



PREMISE® GEL

INSECTICIDE

Specimen Label

- For Pest Management Professionals and Commercial Use Only.
- For control of subterranean termite species of *Coptotermes*, *Heterotermes*, *Reticulitermes*, and *Zootermopsis*.

ACTIVE INGREDIENT:

Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N nitro-2-imidazolidinimine 0.001%

INERT INGREDIENTS: 99.999%

Total: 100.000%

EPA Reg. No. 432-1368

EPA Est. No.

STOP - Read the label before use.

Keep out of reach of children.

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

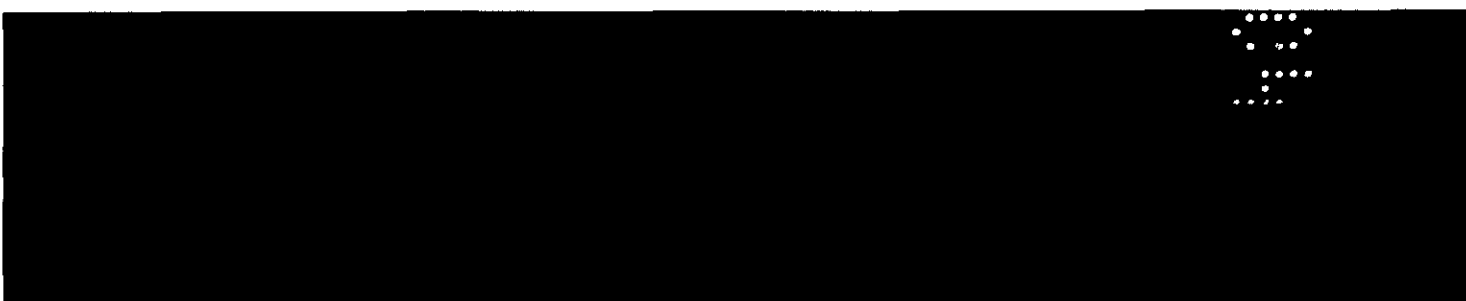
FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
In case of emergency call toll free the Bayer Environmental Science Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

NET CONTENTS:

BACKED
by **BAYER**



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GENERAL INFORMATION

PREMISE Gel is a ready-to-use formulation of imidacloprid intended for use in spot treatments for the control of existing infestations of subterranean termite species of *Coptotermes*, *Heterotermes*, *Reticulitermes*, and *Zootermopsis*. PREMISE Gel is a moisture source in a formula that maintains a high moisture content that attracts termites. When applied into a termite gallery system, or into a termite-infested void, the moisture draws termites to the gel and the imidacloprid it contains. Speed of control will vary, depending on termite species, population density, and moisture content of the wood itself, and other factors.

Do not use this product as the sole source of control for active, structural infestations by subterranean termites; it is not a substitute for mechanical alteration, soil and foundation treatments. For active, structural infestations by subterranean termites, this product can only be used to supplement a soil-applied termiticide (e.g., Premise Insecticide), a termite bait system (e.g., Outpost TBR), or other product registered as a sole source for termite control. This product is intended as a supplemental tool to kill subterranean termites that are found in above ground and other locations.

Spot treatments with PREMISE Gel can be made, as a temporary control measure, in advance of the date when final treatment of the structure with soil and foundation treatments is completed.

APPLICATION

Use gel placements of 1.0 to 2.0 grams per treatment site. A 1.0-gram placement is sufficient for typical infestations. Where severe infestations occur, a 2.0-gram placement may be used. Generally, a greater number of small placements will be preferred over a lesser number of large placements.

Repeat applications as needed to maintain control of re-infestations.

Feeding Galleries and Structural Voids: To control subterranean termite infestations in localized, aboveground areas of the structure, apply PREMISE Gel into galleries or voids in termite-damaged wood, or into spaces between termite-damaged wooden structural members. Locate galleries by using visual signs (e.g., shelter tubes, blistered wood), the presence of live insects, mechanical sounding techniques, or listening devices (e.g., stethoscopes, acoustic emission detectors). Where necessary, penetrate the galleries or voids by drilling holes to receive the injector tip. Distribute drill holes to adequately treat the infestation.

Applications may also be made to inaccessible structural voids by drilling, then inject PREMISE Gel into the infested void.

PREMISE Gel can also be used as a spot treatment to control existing infestations in trees, utility poles, fencing and decking materials, landscape timbers and similar non-structural wood. Wherever possible, locate an interior infested cavity and inject PREMISE Gel in the appropriate quantities.

Nest Sites: Carton nests in building voids or in trees may also be treated with PREMISE Gel. Multiple injection points to varying depths may be necessary.

Use in Shelter Tube Dispensers: To dispense PREMISE Gel from termite shelter (mud) tubes, scrape away a section of the tube about 1 inch in length. Install the gel dispenser over this section where the tube was cleared away; be careful to align openings in the dispenser with openings created in exposing the shelter tube. Do not disturb more of the shelter tube than necessary when installing the dispenser. Apply PREMISE Gel into the dispenser through the opening. For larger shelter tubes, more than one dispenser may be used. Re-apply PREMISE Gel if termite activity continues on subsequent inspections.

After termite activity in the shelter tube has been eliminated, remove the used gel dispenser and scrape away any remnants of the shelter tube on the structure. Follow directions for Container Disposal on this label when disposing of used dispensers.

RESTRICTIONS

Do not apply PREMISE Gel in open or exposed surfaces, or areas accessible to children.

Do not apply until location of heat pipes, ducts, water and sewer lines, and electrical conduits are known and identified. Caution must be taken to avoid puncturing and injection into these structural elements.

Avoid drilling where heat pipes, ducts, water and sewer lines and electrical conduits are located. Do not apply where electrical shock hazards exist.

Holes drilled in living areas should be sealed after treatment.

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 the container is leaking or material is spilled for any reason or cause, carefully remove spilled gel and wash exposed area. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed above. 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 or contact Chemtrec at 800-424-9300.

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: Wrap used cartridge or shelter tube dispensers in paper and place in trash.

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 Environmental Science's control it is impossible for Bayer Environmental Science 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 ENVIRONMENTAL SCIENCE 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 Environmental Science is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. Bayer Environmental Science 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 ENVIRONMENTAL SCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

Premise® Gel Insecticide is specially formulated and sold by Bayer Environmental Science USA LP for the control of insects according to the directions on this label. Bayer is the owner of United States patent rights to the active ingredient imidacloprid, formulations containing the active ingredient and methods of use, particularly U.S. Patent No. 4,742,060, 6,323,224,B1. The purchase price of Premise® Gel Insecticide includes a royalty whereby the purchaser acquires a prepaid

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license under which purchase agrees to employ the purchased quantity of Premise® Gel Insecticide only for the above-specified uses under Bayer's United States patent rights and to provide notice of the terms and conditions of this license to any subsequent purchaser. Uses of Premise® Gel Insecticide other than those specified on this label are not licensed through the purchase of this product and the use of this product for other purposes may violate this license and patent rights of Bayer.

©Bayer AG, 2004

Premise is a registered trademark of Bayer.

Backed by Bayer is a trademark of Bayer.

D - 9600 081103
Premise Gel-SL-0903-Eng

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Bayer Environmental Science



August 19, 2004

VIA FEDEX

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1801 South Bell Street
Arlington, VA. 22202-4501

Attention: Mr. Dan Kenny
PM Team 4A

RE: Premise Gel Insecticide
EPA Reg. No. 432-1368
Label Notification

Dear Mr. Kenny:

Bayer Environmental Science is submitting the label notification for the product referenced above. Specifically this notification addresses the addition of patent language which is presented on the last page of the label. The following documents are enclosed for this submission:

1. EPA Form 8570-1, Application for Pesticide (OPP Identifier No. 298815)
2. Five (5) copies of revised product labeling. One copy has the Revision highlighted.
3. Notification Certification per PR Notice 98-10

Please contact me should there be additional questions regarding this submission.

Sincerely,

Adrian Krygsmar
Manager, Registration

Cc: J. Conti
S. Burt
C. Cole

Bayer Environmental Science

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A Business Group of
Bayer CropScience