

499-488

3-21-2005

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 499-488	2. EPA Product Manager Dan Kenny	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Prescription Treatment brand TC 223	PM# 4A	
5. Name and Address of Applicant (Include ZIP Code) Whitmire Micro-Gen Research Laboratories Inc. 3568 Tree Court Industrial Blvd. St. Louis, MO 63122-6682 <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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION MAR 21 2005
<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 the addition of a second EPA Est. No., 499-MO-2, and associated text directing the reader to "See code in lot number" to determine at which establishment the product was produced, per PR Notice 98-10 Sec. II, N.

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 CSF 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
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"/>	
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 Dana Thomas	Title Manager, Product Registrations	Telephone No. (Include Area Code) 636-861-4223
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 <i>Dana M. Thomas</i>	3. Title Manager, Product Registrations	
4. Typed Name Dana M. Thomas	5. Date March 10, 2005	

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[UNIT LABEL]

v4.3 (3/10/05)

PRESCRIPTION TREATMENT® brand TC 223

[Alternate Brand Name: Prescription Treatment® brand ADVANCE® Compressed Termite Bait]

- Termite Bait Cartridge (TBC)
- For Professional Use Only by Individuals Licensed by the State to Apply Termiticides.

ACTIVE INGREDIENT:

Diflubenzuron0.25%

OTHER INGREDIENTS: 99.75%

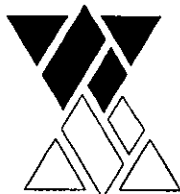
TOTAL: 100.00%

EPA Reg. No. 499-488 • EPA Est. No(s). 499-MO-1^A 499-MO-2^B
(See code in lot number.)

CAUTION: KEEP OUT OF REACH OF CHILDREN

See complete label for additional Precautionary Statements and Directions for Use.

NET WEIGHT: _____



WHITMIRE MICRO-GEN RESEARCH LABORATORIES, INC.
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682 (800) 777-8570

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PRESCRIPTION TREATMENT® brand TC-223

[Alternate Brand Name: Prescription Treatment brand ADVANCE Compressed Termite Bait]

- Compressed Termite Bait
- For Professional Use Only by Individuals Licensed by the State to Apply Termiticides.

Active Ingredient:

Diflubenzuron 0.25%

OTHER Ingredients: 99.75%

Contains 0.25 grams of diflubenzuron per 100 grams of formulation TOTAL: 100.00%

U.S. Patent No. 6,416,752

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS ENVIRONMENTAL HAZARDS

This product is highly toxic to aquatic invertebrates. Do not place TC 223 in any area where, because of the movement of water, it could be washed into a body of water containing aquatic life, such as ponds or streams.

Important: Before buying or using this product, read the entire label including the "Warranty" section [Alternate Language: "Warranty Disclaimer", "Inherent Risks of Use" and "Limitation of Remedies" sections] of this label. If terms are not acceptable, return the unopened product container at once. Use this product only according to label directions.

EPA Reg. No. 499-488 • EPA Est.No(s). 499-MO-1^A 499-MO-2^B
(See code in lot number.)



WHITMIRE MICRO-GEN
RESEARCH LABORATORIES, INC.
800-777-8570

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Read the GENERAL INFORMATION and GENERAL USE DIRECTIONS carefully before using. TC 223 is part of a termite baiting system and is intended for use in TERMATROL* bait stations which may be purchased from most professional pest control product distributors. [ALTERNATE LANGUAGE 1: "...intended for use only in OUTPOST Termite Detection System."] [ALTERNATE LANGUAGE 2: "...intended for use in [BRAND NAME] system."] Use of TC 223 in any other type of station or system not designed for termites is prohibited. Contact Whitmire Micro-Gen at 1-800-777-8570 for assistance in using TC 223 or any other components of the termite baiting system.

* TERMATROL is a registered trademark of Sector Diagnostic LLC.

GENERAL INFORMATION

TC 223 is intended for use in an ongoing program of management and control of subterranean termite colonies in the ground around and under any type of building or other object (structure). TC 223 does not exclude termites from a structure. Instead, it suppresses or eliminates termite colonies. Sufficient consumption of TC 223 by all subterranean termite colonies that present an existing or potential hazard to the structure may, subject to the limitations stated herein, protect the structure against subterranean termite attack.

The active ingredient in TC 223, diflubenzuron, is an insect development inhibitor. When consumed by a termite, diflubenzuron impairs the ability of a termite to molt. Molting is the process by which termites, at certain points in their development, shed their existing exoskeleton and form a replacement exoskeleton. Termites that attempt to molt after ingesting an amount of TC 223 sufficient to impair their molting process either die or are incapacitated by their inability to complete the molting process. Insect development inhibitors such as diflubenzuron are characterized as slow acting toxicants, however their action is slow only to the extent that they affect a termite only at the points in its life cycle when it molts. Because all the termites in a colony do not molt at the same time, the effect of diflubenzuron on the colony as a whole is progressive. This progressive effect is one of the key attributes of diflubenzuron as a termite colony toxicant.

Sufficient consumption of TC 223 by a termite colony can cause a decline in the number of members of the colony. Such a decline, if sustained by continued consumption of TC 223 by the colony, can significantly impair the vitality of the colony. Further, continued consumption of TC 223 by remaining colony members may ultimately result in the total elimination of the colony. The extent of the decline of the colony, the speed of its decline and the possibility of its elimination depends upon the extent to which TC 223 is made continuously available to a colony for consumption and the extent to which members of the colony consume it. Close adherence to the General Use Directions can increase the likelihood of colony elimination, however conditions or circumstances beyond the control of the user may prevent or substantially delay colony elimination. Such conditions may include, but are not limited to, alternate non-bait food sources that reduce the extent to which the colony depends on TC 223 as a food source, excess moisture, low or high temperatures or abandonment of feeding on the bait by the colony.

Because termites cannot be attracted, they must instead find the station as they randomly forage for food. TC 223 affects termite colonies only if they consume it. Pre-baiting is a process by which termite activity is established at a location prior to the application of TC 223 at that location. However, once they have consumed the pre-bait, termites can normally be induced to consume TC 223. These termites then guide other colony members back to the bait station where they also consume TC 223.

After termite activity has been absent from a baited station for at least 60 days, the monitoring (pre-baiting) process is resumed by cleaning out the station and replacing the monitor or pre-bait. In order to affect as many of the termites as possible that currently or could potentially infest a structure, every termite colony that inhabits the ground under and around the structure must be pre-baited and/or baited with TC 223.

If the cycle of pre-baiting and baiting around a structure is interrupted or discontinued, new colonies occupying the territory of suppressed or eliminated colonies, existing colonies that were suppressed but not eliminated, existing colonies never baited or colonies that were pre-baited may forage at points of possible entry into and infest the structure. For this reason, the cycle of pre-baiting and baiting should continue for as long as it is desirable to suppress or eliminate subterranean termites.

If a conventional termite liquid barrier treatment is performed in conjunction with an installation of TC 223, care must be taken not to treat in the area of installed stations (preferably not within two feet of stations). Because the use of TC 223 may be a multi-step process, localized treatment(s) of areas of the structure infested with active termites at the time of pre-baiting or baiting, using soil type termiticides may provide more immediate control of termites in those parts of the structure than TC 223.

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Preventative critical area soil or wood treatments may be performed in conjunction with station installation. Do not treat in areas of installed stations during routine pesticide applications.

PRE-BAITING

Pre-baiting is a process by which termite activity is established at a location prior to the application of TC 223 at that location. Wood, cardboard, or other cellulose containing substances which are readily consumed by subterranean termites may be used as pre-bait. The non-toxic food materials provide a pre-baiting food source for termites that, upon being fed on by termites, establishes termite activity within the station. If there is termite activity at a pre-baiting site, make TC 223 continuously available for colony consumption by placing TC 223 in the station and replenishing consumed amounts of TC 223 for as long as termite activity is present in the station. See section entitled "INSPECTING STATION AND Placing TC 223" for details.

DIRECT BAITING

Placing the TC 223 bait directly into a station is permitted in areas of suspected termite activity. Follow directions for station installation and fill with TC 223.

GENERAL USE DIRECTIONS

PRE-CONSTRUCTION USE

TC 223 can be used for preventative treatment (before signs of infestation) of structures under construction or newly completed (as a substitute for and in lieu of pre-construction soil treatment). *[ALTERNATE LANGUAGE: "In [state name(s)], where pre-construction use of bait only is prohibited, TC 223 may be used in conjunction with, but not in lieu of, pre-construction soil treatment.]* Place stations around the outside of the structure only after the final exterior grade is installed (and preferably after landscaping is completed).

POST-CONSTRUCTION USE

TC 223 can be used for remedial treatment of infested existing structures or for preventative treatment (before signs of infestation) of existing structures.

STATION PREPARATION AND LOCATION SELECTION

To reduce the potential for tampering with and disturbance of stations, points of station installation should be chosen that, where possible, minimize installed station visibility. Areas where barrier type termiticides may have been previously applied, such as within two feet of the foundation wall, should be avoided if possible.

Install stations at or near points of known or suspected termite entry into the structure. If a point of accessible ground is not located within ten feet of a point of known termite entry (due to an intervening hardened construction surface such as a concrete slab), it may be advisable to create an access to the ground through that surface close to the point of known entry and install a station at that access. Install stations at, or preferably within five feet of points of known, probable or suspected termite foraging, and at other critical areas. Such areas may include areas with concentrations of cellulose-containing debris, such as mulch or wood scraps, in contact with the ground, areas of moderate soil moisture, shaded areas, areas containing plant root systems, bath traps, visible termite foraging tubes, etc.

Install stations around a structure such that, except where sufficient access to the ground is not available, the maximum interval between any two stations does not exceed twenty feet. If the distance between two points of accessible ground around the structure exceeds thirty feet, it may be advisable to form one or more openings in the surface creating the inaccessibility to facilitate baiting between those points.

If the structure has an accessible crawl space, stations can be installed in the crawl space in lieu of or in addition to installing stations around the structure. Stations can be installed within a slab structure at

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existing or created openings in the slab surface through which ground is accessible and into which the station can be installed in a secure manner.

Once termite activity has occurred at a station and bait consumption has begun, it may be advisable, depending on the rate of bait consumption in that station and nearby stations, to locate one or more supplemental stations in the immediate vicinity of the infested station(s) in order that bait consumption by the colony be maximized.

If termites have not been present in the station for at least approximately sixty days, remove any remaining bait (clean out station) and replace the monitor (pre-bait). If termites have abandoned the station possibly due to reductions in termite activity related to low temperatures during the period of predicted limited termite activity (see below), it may be advisable to leave the station and bait in place and recheck the station again after the period of predicted limited termite activity has elapsed before removing and replacing the station. If termites have abandoned the station possibly due to excessive moisture, it may be advisable to remove the saturated bait and re-bait the station with fresh bait at that time or after the excess moisture condition has abated.

If a station, upon repeated inspection, is found to contain excess moisture (water standing at the bottom of the station or cavity, etc.), it may be advisable to relocate the station, if possible, to a nearby area where the soil is better drained or alternately, modify the station location to prevent water from collecting in the station by, for example, creating a sump area under the installed station or at the bottom of the cavity.

STATION INSTALLATION

To install a station, excavate or form a hole in the ground approximately the same size and dimensions as those of the station. Insert the station into the hole. Maximizing contact between the exterior of the station and the earth during installation will increase the probability of termite entrance into the station. If the station is inserted into an opening created through a hardened construction surface (such as a concrete slab, asphalt, etc.), insert station below the surface (in contact with the ground) and seal securely.

INSPECTING A STATION AND PLACING TC 223

To inspect a station, remove the cover and visually examine the interior for the presence of termites, being careful to minimize disturbance of the termites. If live termites are present in the station, bait with TC 223 or replenish. If termites are not present, further inspect bait or pre-bait for excessive decay or moisture saturation. Replace excessively decayed bait or pre-bait. Replace the station cover securely.

SCHEDULING OF INSPECTIONS

When using non-compressed TC 223: If termite activity is known to be present in the structure at the time stations are initially installed, inspect all stations three times at approximately 30, 60 and 90 days after the date of completion of initial station installation. If no termite activity is present in the structure at the time stations are initially installed, inspect all stations for the first time within approximately 90 days after the date of completion of initial station installation. Thereafter, inspect any station that does not have termite activity within approximately 90 days after the date of the last inspection of that station. Inspect termite active stations two times at approximately 30 and 60 days after the date of initial termite activity. Thereafter, as long as the station continues to be active, inspect the station within approximately 45 days of the date of the last inspection of the station.

When using compressed TC-223: If termite activity is known to be present in the structure at the time stations are initially installed, inspect all stations two times at approximately 45 and 90 days after the date of completion of initial station installation. If no termite activity is present in the structure at the time stations are initially installed, inspect all stations for the first time within approximately 90 days after the date of completion of initial station installation. Thereafter, inspect stations within approximately 90 days after the date of the last inspection of the stations.

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ADJUSTMENTS TO INSPECTION SCHEDULING

Decreases in elapsed time between inspections of a baited station may be warranted if consumption of all the bait in the station occurs during the interval between any two inspections.

Because subterranean termites are cold-blooded (poikilothermic) animals, low temperatures can substantially reduce or stop their activity close to the earth's surface during a certain period of the year. For this reason, if the temperature falls low enough, termites may cease to feed in stations or the onset of feeding in stations may be delayed until temperatures have recovered above a certain level for a long enough period of time. Reductions in termite activity that are the result of low temperatures may make inspections of stations unnecessary for as long as low temperatures prevail in the area.

The temperature at which termite activity is substantially curtailed may vary significantly between different geographic areas and with different species of termites. However, generally speaking, termite activity will be reduced in the stations during those times of the year during which the average daily mean exterior air temperature is below 50° F. The operator should always make allowances for local circumstances when considering increasing elapsed time between inspections. Under no circumstances should more than six months elapse between inspections of stations.

Allowing extra time between inspections may not be advisable if stations are located in an area in or under a structure in which the average daily mean air temperature is expected to remain above 50° F and termites are actively consuming bait in the stations. Inspection intervals must comply with state regulations, where applicable.

STORAGE AND DISPOSAL

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

STORAGE: Store in original container in a dry storage area out of reach of children and animals.

CONTAINER DISPOSAL: Place container in a trash can.

PESTICIDE DISPOSAL: Product not disposed of by use according to label directions should be wrapped in paper and placed in a trash can.

WARRANTY

WARRANTY DISCLAIMER: *[Distributor's Name]* warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions for use, subject to the inherent risks *[Alternate Language: Conditions of Sale]* set forth below. *[Distributor's name]* MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

[Alternate Language: CONDITIONS OF SALE: The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors under conditions similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. *[Distributor's Name]* offers, and the buyer accepts and uses, the product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of *[Distributor's Name]* and are, therefore, the responsibility of the buyer.]

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with use of this product. Lack of performance or other unintended consequences may result because of factors such as use of the product contrary to the label directions, adverse conditions (such as unfavorable temperatures, soil conditions, excessive rainfall, etc.), abnormal conditions (such as drought, tornadoes, hurricanes, earthquakes, etc.),

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presence of other materials, the manner of application or other factors, all of which are beyond the control of Whitmire Micro-Gen or the seller. All such risks shall be assumed by the Buyer and User.

LIMITATION OF REMEDIES

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Whitmire Micro-Gen's election, one of the following:

(1) Refund of purchase price paid by buyer or user for product bought, or (2) Replacement of amount of product used.

Whitmire Micro-Gen shall not be liable for losses or damages resulting from handling or use of this product unless Whitmire Micro-Gen is promptly notified of such loss or damage in writing. In no case shall Whitmire Micro-Gen be liable for consequential or incidental damages or losses even if Whitmire Micro-Gen knew of, was advised of or should have been aware of the possibility of such damages.

The terms of the "Warranty Disclaimer" above and this "Limitation of Remedies" cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Whitmire Micro-Gen or the seller is authorized to vary or exceed the terms of the "Warranty Disclaimer" or this "Limitation of Remedies" in any manner.

A Prescription Treatment® brand insecticide from:
Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682
www.wmmg.com
© 2005 Whitmire Micro-Gen Research Laboratories, Inc.

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NOTIFICATION

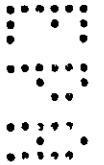
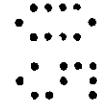
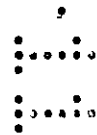
MAR 21 2005



WHITMIRE MICRO-GEN
RESEARCH LABORATORIES, INC.

March 10, 2005

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202



**RE: LABEL NOTIFICATION PER PR NOTICE 98-10 §II N
TC 223, EPA Reg. No. 499-488**

Dear Ms. Edwards:

Enclosed in support of this action is a completed application and one copy revised finished labeling.

A second EPA Est. No., 499-MO-2^B, and associated text directing the reader to "See code in lot number" to determine at which establishment the product was produced, have been added to the product label.

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 CSF 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.

Also enclosed is a self-addressed, "No Postage Necessary" postcard that, when filled out, would indicate the status of this notification. Please take a moment to fill in the appropriate information and drop it in the mail for our records. Your assistance in this regard is certainly appreciated.

Thank you for your assistance in this process. Please don't hesitate to contact me at (636) 861-4223, or via electronic mail at dana.thomas@wmmg.com, should you have any questions or require additional information.

Sincerely,

WHITMIRE MICRO-GEN RESEARCH LABORATORIES, INC.

Dana M. Thomas
Manager, Product Registrations

Encl.