

73912-3

4.6.2007

47



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 6, 2007

Ms. Dolana Blount
Regulatory
PURE BIOSCIENCE
1725 Gillespie Way
El Cajon, CA 92020

Subject: Notification for Additional Marketing Claims
RoachX
EPA Reg. No. 73912-3
Your Application Dated March 13, 2007

Dear Ms. Blount:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated March 13, 2007 for the above mentioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

March 13, 2007

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



Attention: Marion J. Johnson (PM-10)

Subject: **RoachX, EPA Reg. No. : 73912-3**
Notification of other labeling revisions per PR Notice 98-10

Dear Mr. Johnson:

We are notifying of the following changes to the above referenced master label:

1. The following optional, general marketing phrases have been added:
 - Easy to use
 - Ready to use
 - Pest control
 - Specialty [Line]
 - Food Service [Line]
 - Commercial [Line]
 - Institutional [Line]
 - For hard to reach places such as cracks and crevices
 - No vapor, no fumes, no odor
 - [For]Crack & Crevice Applicator(s)
 - Eliminates Roaches
 - Kills without vapors or fumes
 - Cockroach bait
 - Kills Cockroaches, Palmetto bugs, Water Bugs & Silverfish
 - 50% More Free!
 - X oz cartridge [for large jobs]
 - "X" for the price of "X"
 - "x" Applicators per box
 - "x" boxes per case
 - "x" RoachX Crack & Crevice Applicators
 - "x" RoachX Bait Stations
 - Patented Technology
 - Patent Pending
 - From the makers of AntX75™
 - IPM Compliant
 - Does not dry out
 - Non-Drying Formula
2. Update the company contact information on the master label. This information was previously submitted to the Agency in 2004. Please see attached EPA letter dated May 4, 2004, confirming the change

This submission is in full compliance with the notification procedure as identified in PR Notice 98-10. As required by PR Notice 98-10 for notification of other labeling revisions, enclosed please find the following:

1. Application Form(8570-1), including the PR Notice 98-10 certification statement
2. One copy of the product labeling with each of the changes highlighted.

Please contact me if you have any questions about the enclosed items. Please fax a copy of the Agency's acceptance of this notification to 619-596-8790.

Sincerely,
PURE Bioscience

Doriana Blount
Regulatory

www.purebio.com

voice: 619.596.8600 facsimile: 619.596.8790
1725 Gillespie Way El Cajon, California 92020



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73912-3	2. EPA Product Manager Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RoachX	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) PURE Bioscience 1725 Gillespie Way El Cajon CA 92020 <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

NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Other - Explain below.	APR 6 2007
<input type="checkbox"/> Notification - Explain below.		

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

Notification of Other Labeling Revisions per PR Notice 98-10.
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 98-0 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 checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
* 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 oz - 10 oz; bulk 55 gal		5. Location of Label Directions <input checked="" type="checkbox"/> ON LABEL	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 Dolana Blount	Title Regulatory	Telephone No. (Include Area Code) 619-596-8600 Ext. 105
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 Regulatory	
4. Typed Name Dolana Blount	5. Date 03.13.2007	

RoachX

RoachX EPA Reg. No.:73912-3
Notification Label Dated March 13, 2007

4/7

ACTIVE INGREDIENT:
Boric Acid 35%
INACTIVE INGREDIENTS 65%
100%

EPA Reg. No. 73912-3
EPA Est. 73912-CA-001

Net Weight: X oz (X g)

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS	
CAUTION: Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with clothing, skin or eyes. Wash thoroughly with soap and water after handling.	
FIRST AID	
If on skin or clothing	<ul style="list-style-type: none">Take off contaminated clothing.Rinse skin immediately with plenty of water for 15-20 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 15-20 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.
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 the poison control center or doctor.Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER: CHEMTREC 800-424-9300	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information, call 1-619-596-8600 from 9 a.m. to 5 p.m. PST Monday through Friday.	



NOTIFICATION

APR 6 2007

DIRECTIONS FOR USE

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

1. Place bait stations under sinks, behind stoves, refrigerators, washers and dryers.
2. Bait station may be tossed into dark recesses of attics and basements or other inaccessible locations around home or garage.
3. Locate area where pipes enter the home and place bait station near the opening.
4. Look for small cracks or crevices in walls or foundation and place a station in the general area.
5. At night, turn on light in areas where roaches are known to frequent. Locate the holes they scurry into and place bait stations nearby or squeeze several small beads of Crack and Crevice paste into and around area.

GENERAL INFORMATION

RoachX is intended for the control of cockroaches, including German, American, Smokey Brown, Oriental and other cockroach species, including Water Bugs and Silverfish. Apply as a spot and/or crack and crevice application to spaces within structures, their walls and ceilings (both inside and out), and the immediate adjacent surrounding grounds. Such structures include [residential (e.g. houses, apartments)], [commercial], [industrial], and [institutional] buildings (e.g. [restaurants], [supermarkets], [offices], [hospitals], [motels] and [utilities]), and [agricultural structures] (e.g. [barns], [livestock housing facilities]), [pet kennels], [zoos], and on [various modes of transport] (e.g. [aircraft], [buses], [trucks], [trailers], [rail cars], and [marine vessels]).

SPOT OR CRACK AND CREVICE APPLICATIONS

Spot treatments: RoachX should be applied as spots or droplets of approximately 4 to 6 mm in diameter. Approximately 10 droplets per 100 sq. ft. are recommended for use under conditions with low to moderate insect infestations. Approximately 20 droplets per 100 sq. ft. are recommended for more

NOTE: Text in brackets [] indicates optional wording

RoachX

severe infestations or where the population occurs in inaccessible locations, such as in wall voids. Under most circumstances, more numerous, smaller bait placements will provide faster and more effective control than fewer large placements.

Crack and Crevice Treatments: RoachX may also be applied as a bead or thin film where appropriate. Bait should be applied into cracks and crevices in which insects hide or through which they may enter the building. Such openings commonly occur at expansion joints, between different elements of construction, between, behind or under various types of equipment such as [cabinets], [refrigerators], [sinks], [stoves], [dishwashers], and through [floors], [doors], [windows], [walls] and [ceilings]. These openings may lead to voids such as [hollow walls], [hollow equipment legs and bases], [utility entrances], [electrical conduits], [junction and switch boxes], and [wall and floor drain exits]. Trapping techniques or spot flushings will aid in determining areas with insect activity. Apply RoachX by placing the applicator tip directly into cracks and crevices and other openings or voids where insects may hide or harbor and deposit the bait as multiple spots or as a continuous bead. Care should be taken to avoid depositing the product onto open or exposed surfaces. During follow up visits, inspect bait placements and reapply as needed. If bait is completely consumed, reapply in the same location, as many insects (such as cockroaches) leave behind secretions and droppings to attract other insects to harborage and food sources. Do not use this product where a possibility of a shock hazard exists.

FOOD/FEED/HANDLING ESTABLISHMENT APPLICATIONS

Application within food/feed areas of food/feed handling establishments is limited to crack and crevice treatment only. Apply with syringe applicator directly into cracks, crevices, holes and other small openings where roaches may be a problem. Apply small amounts of RoachX paste (up to 1/2 gram) per spot. Do not apply bait to areas where food/feed, food utensils or food processing surfaces may become contaminated. Do not apply bait to areas that are routinely washed such as cracks and crevices in tops of tables, food/feed preparation and prepared food holding surfaces as bait may be removed by washing. Do not apply bait to surfaces where the temperature exceeds 130F as bait may run. Examples include portions of stoves, ovens, grills, fume hoods, heat lamps, coffee urns, steam tables, toasters, fryers, dishwashers and hot water pipes. Care should be taken to avoid depositing RoachX paste onto exposed surfaces. If RoachX paste contacts an exposed surface, remove RoachX paste and wash exposed surface. Food/feed areas include areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing edible waste storage, and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas are also considered a food/feed area when food is exposed and facility is in operation. Apply bait in small amounts between different elements of construction, between equipment and floors, walls, ceilings, equipment legs and bases,

around plumbing pipes, doors and windows, behind and under refrigerator, cabinets, sinks, closets, stoves and other equipment where cockroaches hide. During follow-up visits inspect bait placements and reapply when necessary.

Application of this product in food/feed areas of food/feed handling establishments other than as a crack and crevice treatment is not permitted.

INDOOR PEST CONTROL

For indoor uses, make applications in a manner as previously described above under "Spot or Crack and Crevice Applications." Particular attention should be given to treating entry points and harborage areas. Place the applicator tip into cracks, crevices, voids, holes, and other small openings where insects may hide. Apply small amounts of bait (up to 1/2 gram/spot) or as a bead or film at insect activity sites. Cleaning of all areas prior to use of RoachX will increase levels of control. Any foodstuffs infested with insect pests should be removed and destroyed. Applications to furniture should be restricted to those areas where contact to humans will not occur. Applications to textiles or fabrics may cause discoloration or staining.

OUTDOOR PEST CONTROL

Apply [RoachX bait stations] or [RoachX paste as crack and crevice treatment. Spot, bead or thin film outside surfaces of [buildings], [porches], [patios], [door and window openings], [crawl spaces], [air conditioning units], [utility entrances through outside walls], [under siding/molding], [water drains], [electrical boxes], [in garages] and other adjacent areas where pests may be active and may find nesting sites or harborage. Applications should be made to substrates adjacent to buildings, the building foundations, wall voids, attic and soffit vents, expansion joints, around doors and windows, soffit areas, eaves, under stairways, around screens, on fences, trees and other areas conducive to infestation. Do not apply RoachX to areas that have been recently sprayed with insecticides, and do not spray insecticides over RoachX paste, as it will cause the bait to become repellent.

STORAGE AND DISPOSAL

Pesticide Storage: Store in cool dry area inaccessible to children and pets.

IF EMPTY: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Mfg. by



1725 Gillespie Way • El Cajon, CA 92020

Phone: 619-596-8600

Fax: 619-596-8790

www.purebio.com

NOTE: Text in brackets [] indicates optional wording

Alternate Wording for Front or back of label

- Easy to use
- Ready to use
- Pest control
- Specialty [Line]
- Food Service [Line]
- Commercial [Line]
- Institutional [Line]
- For hard to reach places such as cracks and crevices
- No vapor, no fumes, no odor
- [For]Crack & Crevice Applicator(s)
- Eliminates Roaches
- Kills without vapors or fumes
- Cockroach bait
- Kills Cockroaches, Palmetto bugs, Water Bugs & Silverfish
- 50% More Free!
- X oz cartridge [for large jobs]
- "X" "for the price of "X"
- "x" Applicators per box
- "x" boxes per case
- "x" RoachX Crack & Crevice Applicators
- "x" RoachX Bait Stations
- Patented Technology
- Patent Pending
- From the makers of AntX75™
- IPM Compliant
- Does not dry out
- Non-Drying Formula

(In graphic on front of box/label – See first page for example):

"Schools • Home • Day Care • Office • Institutions • Boats • Industrial • Grocery Stores • Storage • Restaurants • Hospitals"

"Kills Cockroaches, Palmetto Bugs, Water Bugs & Silverfish"

NOTE: Text in brackets [] indicates optional wording



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

7/7

May 4, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DOLANA BLOUNT
PURE BIOSCIENCE
1725 GILLESPIE WAY
EL CAJON, CA 92020

Dear Registrant:

Your request for a change in your Official EPA Company Name and Address record has been completed. For your confirmation the Official EPA Company Name and Address record for EPA Company Number: 73912 is listed below.

DOLANA BLOUNT
PURE BIOSCIENCE
1725 GILLESPIE WAY
EL CAJON, CA 92020

Any future changes in company name and/or address or changes in designation/withdrawal of authorized agent should be directed to the following address. It can also be faxed to (703) 305-7670.

Document Processing Desk (COADR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

If you have any questions, please call me at (703) 305-5361.

Sincerely,

A handwritten signature in cursive script, appearing to read "M Sherrill".

Maureen Sherrill
Information Management Specialist
Office of Pesticide Programs