

73049-374

01/31/2012

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Nasser A. Assaf
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Subject: Notification to add additional warranty statements
EPA Registration Number: 73049-374
Decision: 459213

JAN 31 2012

Dear Dr. Assaf:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN)98-10 dated December 20, 2011, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls 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 regarding this letter, please contact Samantha Hulkower at (703) 603-0683.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", with a stylized flourish extending to the right.

Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosures: Copy of Label Stamped "Notification"



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-374	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Industrial aqueous Pressurized 2.0-0.4	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <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 _____
<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.) Label Notification - No Fee
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.
NOTIFICATION OF CHANGE in Warranty statement PER PR NOTICE 98-10 II J.
Addition of: Optional warranty test consistent with OPP Guidance on Warranty Statements Oct. 17, 2006 -No other changes have been made to the label other than those clearly marked.

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 <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 type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on label	
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 Nasser A. Assaf, Ph.D		Title Manager, Product Safety and Regulatory Affairs		Telephone No. (Include Area Code) (847) 968-4788; FAX (925) 817-5160 Nasser.Assaf@valent.com	
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.				C. Date Application Received (Stamped)	
2. Signature NAASSAF		3. Title Manager, Product Safety and Regulatory Affairs			
4. Typed Name Nasser A. Assaf, Ph.D		5. Date December 20, 2011			



870 TECHNOLOGY WAY
LIBERTYVILLE, IL 60048 - 800-323-9597

December 12, 2011

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

ATTN: Richard Gebken
Product Manager 10
Insecticide Branch

SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION – No PRIA Service Fee Required
Submission of Revised Labeling For:
Industrial Aqueous Pressurized 2.0-0.4; EPA Reg. No. 73049-374

Dear Mr. Gebken:

This application for label notification for the above subject product is being submitted in compliance with PR Notice 98-10. We are proposing to add an additional optional warranty statement to allow Supplemental Distributors a variation in warrantee information.

Two (2) copies of revised draft labeling with changes clearly marked are enclosed. Additions are noted in underlined italics. Deletions, if any are shown struck through.

If you need additional information or have any questions regarding this submission, please do not hesitate to contact me at (847) 968-4844 or e-mail to: Nasser.assaf@valent.com.

Sincerely,

A handwritten signature in dark ink, appearing to read "NASSAF", written in a cursive, stylized script.

Nasser A. Assaf, Ph.D.
Manager, Product Safety and Regulatory Affairs

Enclosures

cc: VBC Regulatory File

ENCLOSURES

ENCLOSURES

INDUSTRIAL AQUEOUS PRESSURIZED 2.0-0.4

- *[A Pyrenone® Insecticide*
- *Industrial Strength - Low Dosage Required*
- *For Use In Schools, Hospitals, Institutions, Hotels, Dairies, Supermarkets, Restaurants, Drive-Ins, Motels, Drugstores, Food Plants And Animal Quarters*
- *Provides Rapid Control Of Flies, Mosquitoes, Flying Moths (Millers), Gnats, Wasps And Accessible Stages Of Roaches, Ants, Waterbugs, Silverfish, Flour Beetles, Grain Mites And Spiders]*

ACTIVE INGREDIENTS:

Pyrethrins 0.4%

Piperonyl Butoxide* 2.0%

OTHER INGREDIENTS:** 97.6%

100.0%

NOTIFICATION**JAN 31 2012**

* (butyl carbityl) (6-propylpiperonyl) ether and related compounds.

**Contains petroleum distillate.

PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.**(TO THE USER:** If you cannot read English, do not use this product until the label has been fully explained to you.)**EPA REG. NO. 73049-374****EPA EST. NO.****KEEP OUT OF REACH OF CHILDREN
CAUTION****See Side/Back Panel For Additional Precautionary Statements**

FIRST AID	
If Swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819.	
NOTE TO PHYSICIAN	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

NET CONTENTS:

LOT NUMBER:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

CAUTION:

Harmful if swallowed. Avoid contact with skin or clothing. Wear long sleeved shirt and long pants, shoes and socks.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks

User Safety Requirements:

- Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.
- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.

User Safety Recommendations:

- User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should 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.

Physical and Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

DIRECTIONS FOR USE

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

Use Restrictions

- For Indoor Use only
- [Except when applying to clothing,] do not allow adults, children, or pets to enter until vapors, mists and aerosols have dispersed, sprays have dried and the treated area has been thoroughly ventilated.
- [Except when applying to clothing,] 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 applications.
- Do not remain in treated area. Exit area immediately and remain outside the treated area until aerosols, vapors, and/or mist have dispersed.
- Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental fish ponds) before application. Turn off aquarium filtering systems before spraying and wait approximately 15 minutes after application before turning the filter back on.
- Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.
- Do not wet articles to point of runoff or drip. Do not use treated article until spray has dried.
- When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.
- Not for use in metered release systems or in outdoor misting systems
- Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces, or wash them before use.
- Do not make space spray applications when facility is in operation.
- Prior to space spray applications, cover or remove food.
- Prior to space spray applications, cover food processing surfaces or clean after treatment and before use.
- Do not use in aircraft cabins.]

SHAKE BEFORE USING AND AT INTERVALS DURING PROLONGED USE.

Hold container upright with nozzle away from you. Press valve down and spray as directed. To avoid possible staining of fabrics or surfaces, do not spray at close range.

Flies, Mosquitoes, Gnats, Wasps and Flying Moths (Millers): Close all doors and windows and spray room at the rate of 1 second per 1000 cubic feet. Direct spray to all parts of the room, especially windows and other light sources which attract these insects. Keep nozzle in constant motion. Keep room closed for 10 to 15 minutes after treatment.

Roaches, Waterbugs, Silverfish, Crickets, Spiders, Centipedes and Sowbugs: Spray into hiding places such as cracks and crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray whenever possible.

Ants: Spray trails, nests and points of entry. Spray on ants where possible.

Indian Meal Moths and Angoumois Grain Moths: Close doors and windows. Direct spray into all parts of room especially around stored food product containers, pallets and darkened areas. Spray 7 to 10 seconds for each 1000 cubic feet of space. Keep area closed for 15 minutes following treatment.

Carpet Beetles: Spray directly on beetles, baseboards, floors, shelves and carpets.

Confused Flour Beetles, Saw-Toothed Grain Beetles, Granary Weevils, Rice Weevils, Red Flour Beetles, Grain Mites: Spray into cracks and crevices, processing and handling equipment, around cartons or containers and other areas where these insects tend to congregate. Spray 30 seconds for each 100 square feet of surface. Keep area closed for 45 minutes to 1 hour after treatment.

Lice: Spray on garments, bedding, mattresses, furniture, floors, carpeting and inanimate surfaces. First spray an inconspicuous area to test for possible staining or discoloration. Inspect after drying, then proceed to spray entire area to be treated. Hold can upright with nozzle away from you. Press button and spray surface to be treated from a distance of 10 inches. Spray each square foot for 3 seconds, directing spray into all infested surfaces until moist.

FOR BEDDING: Make sure spray is directed into corners of fitted sheets and blankets as well as inside and outside of pillow cases. In the case of garments and headgear, close attention should be given to seams, hems, cuffs, collars, and creases. After treatment, bedding and all garments must be either laundered in hot water or dry cleaned as required. For mattresses, furniture and carpeting: Direct spray into all folds, tucks, seams and crevices of infested areas until moist.

Bedbugs: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and frames.

Fleas: Spray sleeping quarters, bedding, floor and floor covering where pets are kept. Use only a recommended pet spray on pets.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area away from heat or open flame. Do not transport or store below 32°F. [Protect from freezing.] [Do not freeze.] [Do not transport or store below 32°F.]

Pesticide Disposal and Container Handling: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions.

[This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label.]

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 must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the

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manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

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[Or alternate text

Note [Notice]: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, seller shall have no liability for consequential damages.

Or

Notice: To the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.]

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Pyrenone is a registered trademark of Bayer AG.

Valent BioSciences Corporation
Environmental Science Division
870 Technology Way
Libertyville, IL 60048