

73049-176

12/12/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 12, 2010

Mr. Nasser A. Assaf, Ph.D.,
Regulatory Manager, ESD
Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048-6316

**Subject: Label Notification(s); Pesticide Registration Notifications (PRNs) 98-10 & 2007-4
PYRETHRUM 50% CONCENTRATE, EPA Reg. No. 73049-176
Your Submission Dated November 10, 2010**

Dear Mr. Assaf:

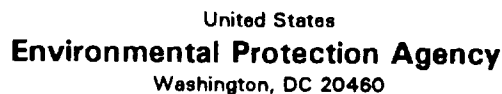
The Agency is in receipt of your application for Pesticide Notification under Pesticide Registration Notifications (PRNs) 98-10 & 2007-4, dated November 10, 2010, for the referenced product. The Registration Division has conducted a review of this request for its applicability under PRNs 98-10 & 2007-4, and finds that the actions requested fall within the scope of PRNs 98-10 & 2007-4.

Please be reminded that 40 CFR §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 non-refillable containers. The code may appear either on the label (and can be added by non-Notification/PRN 98-10) or durably marked on the container itself.

The label submitted with this application has been time-stamped "Notification," and will be placed within the administrative file for this product. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

For
Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)



<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-176	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pyrethrum 50% Concentrate	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.

DEC 12 2010

See Self Certifications statements on cover letter.

Changes include:

- Revise Storage & Disposal Statements in Compliance with PR Notice 2007-4,
- Updated warranty statement in agreement with US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)
- Updated First Aid Hot Line statement; removed "Not For Resale Under This Label"; addition of bilingual statement, and of Pet. Dist. statement to ingredients
- No other changes have been made to the label other than those clearly marked.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 to 55 gallons	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 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
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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.

2. Signature <i>NAASSAF</i>	3. Title Manager, Product Safety and Regulatory Affairs
4. Typed Name Nasser A. Assaf, Ph.D	5. Date November 10, 2010



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

November 10, 2010

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

NOTIFICATION

DEC 12 2010

ATTN: Richard Gebken
Product Manager 10
Insecticide Branch

SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION – No PRIA Service Fee Required
Submission of Revised Labeling Per:
- PR-Notice 2007-4, Container Disposal
- PR-Notice 98-10, Warranty Statement update
- PR-Notice 98-10, Miscellaneous changes
Pyrethrum 50% Concentrate, EPA Reg. No. 73049-176

Dear Mr. Gebken:

This application for label notification for the above subject product is being submitted to comply with the PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment Revision of Container Disposal and US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006) among other minor changes which are clearly marked.

Due to the limited space on EPA Form 8570-1, Section II, the self certification statements are as follows:

PR Notice 2007-4, Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal 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.

US EPA OPP Guidance on Warranty Statements (Oct. 17, 2006)

This notification is consistent with the provisions of PR Notice 98-10 and the EPA regulations at 40 CFR 152.46, and 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 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 warranty statements per PR Notice 98-10 II J.

Notification of non-pesticial characteristics per PR-Notice 98-10 IV F & I,
removal of "Not for resale under this label"
updating of First Aid hot line statement
addition of bilingual statement

Two (2) copies of revised draft labeling with changes clearly marked are enclosed. Additions are noted in highlighted underlined italics. Deletions 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,



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

Enclosures

cc: VBC Regulatory File

5066

PYRETHRUM 50% CONCENTRATE**NOTIFICATION**

- For The Formulation Of Insecticides Only
- Not For Resale Under This Label

DEC 12 2010**ACTIVE INGREDIENT:**

Pyrethrins 50.0%

OTHER INGREDIENTS*: 50.0%

100.0%

*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. 73049-176

EPA EST. NO.

KEEP OUT OF REACH OF CHILDREN**CAUTION**

See Side Panel for Additional Precautions

FIRST AID	
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"> • 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.
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 Inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of Medical emergencies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained by calling 1-877-315-9819. 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:

10066

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if swallowed, absorbed through skin or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Environmental Hazards

This pesticide is highly toxic fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Physical and Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

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

FOR MANUFACTURING INSECTICIDES ONLY

Mix well in drum before sampling and use. Formulators using this product are responsible for obtaining EPA registration for their products.

STORAGE AND DISPOSAL

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

Pesticide Storage and Spill Procedures: Keep container tightly sealed. Store indoors in an upright position and in a cool, dry place. If container is damaged, check for any leaks. If leaking, transfer contents into another suitable container. Avoid contamination with other chemicals. Spillage should be washed off with a 5% sodium hydroxide solution then rinsed with water.

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: Triple rinse (or equivalent). ~~Non-refillable container. Do not reuse or refill this container.~~ Then Offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other approved by State and local procedures.

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~~ ^{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 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.

DISCLAIMER OF WARRANTIES: ~~TO THE EXTENT CONSISTENT WITH APPLICABLE LAW,~~ VALENT BIOSCIENCES CORPORATION 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 Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: ~~TO THE EXTENT CONSISTENT WITH APPLICABLE LAW,~~ 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 VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

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Libertyville, IL 60048
List No. 73049176
02-0340/R2

PRODUCT OF [RWANDA, TANZANIA, AUSTRALIA]