

73049-440

06-13-2009

1/6



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Nasser A. Assaf, Ph.D.
Product Registration
Valent U.S.A. Corporation
1600 Riviera Ave., Suite 200
Walnut Creek, CA 94596-8025

JUN 13 2008

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request General Label Change
EPA Reg. No. 73049-440
Application Dated May 16, 2008

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 05/16/08 for the above 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 call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

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

872



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-440	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pyrethrins Concentrate 50	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 to: NOTIFICATION EPA Reg. No. <u>JUN 13 2008</u> 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.) 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: addition of "Net Weight" per PR Notice 98-10. This is a manufacturing use, liquid product which is sold and manufactured in weight measurements. We are proposing to include both "Net Weight" and "Net Contents" on the label.

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) _____	
* Notification 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	Title Regulatory Manager, ESD	Telephone No. (Include Area Code) (847) 908-4444
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 Manager, ESD	
4. Typed Name Nasser A. Assaf	5. Date May 16, 2008	



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

May 15, 2008

Document Processing Desk
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 Team 10
Insecticide Branch

SUBJECT: Pyrethrins Concentrate 50, EPA Reg. No. 73049-440
Submission of Application for Pesticide - Notification
Addition of "Net Weight"

Dear Mr. Gebken:

Pyrethrins Concentrate 50 is a liquid, manufacturing use product. Manufacturers use this product in weights rather than in volumes, for production into concentrates and end-use consumer products. It is beneficial to our customers to have the weight clearly marked on the container to prevent potential conversion mistakes or delays in their process.

We respectfully request that we are allowed to have both "Net Contents" and "Net Weight" on the label for Pyrethrins Concentrate 50, EPA Reg. No. 73049-440. We currently have both "Net Weight" and "Net Contents" accepted on the similar situation for Bioallethrin Technical, EPA Reg. No 73049-359.

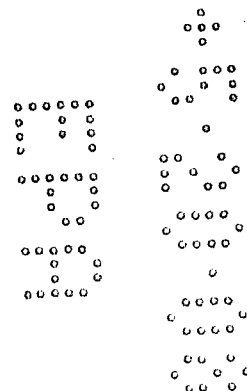
If you need additional information or have any questions regarding this submission, please do not hesitate to contact me at (847) 968-4844 or e-mail to: Nasser.assaf@valent.com.

Sincerely,

Nasser A. Assaf, Ph.D.
Regulatory Manager, ESD

Enclosures

cc: VBC Regulatory File



4
6

PYRETHRINS CONCENTRATE 50

NOTIFICATION

JUN 13 2008

- *For The Formulation Of Insecticides Only*

ACTIVE INGREDIENT:

Pyrethrins 50.0%

OTHER INGREDIENTS*: 50.0%

Total 100.0%

*Contains petroleum distillates.

EPA REG. NO. 73049-440

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"> • Call a poison control center or doctor immediately for treatment advice. • 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. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-877-315-9819 or the National Pesticide Information Center at 1-800-858-7378.	
NOTE TO PHYSICIAN	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

NET CONTENTS:

NET WEIGHT:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Contains petroleum distillate.

Harmful if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes and gloves. Remove contaminated clothing and wash clothing before reuse.

Environmental Hazards

This product is toxic to aquatic organisms, including fish and invertebrates. 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. Do not contaminate water when disposing of equipment washwaters or rinsate.

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

INSTRUCTIONS TO FORMULATORS: Formulators using this product are responsible for obtaining EPA registration of their formulated products. Mix well in drum before sampling and use.

Only for formulation into an insecticide for the following uses: Domestic Indoor (household); Domestic Outdoor (perimeters, lawns & ornamental and vegetable gardens); Commercial/Industrial/Institutional Food/Feed & Non-Food/Feed Areas (indoor & outdoor); Treatments of Animals (including livestock & pets) and Terrestrial Food/Feed and Non-Food/Feed; Aquatic Non-Food; Greenhouse Food & Non-Food.

Nor for formulation into wettable powder end-use products (EUP), unless the EUP is packaged in water soluble bags.

Not for formulation into granular end use products.

This product may be used to formulation products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

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

Pesticide Storage and Spill Procedures: Keep this product dry in a tightly closed container, when not in use. Store indoors in an upright position and in a cool, dry, well-ventilated area away from heat or open flame. If container is damaged, check for any leaks. If leaking, transfer contents into another suitable container. Avoid contamination with other chemicals. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse damaged container but place in trash collection. Spillage should be washed off with 5% sodium hydroxide solution then rinsed with water. Do not contaminate food or feed by storage, disposal or cleaning of equipment.

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). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions 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. Crop injury, 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. 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.

©Valent BioSciences Corporation, 2008

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

PRODUCT OF [KENYA; RWANDA; TANZANIA]

02-0778/R1

