

8709-9

10/19/2005

1/3

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<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 8709-9	2. EPA Product Manager R. Kumar	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pond Care Dimilin	PM# 17	
5. Name and Address of Applicant (Include ZIP Code) Aquarium Pharmaceuticals, Inc. 50 East Hamilton St. Chalfont, PA 18914-0218 <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 OCT 17 2005
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input 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 minor text addition, as dictated by the State of New York through 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 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.

"DO NOT" post this label on the PPLS system since it is not meant to replace the Master Label on file with the agency but to clarify the minor text change requested by New York.

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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
		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 Bob MacDonald	Title Agent for Aquarium Pharmaceuticals, Inc.	Telephone No. (include Area Code) (260) 244-6270
-----------------------	---	---

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 Agent for Aquarium Pharmaceuticals, Inc.
4. Typed Name Bob MacDonald	5. Date 9/19/05

EPA Reg No.
8709-9
EPA Est No.
8709-PA-1



For use on ornamental fish only.

Not for use in commercial food fish production ponds.

Anchor worms (*Lernaea*) are parasites that infest koi and goldfish in ornamental ponds. Severe infestations can kill fish. Left untreated, anchor worm will spread to other fish.

ACTIVE INGREDIENT

Dimilzinon: N-[[[(4-Chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide

0.10%

OTHER INGREDIENTS

99.90%



LOT NO.

Anchor worms (*Lernaea*) – The most common symptom is the female worm embedded in the side of the fish. The head of the worm penetrates the fish and forms an "anchor" under the skin. These parasites cause unsightly wounds often leading to secondary bacterial and fungal infections.

DIMILIN® should be used as soon as parasites are observed on the fish. Anchor worm infections are easily spread to other ornamental ponds and holding tanks. Moving an infested fish to another pond / tank will spread the disease to other fish. Adult anchor worms embedded in the fish will remain after treatment. It is acceptable to let the worms fall from the fish naturally.

Directions for Use: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **SHAKE WELL.** For synthetically lined ponds, aquariums or holding tanks containing ornamental fish only, and where all water is contained without any outflow. DIMILIN® is intended for control of only the unattached form of the anchor worm. Discontinue activated carbon filtration during treatment with DIMILIN®. Do not add or remove fish when treating for a parasitic infestation. Shake the bottle **vigorously** for at least one minute. Add 1 tablespoon (15 ml) for every 60 gallons (228 L) or 1/2 cup (120 ml) for every 480 gallons (1,817 L) of water. Wait 14 days then repeat treatment to ensure control of the parasites. **Do not change the water between treatments.** After the second treatment is complete, wait another 14 days before discharging or disposing of treated water.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.

FIRST AID: If swallowed, call a Poison Control Center or Doctor immediately. If in eyes: hold eye open and gently flush with water for 15 minutes. Remove contact lens, if present, after the first 5 minutes, then continue rinsing. If on skin: thoroughly wash with soap and water. Have the product container with you when calling a Poison Control Center or Doctor or going for treatment.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to aquatic invertebrates. Do not contaminate natural waters when disposing of equipment, rinsate or treated water.

STORAGE AND DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling. **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.

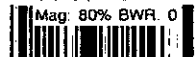
AQUARIUM PHARMACEUTICALS, INC.
P.O. Box 218 • Chalfont, PA 18914
For more information, contact our Technical Services
Department at 1-800-847-0659
or visit our web site at www.pondcare.com

DIMILIN® is a registered trademark of Crompton Corp., Middlebury, CT 06749. ® registered trademark of Aquarium Pharmaceuticals, Inc. ©2005 Aquarium Pharmaceuticals, Inc. 1849-02-0805

PRODUCT # 177B



Ht. 0 816", Wd. 1 1752"



3 171 63 021 77 4

*changed from
ORNAMENTAL to synthetically lined*

9/19/05 ydm

NOTIFICATION
OCT 17 2005

2/3

SRC
Scientific & Regulatory
Consultants, Inc.

September 19, 2005

Ms. Joyce M. Edwards
Notifications Review Coordinator
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
EPA
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

SUBJECT: Pond Care Dimilin EPA Reg. No. 8709-9

Dear Ms. Edwards:

Per your response of August 12, 2005 (copy enclosed) we have enclosed a copy of our clients proposed container label for their notification on the above product. This is being submitted on behalf of our client Aquarium Pharmaceuticals, Inc. The primary purpose of this notification is to add minor text dictated to cover a recent directive from the State of New York for the Pond Care Dimilin label.

Per the state of New York we are adding "synthetically lined" to the standard sentence below in place of the word ornamental:

"For use in ornamental ponds, aquariums or holding tanks containing ornamental fish only, and where all water is contained without any outflow."

So it reads:

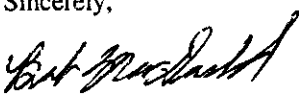
"For synthetically lined ponds, aquariums or holding tanks containing ornamental fish only, and where all water is contained without any outflow."

We have circled this change on the enclosed copy to assist you in noting the change and for ease in any necessary copying. *We request that you do not post this label on the PPLS system since it is not meant to replace the Master Label on file with the agency, which includes alternate text available to our client in any future labeling, but to only clarify the specific statement in the labeling as noted above.*

This notification is consistent with PR Notice 98-10 since there is no change in the mixing directions affecting the dilution rate or the minimum or maximum use dilutions.

If you have any questions regarding this submission, please contact me at 260-244-6270.

Sincerely,



Bob MacDonald
Agent for Aquarium Pharmaceuticals, Inc.

cc: P. Sauter

