

8709-9

12/30/2002

1/5



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg Number:

8709-9

Date of Issuance

DEC 30 2002

Term of Issuance: Conditional

Name of Pesticide Product:

Pond Care Dimilin

NOTICE OF PESTICIDE:

 x Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code)

Aquarium Pharmaceuticals
50 East hamilton Street
Chalfont, PA 18914

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase "EPA Registration Number 8709-9".
3. Make the following label changes:
 - a. At the top of the front panel, add the heading Master Label, and include the appropriate text from the administrative note on this subject. Also, add "for use on ornamental fish only" to the statement "Not for use in commercial fish production ponds."

(continued on page 2)

Signature of Approving Official:

Rita Kumar

Date: DEC 30 2002

- b. Under the active ingredient statement, add the word "Diflubenzuron" in front of the chemical name.
 - c. Delete the text about secondary infections at the bottom of page 2. This information is already included in the paragraph titled "Diagnosis" for anchor worms.
 - d. On page 3, in first paragraph titled Directions for Use, remove the brackets from the intended use sites. The third sentence should be revised as follows: "For use in ornamental ponds, aquariums, or holding tanks containing ornamental fish only, and where all water is contained without any outflow." Delete the next sentence: "Do not apply to lakes, streams, or areas that contain fish intended for human consumption." This sentence implies that the product can be added to natural bodies of water, which is not true.
 - e. On page 3, add the following to the first paragraph titled Directions for Use: "Dimilin is intended for control of only the unattached form of the anchor worm."
 - f. On page 3, add the following to the First Aid for eye exposure: "Remove contact lenses, if present, after the first 5 minutes, then continue rinsing."
 - g. On page 1, delete the second, and last bullets. The second bullets is a mandatory statement, and should not be included in these optional statements, and the last bullet is a safety claims that needs to be substantiated with data.
5. Submit results of the ongoing 12-month storage stability and corrosion characteristics study upon completion, within the next 12 months.
 4. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(a). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,

Rita Kumar

Rita Kumar
 Senior Regulatory Specialist
 Insecticide Rodenticide Branch
 Registration Division (7505C)

Enclosure

Pond Care®

[Product # xxxx]

Dimilin®

Not for use in commercial food fish production ponds

[Administrative note: This Master Label contains use directions for various size containers and may be marketed as sub-labels with some or all of the use sites given on this label]

- [For the control of anchor worm (*Lernaea*) in / ornamental ponds / water gardens / koi ponds / goldfish ponds / display tanks / aquariums / holding tanks / containing / ornamental fish / including / koi / goldfish / comets / shubunkins / fantails / carp / fresh and saltwater tropical ornamental fish / coldwater aquarium fish / shiners / minnows].
- [For the control of unattached external parasites (*Lernaea*) in ornamental ponds / water gardens / koi ponds / goldfish ponds / display tanks / aquariums / holding tanks].
- [Effectively controls anchor worm by interrupting the parasite's life cycle and reproductive processes.]
- [Will not discolor the water]
- [Easy to use liquid]
- [No messy powders]
- [Can be used at any water temperature]
- [Will not affect the biological filter]

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

DEC 30 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
8709-9

ACTIVE INGREDIENT:

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

0.10%

OTHER INGREDIENTS:

99.90%

Keep out of Reach of Children

CAUTION

See back panel for Precautionary and First Aid statements

Net: {actual volume of each package size is inserted here}

{Administrative note: the following language may appear on the label depending on container size}

- [treats 120 gallons (454 L)] *{for 1.0 oz bottle}*
- [treats 148 gallons (560 L)] *{for 1.25 oz bottle}*
- [treats 240 gallons (908 L)] *{for 2 oz bottle}*
- [treats 480 gallons (1816 L)] *{for 4 oz bottle}*
- [treats 960 gallons (3633 L)] *{for 8 oz bottle}*
- [treats 1 920 gallons (7267 L)] *{for 16 oz bottle}*
- [treats 3 840 gallons (14534 L)] *{for 32 oz bottle}*
- [treats 7 680 gallons (29 068 L)] *{for 64 oz bottle}*
- [treats 15 360 gallons (58 137 L)] *{for 128 oz bottle}*

EPA Reg No: 8709-xx

EPA Est No.: 8709-PA-1

{Administrative note: any language which appears between { } will NOT appear on final printed labels. Any language that appears between [] and/or is separated by a front slash (/) is considered interchangeable language and may or may not appear on final printed labeling}

{Dimilin Label page 2}

{Administrative note: portions or all of the optional paragraphs on this page may appear on any label panel}

[Anchor worms (*Lernaea*) are parasites that infest koi / goldfish / carp / freshwater and saltwater ornamental fish / minnows / shiners / in ornamental ponds / water gardens / koi ponds / goldfish ponds / display tanks / aquariums / holding tanks. These parasites cause unsightly wounds often leading to secondary bacterial and fungal infections. Severe infestations can kill fish. Left untreated, anchor worm will spread to other fish. Dimilin® controls the unattached anchor worm by interrupting the parasite's life cycle and reproduction. Reference sources may describe Dimilin® as Diflubenzuron or Difluron.]

[**Diagnosis**] *{Administrative note: this optional heading is not required to be used in conjunction with the following optional paragraph.}*

[**Anchor worms** (*Lernaea*) are elongated parasitic copepods that attach to the skin of the fish. The most common symptom is the female worm embedded in the side of the fish. The anchor worm appears as a gray or black strand up to one inch (2.5 cm) in length. Algae can collect on the worm, giving it a green appearance. Two egg sacs may be seen hanging from the worm. Eggs are released into the water, where they hatch into microscopic free-swimming copepods. The microscopic parasites undergo several molts as they mature. The free-swimming copepods feed on the fish mucus, but do not damage the fish. After mating, the female parasite penetrates the fish's skin. The head of the worm penetrates the fish and forms an "anchor" under the skin. The anchor can penetrate organs in smaller fish. The point of entry may develop a red ulcer, due to secondary bacterial infections. The female worms then develop two large egg sacs that can contain up to 700 eggs. Once the eggs hatch, the free-swimming parasites re-infest the fish. The parasite's life cycle is temperature dependent and can take as little as 15 days when the water is 86°F (30°C). Anchor worm infestations are most common on koi and goldfish.]

[**Treatment instructions**] *{Administrative note: this optional heading is not required to be used in conjunction with the following optional paragraph.}*

[Dimilin® should be used as soon as parasites are observed on the fish. Anchor worm infestations are easily spread to other ornamental ponds / water gardens / koi ponds / goldfish ponds / display tanks / aquariums / holding tanks / by nets, boots, clothing and hands. Moving an infested fish to another pond / tank will spread the disease to other fish. Dimilin® is intended for the control of the unattached form of anchor worm. Adult anchor worms embedded in the fish will remain after treatment. It is acceptable to let the worms fall from the fish naturally. Attached worms can be removed with tweezers.]

[**Secondary infections**] *{Administrative note: this optional heading is not required to be used in conjunction with the following optional paragraph.}*

[Because anchor worms embed into the fish tissue, secondary bacterial infections often occur. Bacterial infections appear as red ulcers on the surface of the fish. Fungal infections appear as white cottony tufts on the surface of the fish.]

{Administrative note: any language which appears between { } will NOT appear on final printed labels. Any language that appears between [] and/or is separated by a front slash (/) is considered interchangeable language and may or may not appear on final printed labeling}

{Dimilin label page 3}

Directions for use: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **SHAKE WELL.** For use in [ponds / aquariums / holding tanks] containing ornamental fish only and where all water is contained without any outflow. Do not apply to lakes, streams or areas that contain fish intended for human consumption.

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 [½ teaspoon (2.5 ml) for every 10 gallons (37.85 L) / 1 tablespoon (15 ml) for every 60 gallons (227 L) / ¼ cup (60 ml) for every 240 gallons (908 L) / ½ cup (120 ml) for every 480 gallons (1816 L) / 1 cup (240 ml) for every 960 gallons (3633 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. 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.
PO Box 218
Chalfont PA 18914

[For more information, contact our Technical Services Department at 1-800-847-0659 or visit our web site at <http://www.aquariumpharm.com> / <http://www.pondcare.com>]

[Dimilin® is a Registered Trademark of the Crompton Corp., Middlebury, CT 06749]