

8709-8

04/09/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 9, 2007

Robert MacDonald
Scientific & Regulatory Consultants
C/o Aquarium Pharmaceuticals, Inc.
P. O. Box 1014
Columbia City, IN 46725

Subject: Notification Application per PR Notice 98-10
Product Name: AlgaeFix
EPA Registration No.: 8709-8
Application Date: 04-Apr-2007
Receipt Date: 04-Apr-2007

Dear Mr. MacDonald:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

- Alternate Brand: AlgaeFix Marine
- Minor label revisions

General Comment:

Based on a review of the material submitted, the following comment applies:

The notification is acceptable and a copy has been inserted in your file for future reference. Note that this approval supersedes the previously accepted notification letter dated February 5, 2007.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or by email at heyward.adam@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward", written over a horizontal line.

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 8709-8	2. EPA Product Manager A. Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AlgaeFix	PM# 34	
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 _____
<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 per 98-10 - bringing Master Label up to date with past notifications, minor label additions and request for additional brand name.
 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.

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	If "Yes" Unit Packaging wgt. No. per container		Metal Plastic Glass Paper Other (Specify) _____
* Certification must be submitted			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 4/12/07	



April 2, 2007

Mr. Adam Heyward, PM 34
 Document Processing Desk (NOTIF)
 Office of Pesticide Programs (7504P)
 EPA
 Room S-4900, 4th Floor
 One Potomac Yard
 2777 S Crystal Drive
 Arlington, VA 22202

SUBJECT: AlgaeFix

EPA Reg. No. 8709-8

Dear Mr. Heyward:

Enclosed is a follow up notification to our January 17th notification for the above product, submitted on behalf of our client Aquarium Pharmaceuticals, Inc. This notification reflects the same labeling provided in that original filing (no other new changes) and as you may recall brings their Master Label up to date for this submission. The enclosed label reflects the current labeling text, the minor label additions requested in the January notification and includes the previous acceptances granted to date through your reviews.

We are also reconfirming our request for an "alternate brand name" of: **AlgaeFix Marine**

All labeling additions have been "**boxed**" to assist you in your review process and to more clearly note the additions. You will also note that we have included []'s around the parenthesis surrounding the dosage measurements to allow flexibility on whether () are used or not.

One other item they wish to include in this notification is that in addition to the 50% free and 25% free declarations in their July 18, 2005 notification they wish to also stipulate a potential **20% free** special offering. The associated statement for this size would be:

"[Treats 28,800 US gallons (10,990 l)]"

The "safe for use" text has been maintained since as we discussed with your over the phone the competitive product Tetra Algae Control 81584-1 has been allowed to maintain this text and it continues to be reflected in their most current notification 8/11/05 (copy enclosed).

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. We have enclosed two copies of labeling.

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

ALGAEFIX

[Aquarium Algaecide]

[Pond Algaecide]

[Pro Series]

[Products / designed / with the specialist in mind]

NOTIFICATION
Date Reviewed: 4.9.07
Reviewed By: *A. Reynolds*

{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}

- [Benefits]
 - [Controls many types of algae in freshwater aquariums / marine aquariums / reef aquariums / saltwater aquariums / water gardens / container water gardens / Koi and goldfish ponds / ornamental fountains containing live plants and fish]
 - [Controls many types of algae in marine and reef aquariums containing live corals, invertebrates and fish]
 - [Controls many types of algae in freshwater aquariums / marine aquariums / reef aquariums / saltwater aquariums / water gardens / container water gardens / Koi and goldfish ponds / ornamental fountains / while keeping water clean and clear]
 - [Safe / for use in aquariums / ponds / fountains / containing live plants and fish]
 - [Effectively controls "green water" algal blooms / String or Hair algae (*Cladophora*) / Blanketweed (*Oedogonium*) / Green algae]
 - [Effectively controls many types of algae on aquarium glass, ornaments and plants]
 - [Helps resolve algae problems]
 - [Controls algae growth in aquariums]
 - [Reduces aquarium maintenance]
 - [Controls many types of algae in outdoor, indoor, and table-top ornamental fountains]
 - [Keeps freshwater aquariums / marine aquariums / reef aquariums / saltwater aquariums / Koi ponds and goldfish ponds / ornamental ponds / water gardens / fountains / clean and clear]
 - [Helps remove Red Slime / Red Slime algae]
 - [Does not alter the pH]
 - [Does not discolor the water or cause foaming]
 - [Does not contain copper]
 - [Will not harm / Safe for use with / live / aquatic / pond / aquarium / plants / and / or / koi / goldfish / freshwater / or / saltwater / marine / fish / {Following text authorized only for saltwater Algaefix offering} / and / or / corals / and / or / other / invertebrates]
- {Following bullet authorized only for saltwater Algaefix offering}*
- [When used / safe for use / in salt water / containing / will not harm / snails / clams / scallops / shrimp / anemones / sea cucumbers / coralline algae / feather dusters / corals / soft corals / hard corals / and other invertebrates]

ACTIVE INGREDIENT: Poly[oxethylene(dimethyliminio)ethylene (dimethyliminio)ethylene dichloride]

4.50%

OTHER INGREDIENTS:

95.50%

{for packages greater than 64 fl oz} Total: 100%

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

See back panel for precautionary and first aid statements

[See blister card for precautionary and first aid statements, directions for use and storage and disposal information. Do not throw blister card away]

[See pullout label for precautionary / first aid statements / directions for use / storage and disposal information]

[To open: With one hand, push red tab left with thumb while unscrewing cap with free hand]

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

- [Treats 300 U.S. gallons (1,134 l) / of / fresh / or / salt / water]
- [Treats 370 U.S. gallons (1,399 l) / of / fresh / or / salt / water]
- [Treats 1,200 U.S. gallons (4,536 l) / of / fresh / or / salt / water]
- [Treats 1,800 U.S. gallons (6,804 l) / of / fresh / or / salt / water]
- [Treats 2,400 U.S. gallons (9,072 l) / of / fresh / or / salt / water]
- [Treats 2,880 U.S. gallons (10,900 l) / of / fresh / or / salt / water]
- [Treats 3,000 U.S. gallons (11,340 l) / of / fresh / or / salt / water]
- [Treats 4,800 U.S. gallons (18,144 l) / of / fresh / or / salt / water]
- [Treats 9,600 U.S. gallons (36,288 l) / of / fresh / or / salt / water]
- [Treats 19,200 U.S. gallons (72,576 l) / of / fresh / or / salt / water]
- [Treats 38,400 U.S. gallons (145,152 l) / of / fresh / or / salt / water]
- [Treats 96,000 U.S. gallons (362,880 l) / of / fresh / or / salt / water]
- [Treats 192,000 U.S. gallons (725,760 l) / of / fresh / or / salt / water]

EPA Reg. No. 8709-8

EPA Est. No. 8709-PA-1

[**Benefits:** / AlgaeFix effectively controls these types of [freshwater] algae: Green or Green water algae (*Chlorella*) / Blue-Green algae (*Aphanizomenon*) / Black Beard algae (*Audouinella*) / String or Hair algae (*Cladophora*) / Blanket weed (*Oedogonium*) / in freshwater aquariums / ornamental ponds / fountains / containing live plants and fish.]

[**Benefits:** / AlgaeFix effectively controls these types of [saltwater] algae: Green algae (*Cladophora*) / "Red Slime" (*Oscillatoria* / *Spirulina major*) / "Brown Algae" (*Cyclotella*) / in marine aquariums / reef aquariums / saltwater aquariums / containing live corals, invertebrates and fish.]

[Algal growth can appear as "green water" blooms / filamentous algae on plants / floating algal mats (blanket weed) / [algae / brown] growth on aquarium glass / ornaments / rocks / fountains / waterfalls.]

{To maintain segmentation between individual brand names, four sets of "Directions" are provided. One of the following statements will be used on each applicable label}

Directions For Use {for aquarium AlgaeFix and Algae Destroyer Advanced label}

It is a violation of federal law to use this product in a manner inconsistent with its labeling. [The most effective use of AlgaeFix is achieved by first cleaning the aquarium glass and ornaments. Trim plant leaves that are covered with algae. For best results remove activated carbon during treatment.] Add [14 drops {due to differences in applicator orifice the drops used will vary in packages of 4 ounces or less, see chart at end of label for drop dosage for each size container} / [(1 ml)] / [(1/5 tsp.)] / for each 10 U.S. gallons (38 L) / [(15 ml)] / [(1 / teaspoon / tsp.)] / for each 50 U.S. gallons (190 L) / [(2 / teaspoons / tsp.)] / [(10 ml)] / for each 100 U.S. gallons (378 L) / [(10 / teaspoons / tsp.)] / [(150 ml)] / for each 500 gallons (1 890 L) / [(1/4 cup)] [(60 ml)] for each 600 gallons (2 275 L) / [(20 / teaspoons / tsp.)] / [(100 ml)] / for each 1 000 gallons (3 780 L) / [(1/2 cup)] [(120 ml)] for each 1 200 gallons (4 536 L) / [(2 cups)] [(480 ml)] for each 4 800 gallons (18 144 L)] of aquarium water. Repeat dose every [three / 3] days until algae is controlled. Siphon or scrape any dead algae from aquarium. Once algal growth is under control, add one dose per week. Weekly doses of AlgaeFix will control algal growth and reduce aquarium maintenance. **CAUTION:** Do not use AlgaeFix with freshwater crustaceans, including: shrimp, crabs and lobsters.

Directions For Use *{for saltwater AlgaeFix label}*

It is a violation of federal law to use this product in a manner inconsistent with its labeling. [The most effective use of AlgaeFix is achieved by first cleaning the aquarium glass and ornaments. For best results remove activated carbon during treatment.] Add [14 drops *{due to differences in applicator orifice the drops used will vary in packages of 4 ounces or less, see chart at end of label for drop dosage for each size container}*] / [() 1 ml] / [() 1/5 tsp.] / for each 10 U.S. gallons (38 L) / [() 5 ml] / [() 1 / teaspoon / tsp.] / for each 50 U.S. gallons (190 L) / [() 2 / teaspoons / [tsp.]] / [() 10 ml] / for each 100 U.S. gallons (378 L) / [() 10 / teaspoons / [tsp.]] / [() 50 ml] / for each 500 gallons (1 890 L) / [() 1/4 cup] [() 60 ml] for each 600 gallons (2 275 L) / [() 20 / teaspoons / [tsp.]] / [() 100 ml] / for each 1 000 gallons (3 780 L) / [() 1/2 cup] [() 120 ml] for each 1 200 gallons (4 536 L) / [() 2 cups] [() 480 ml] for each 4 800 gallons (18 144 L)] of aquarium water. Repeat dose every [three / 3] days until algae is controlled. Siphon or scrape any dead algae from aquarium. Once algal growth is under control, add one dose per week. Weekly doses of AlgaeFix will control algal growth and reduce aquarium maintenance.

Directions For Use *{for pond AlgaeFix label}*

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For ornamental / synthetically lined / pond and fountain use only, where all water is contained without any outflow. **Warm weather caution:** Before using AlgaeFix, make certain that the pond has vigorous aeration, i.e., a fountain, waterfall, or aeration device to avoid fish loss due to low oxygen levels. When algae is controlled and removed by the filter or settles to the bottom of the pond, the oxygen level may drop to harmful levels if adequate aeration is not provided. Therefore, when using AlgaeFix during warm weather and high water temperatures, vigorous, 24 hour aeration is required. Do not shut off pond pumps and aeration devices at night. Add [() 5 ml] / [() 1 / teaspoon / tsp.] / for each 50 U.S. gallons (190 L) / [() 2 / teaspoons / [tsp.]] / [() 10 ml] / for each 100 U.S. gallons (378 L) / [() 10 / teaspoons / [tsp.]] / [() 50 ml] / for each 500 gallons (1 890 L) / [() 1/4 cup] [() 60 ml] for each 600 gallons (2 275 L) / [() 20 / teaspoons / [tsp.]] / [() 100 ml] / for each 1 000 gallons (3 780 L) / [() 1/2 cup] [() 120 ml] for each 1 200 gallons (4 536 L) / [() 2 cups] [() 480 ml] for each 4 800 gallons (18 144 L)] of [pond / fountain] water. Thoroughly mix AlgaeFix into [pond / fountain] water by adding near the pump outflow, waterfall, or aeration device. AlgaeFix can be mixed in a bucket of [pond / fountain] water and dispersed evenly around the [pond / fountain]. Repeat dose every [three / 3] days until algae is controlled. Be prepared to siphon out dead filamentous algae. Once algal growth is under control, add one dose per week. Weekly doses of AlgaeFix will control algal growth and reduce [pond / fountain] maintenance. **CAUTION:** Do not use AlgaeFix with freshwater crustaceans, including: shrimp, crabs and lobsters.

Directions For Use *{for fountain label}*

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For best results start with a clean fountain. Scrub away algae and dirt, rinse, and fill with clean water. Add [14 drops *{due to differences in applicator orifice the drops used will vary according to package size, see chart at end of label for drop dosage for each size container}*] / [() 1 ml] / [() 1/5 tsp.] / for each 10 U.S. gallons (38 L) / [() 5 ml] / [() 1 / teaspoon / tsp.] / for each 50 U.S. gallons (190 L)] of water. Repeat dose once a week to keep fountains clean and clear. Add a dose of AlgaeFix every time you change water in the fountain. Weekly doses of AlgaeFix will control algal growth and reduce fountain maintenance.

PRECAUTIONARY STATEMENT
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap or water after handling. NOTE: This product contains a chemical known to the state of California to cause cancer.

FIRST AID: IF ON SKIN, thoroughly wash with soap and water and remove contaminated clothing. IF IN EYES, hold eye open and gently flush with water for 15 minutes. IF SWALLOWED, call a Poison Control Center or Doctor immediately for treatment advice.

{for containers 64 fl. Ounces or less}

STORAGE AND DISPOSAL: Do not contaminate water or feed. Do not reuse empty bottle. Rinse thoroughly before discarding in trash.

{for containers greater than 64 fl. ounces}

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. Do not reuse container. Rinse thoroughly before discarding in trash

Aquarium Pharmaceuticals, Inc.
PO Box 218
Chalfont, PA 18914

[Questions or comments? / For more information / contact our Technical Services Department / call
us / at 1-800-847-0659 / or visit / us on the web / our web site / at www.aquariumpharm.com /
www.pondcare.com]

{Number of drops per 10 gallons based upon package size}

<i>{1 oz size : Dose =}</i>	[14 drops (1 ml)]
<i>{1 1/4 oz size: Dose =}</i>	[25 drops (1 ml)]
<i>{4 oz size: Dose =}</i>	[14 drops (1 ml)]

{Administrative note: any language which appears between { } and is italicized 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}