



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 13, 2004

Sally Hayes
Scientific & Regulatory Consultants, Inc.
Agent for Aquarium Pharmaceuticals, Inc.
P.O. Box 1014
Columbia City, IN 46725

Dear Ms. Hayes:

Subject: **AlgaeFix**
EPA Registration No. 8709-8
Letter dated July 3, 2003

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments:

Proposed Amendment:

- Claim for use in Saltwater and Reef Aquaria
- Addition of two brand names
- Other label revisions

General Comments:

Toxicity Studies in Saltwater and Reef Aquaria

While the submitted data did indicate no mortality from treatment with AlgaeFix, several things make the study of questionable scientific validity. Given the concerns in the attached review, the Agency cannot draw any scientific conclusion from the submitted data. Aquatic studies submitted according to OPPTS Guideline requirements have provided sufficient data to characterize Busan 77 as highly toxic to freshwater organisms, ranging from highly toxic to slightly toxic to marine organisms. Since the concentration of the test chemical was not determined in the study submitted with this package, it is unknown whether the level achieved during application according to label directions will approach levels shown to be toxic to marine invertebrates in the Guideline studies. If you wish to be protective of aquarium organisms such as marine crustacea, further analyses of the concentration of Busan 77 in the water during treatment with AlgaeFix should be conducted to ascertain that it does not approach the levels shown to be toxic to marine invertebrate species in the submitted studies [Mysid, LC50=13ppm (95% confidence interval of 9.1 - 16ppm) NOEC \leq 7.8 ppm; Quahog clam, LC50 = 350 ppb (95% confidence interval of 0 - 710ppb), NOEC = 230 ppb]. Data from published scientific literature may

also provide toxicity endpoints for additional species of interest, some of which may be more sensitive than the species tested in EPA Guideline studies

Acceptable label claims:

1. The word "New" can only be used for six months after the product is sold in Interstate Commerce bearing the amended label.
2. Based on the size of the containers (1oz., 2 oz., 4 oz., and 8 oz.) the Agency approved your request for an exemption from using the term "Total 100%" in the ingredient statement texts for the subject product's small package sizes only.
3. You may use the term "Caution" as long as it does not conflict with the signal word on the labeling.
4. Due to the product's small package size (1 oz., 2oz., 4 oz., and 8 oz.), the storage and disposal statement may remain the same as accepted by the Agency on March 21, 2000 only for the product's small package sizes.

Unacceptable label claims:

With respect to the First Aid Statement, the Agency has denied your request for exemption from using the complete verbiage prescribed in PR Notice 2001-1. The complete first aid instructions verbiage as stated in PR Notice 2001.1 for **"IF ON SKIN OR CLOTHING, IF IN EYES, and IF SWALLOWED"** must be listed on the label regardless of the size of the label package.

Other Comments:

The following additional brand names are acceptable:


- Algae Destroyer Advanced.
- Saltwater AlgaeFix.

For detailed information and consideration, refer to the enclosed AD/RASSB review dated December 27, 2003.

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at 703 308-7003.

Sincerely,


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

Enclosure:

ALGAEFIX

(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)

- [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]
- [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]
- [Does not alter the pH]
- [Does not discolor the water or cause foaming]
- [Does not contain copper]

ACTIVE INGREDIENT: Poly[oxyethylene(dimethyliminio)ethylene (dimethyliminio)ethylene dichloride]
OTHER INGREDIENTS:

4.50%
95.50%
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]

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 13 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

Net: (actual volume of each package size is inserted here)

- [Treats 300 U.S. gallons (1134 l)]
- [Treats 370 U.S. gallons (1399 l)]
- [Treats 1200 U.S. gallons (4536 l)]
- [Treats 2400 U.S. gallons (9072 l)]
- [Treats 4800 U.S. gallons (18144 l)]
- [Treats 9600 U.S. gallons (36288 l)]
- [Treats 19200 U.S. gallons (72576 l)]
- [Treats 38400 U.S. gallons (145152 l)]
- [Treats 192 000 U.S. gallons (725760 l)]

8709-8

EPA Reg. No. 8709-8
EPA Est. No. 8709-PA-1

{Administrative Note: the following bulleted statements are for the Alternate Brand Algae Destroyer Advanced label only and may appear on the front panel of that particular label}

- [New Formula] *can six month*
- [Treats more gallons]
- [See new dosing directions]

{Administrative Note: one of the following three paragraphs may appear on the front panel of the various sub-labels}

[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.]

[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} for each 10 U.S. gallons (38 L) / 1 teaspoonful (5 ml) for each 50 U.S. gallons (139 L) / 2 teaspoons (10 ml) for each 100 U.S. gallons (378 L) / 10 teaspoons (50 ml) for each 500 gallons (1 890 L) / ¼ cup (60 ml) for each 600 gallons (2 275 L) / 20 teaspoons (100 ml) for each 1 000 gallons (3 780 L) / ½ 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*} for each 10 U.S. gallon (38 L) / 1 teaspoonful (5 ml) for each 50 U.S. gallons (189 L) / 2 teaspoons (10 ml) for each 100 U.S. gallons (378 L) / 10 teaspoons (50 ml) for each 500 gallons (1 890 L) / ¼ cup (60 ml) for each 600 gallons (2 275 L) / 20 teaspoons (100 ml) for each 1 000 gallons (3 780 L) / ½ 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 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 [1 teaspoonful (5 ml) for each 50 U.S. gallons (189 L) / 2 teaspoons (10 ml) for each 100 U.S. gallons (378 L) / 10 teaspoons (50 ml) for each 500 gallons (1 890 L) / ¼ cup (60 ml) for each 600 gallons (2 275 L) / 20 teaspoons (100 ml) for each 1 000 gallons (3 780 L) / ½ 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*} for each 10 U.S. gallon (38 L), 1 teaspoonful (5 ml) for each 50 U.S. gallons (189 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.

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{AlgaeFix label page 4}

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.

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

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 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}