

81584-1

2/28/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 28, 2005

Herbert Estreicher, Esq.
Counsel, Keller & Heckman LLP
Tetra Holding (US), Inc.
1001 G Street, N.W., Suite 500 West
Washington, DC 20001

Subject: Notification in Accordance with PR Notice 98-10
Tetra Algae Control
EPA Registration Number 81584-1
Application Date: February 18, 2005
Receipt Date: February 18, 2005

Dear Mr. Estreicher:

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

Proposed Notifications:

- Add non-public health claims and clarifying text.

General Comment:

Based on a review of the material submitted, the following comment apply.

The notification applications are acceptable. Copies have been inserted in your file for future reference.

Should you have any questions or comments 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)

WRITER'S DIRECT ACCESS

February 18, 2005

Herbert Estreicher
(202) 434-4334
Estreicher@khlaw.com

Via Courier

Mr. Adam Heyward
Product Manager 34, Antimicrobial Division
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
U.S. Environmental Protection Agency
1801 South Bell Street
Arlington, VA 22202-4501

Re: Notification of Label Changes; *Tetra Algae Control* (EPA Reg. No. 81584-1)

Dear Mr. Heyward:

As discussed yesterday by telephone, we are submitting on behalf of our client, Tetra Holding (US), Inc. (Tetra), a notification request to add certain non-public health claims to the Master Label for *Tetra Algae Control*, an algaecide for ornamental freshwater fish aquaria and ponds. These changes are discussed in detail below.

Addition of Non-public Health Claims

We request the addition of the following alternative non-public health claims to the currently registered Master Label as per the criteria listed in P.R. Notice 98-10, Section II(B):

- For use with fish and [&] plants
- For use with live plants and fish
- For use with ornamental plants and fish
- For use with live ornamental plants and fish
- For use with ornamental plants and fish in aquariums and ponds
- For use with live ornamental plants and fish in aquariums and ponds
- For use with ornamental plants and aquaria and pond fish
- For use with live ornamental plants and aquaria and pond fish
- [Tetra] Algae Control [AlgaeBan™] can be used with ornamental freshwater fish and plants
- [Used as directed,] [Tetra] Algae [Control/ Ban™] can be used with ornamental freshwater fish and plants.

- For maximum effectiveness and to keep fish healthy, ensure that the aquarium is well aerated.
- For maximum effectiveness, ensure the aquarium is well aerated.
- Ensure the aquarium is well aerated.
- Ensure the pond / fountain is well aerated.
- Can be used in fountain and ornamental ponds with plants and ornamental fish.

The underlined terms in the above statements are alternatives to the word "safe" that appears in the otherwise identical statements on the current Master Label. The term "For Use" and in one case the term "healthy" is proposed as an alternative to the term "safe." We have also repeated the simple direction to "ensure the aquarium [pond/fountain] is well aerated" in the directions for use sections as clarifying text.

Clarifying Text

In addition, the label is modified to insert the word "[Tetra] [TetraPond]" in places where the term "Algae Control [AlgaeBan™]" appears in the text in order to make clear that the brand name of the product is being referred to. In addition, administrative text is added to make clear that the "Before/After" on the Master Label refers to the graphic of a split aquaria that appears in the final proof label appended to the Notification dated January 5, 2005 and accepted by EPA on February 2, 2005.

As discussed, the intent of the changes is to provide alternate text for the approved "safe for fish and plant" claim without prejudice to that existing claim.

We certify that no other changes have been made to the labeling (other than those listed above) or the confidential statement of formula. You agreed to process this Notification as soon as possible early this week. Please contact me if you have any questions or need additional information.

Sincerely,


Herbert Estreicher / kro

Herbert Estreicher

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. 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
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Application for Pesticide - Section I

1. Company/Product Number Tetra Holding (US), Inc./81584-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tetra Algae Control	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) Tetra Holding (US), Inc. 3001 Commerce Street Blacksburg, VA 24060 <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. <u>8709-8</u> Product Name <u>AlgaeFix</u>

Section II

<input type="checkbox"/> Amendment - Explain Below <input type="checkbox"/> Resubmission in response to Agency Letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency Letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
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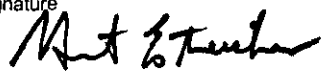
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for addition of non-public health claims and clarifying text per 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 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 section 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 checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "yes," Unit Package wgt. 4 - 28 lbs	No. per container 4 - 36	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 30 50 100 250 500 ml and 3 L		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other (_____) <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Herbert Estreicher	Title Counsel	Telephone No. (Include Area Code) (202) 434-4334
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 for misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Counsel	
4. Typed Name Herbert Estreicher	5. Date February 18, 2005	

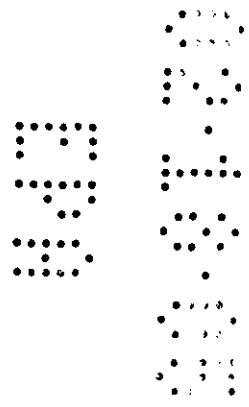
[Tetra [TetraPond] Algae Control] [Tetra [TetraPond]AlgaeBan™]

{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.}

[New]

[Before, After] {Administrative note: Before, After text refers to front panel graphic as submitted in Notification dated January 5, 2004}

- [Algae Control]
- [Tetra [TetraPond] Algae [Control/ [Ban™]
- [Broad spectrum algae control]
- [Helps resolve algae problems]
- [Effectively controls algae on aquarium glass, ornaments and plants]
- [Effectively controls "green water" algal blooms, string or hair algae and blanketweed]
- [Effectively controls "green water" algal blooms ([Chlorella / Selenastrum]) / string or hair algae (Spirogyra) / blanketweed (Oedogonium)]
- [Effectively combats: Algae Blooms (green water), String & hair algae, blanketweed]
- [Safe for plants and fish]
- [For use with [live] plants and fish]
- [Safe for live plants and fish]
- [Safe for fish and plants]
- [For use with fish and plants]
- [Safe for ornamental plants and fish]
- [For use with ornamental plants and fish]
- [Safe for live ornamental plants and fish]
- [For use with live ornamental plants and fish]
- [Safe for ornamental plants and fish in aquariums and ponds]
- [For use with ornamental plants and fish in aquariums and ponds]
- [Safe for live ornamental plants and fish in aquariums and ponds]
- [For use with ornamental plants and fish in aquariums and ponds]
- [Safe for ornamental plants and aquaria and pond fish]
- [For use with ornamental plants and aquaria and pond fish]
- [Safe for live ornamental plants and aquaria and pond fish]
- [For use with live ornamental plants and aquaria and pond fish]
- [Controls algae]
- [Controls green water]
- [Controls algae growth in aquariums]
- [Controls green water and string algae]
- [Controls algae in freshwater aquariums / water gardens / container water gardens / ornamental fountains / Koi ponds / goldfish ponds containing live plants and fish]
- [Reduces aquarium maintenance]
- [Keeps freshwater aquariums / ornamental ponds / Koi ponds / goldfish ponds / fountains / water gardens / clean and clear]
- [For freshwater aquariums / ponds]
- [For ornamental freshwater aquariums / ponds]
- [For use in freshwater aquariums / ponds containing live plants and fish]



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

ACTIVE INGREDIENT:

Poly (oxyethylene (dimethyliminio) ethylene (dimethyliminio) ethylene dichloride).....5.4%

INERT INGREDIENTS:.....94.6%

TOTAL:..... 100.0%

EPA Reg. No. 81584-1

EPA Est No.: 81257-DEU-01

KEEP OUT OF REACH OF CHILDREN

CAUTION:

[See back panel for precautionary and first aid statements]

[See inside for precautionary and first aid statements]

[See inside for precautionary and first aid statements, directions for use and disposal and storage information.]

[Peel back here for directions]

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

[101.4 Fl. Oz, (3 L)]

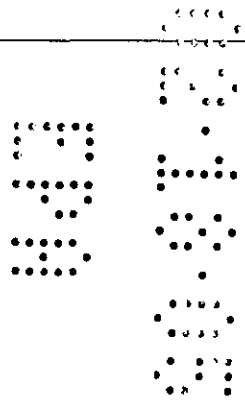
[16.9 Fl. Oz (500 ml)]

[8.45 Fl. Oz (250 ml)]

[3.38 Fl. Oz. (100 ml)]

[1.69 Fl. Oz. (50 ml)]

[1.01 Fl. Oz. (30ml)]



- [Concentrated formula, treats X gallons]

[Treats: 36000 Gallons (136270 L)]

[Treats: 6000 Gallons (22700 L)]

[Treats: 3000 Gallons (11350 L)]

[Treats: 1200 Gallons (4540 L)]

[Treats: 600 Gallons (2270 L)]

[Treats: 360 Gallons (1360 L)]

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{Administrative Note: For Tetra aquarium brand products; one of two paragraphs may be used}

[Tetra][Algae Control / AlgaeBan™]

[Control Unsightly Algae]

[Control Algae with Tetra's Aquarium Algaecide]

[Control Unsightly Algae with Tetra's Aquarium Algaecide]

[Tetra Algae [Control / Ban™] is effective at combating algal blooms (green water) as well as working against algae that grow on glass and décor, such as blue-green algae (, Oscillatoria), diatoms - "brown algae" (Synedra), hair algae (Spirogyra) or blanketweed (Oedogonium). Used as directed, [Tetra] Algae [Control / Ban™] is safe to use with ornamental freshwater fish and plants.] [[Used as directed,] [Tetra] Algae [Control/ Ban™] can be used with ornamental freshwater fish and plants.]

[Tetra Algae [Control / Ban™] effectively combats algal blooms (green water) as well as working against algae that grow on glass and décor. [[[Used as directed,] [Tetra] Algae [Control / Ban™] is safe to use with ornamental freshwater fish and plants.] / [[Tetra] Algae [Control / Ban™] can be used with ornamental freshwater fish and plants.]]

DIRECTIONS FOR USE: {Aquarium brand products}

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

[To be used only in established aquariums]. Before applying, it is recommended you first remove as much algae as possible by cleaning the glass and décor. This allows [Tetra] Algae [Control / Ban™] to be its most effective at reducing the remaining algae and inhibiting new algae growth. Remove activated carbon filters for 6-8 hours after dosing. Be prepared to clean out additional algae as it is killed to prevent deterioration of water quality. [Ensure the aquarium is well aerated.]

{Administrative note: The rate of application is consistent but the method of applying the dose is dependent on the container size. Some containers form droplets, others use an integral measuring cap. The number of drops for correct dosage of 10 gallons will vary depending on dropper insert}

Add 1 ml of [Tetra] Algae [Control / Ban™] for every 12-gallons (45L) of aquarium water. [For smaller aquariums a well-rinsed test vial from a Tetratest kit can be used or use the dropper applicator at a rate of [one / two] drops / gallon (3.8L)]. [For smaller aquariums a well-rinsed test vial from a Tetratest kit can be used or use the dropper applicator at a rate of [10 – 20] drops / 10 gallons (38L)]. [The bottle cap can also be used for measuring. Fill to the inner ring line to treat 60-gallons (225L) or to the top to treat 120-gallons (450 L).] Do not overdose. Adding [Tetra] Algae [Control / Ban™] in areas of high water agitation or by pre-diluting [Tetra] Algae [Control / Ban™] in a cup of aquarium water will help to distribute the active ingredient. [Ensure the aquarium is well aerated.] For maximum effectiveness [and safety to fish / and to keep fish healthy], ensure that the aquarium is well aerated.

[Dosage may be repeated if needed every three days for up to [three/four] total doses, then clean the aquarium of dead algae.]

[Dosage may be repeated every three days until algae is under control. Be prepared to remove dead algae from the aquarium.]

[For regular maintenance, use as algae starts to reappear.]

[For regular maintenance, use once a week]

[For regular maintenance, use once a week once algae growth is under control]

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ATTENTION: [Do not use in newly establish aquariums.]

[Do not use in newly establish aquariums less than [42 / 56 / 84 days old]/ [6 / 8 / 12 weeks old] / [one / two / three months old.]

Do not use in aquariums with invertebrates or crustaceans e.g. crabs, shrimps, or crayfish.

{Administrative Note: For TetraPond brand products; one of three paragraphs may be used}

[TetraPond][Algae [Control / Ban™]]

Benefits

[[TetraPond Algae [Control / Ban™]] effectively combats:

- Algae blooms (green water, [Selenastrum])
- String & hair algae (Spirogyra)
- Blanketweed (Oedogonium)

[Safe for ornamental plants and fish when used as directed.] [Can be used in fountain and ornamental ponds with plants and ornamental fish when used as directed] For ornamental pond or fountains only.

[Do not use in [ponds/environments] with invertebrates or crustaceans e.g. crabs, shrimps, or crayfish.]]

[TetraPond Algae [Control / Ban™] effectively combats algal blooms (green water) as well as working against algae that grow on rocks and décor, such as blue-green algae (Oscillatoria), diatoms - "brown algae" (Synedra), hair algae (Spirogyra) or blanketweed (Oedogonium). [Used as directed, [TetraPond] Algae [Control / Ban™] [is safe to use] [can be used] with ornamental freshwater fish and plants. For ornamental ponds and fountains only]

[TetraPond Algae [Control / Ban™] effective combats algal blooms (green water) as well as working against algae that grow on rocks and décor in ornamental ponds and fountains. [Used as directed,] [TetraPond] Algae [Control / Ban™] [is safe to use] [can be used] with ornamental freshwater fish and plants.]

DIRECTIONS FOR USE: {Pond based products}

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DISLODGE STRING ALGAE off stones with high pressure hose nozzle and scoop out with a fine mesh net or pond vacuum. [Ensure the pond / fountain is well aerated.]

CALCULATE POND GALLONS using following formula:

Length (ft.) x Width (ft.) x Average Depth (ft.) = cubic feet Cubic feet x 7.5 = pond gallons

{Administrative Note: For TetraPond brand 250 and 500 ml products; use following instructions}

[DOSAGE:

- 10 ml for every 120 gallons of pond water (Use top of supplied screw cap) {Picture of cap}
- ¼ Cup (60 ml) for every 720 gallons of pond water

Dedicate use of the measuring cup to algaecide applications only]

{Administrative Note: For TetraPond brand 3 liter product; use following instructions}

[DOSAGE: Using a measuring cup, measure

- 25 ml for every 300 gallons of pond water
- ¼ cup (60 ml) for every 720 gallons of pond water

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Dedicate use of the measuring cup to algacide applications only]

DILUTE the proper dosage in a bucket of [water / pond water]. POUR diluted mixture into the pond or fountain evenly along the edges. DO NOT over dose. [Ensure the pond / fountain is well aerated.] TREATMENT may be repeated if needed every three days up to [three, four] total doses. REMOVE DEAD ALGAE from pond.

[Note: Do not use in ponds established for less than [one / two / three months.]]

WARM WEATHER CAUTION: Before adding TetraPond Algae [Control / Ban™] be sure to provide adequate aeration from a fountain, waterfall or air pump [to keep fish healthy]. Keep pump(s) [and aeration devices] running 24 hours a day when using this product, especially in the warmer months.

[Do not use in ponds with invertebrates or crustaceans e.g. crabs, shrimps, or crayfish.]

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: Harmful if swallowed. Avoid contact with eyes, skin or clothing.
Wash thoroughly with soap and water after handling.

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of soap and water for 15-20 minutes.
If Swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

STORAGE AND DISPOSAL

Store bottle out of reach of children.
Do not reuse empty bottle. Rinse thoroughly and dispose of in trash.

NOTICE: This product contains chemicals known to the State of California to cause cancer.

Questions? Call at 800.526.0650 or visit www.tetra-fish.com
Tetra Holding (US), Inc.
3001 Commerce St., Blacksburg, VA 24060
Made in Germany

[Tetra Care]
[Helps you care for your fish! tetra-fish.com]
LOGO [Treats XX Gallons/ XX Liters]

UPC

{Tetra label part numbers for manufacturing will be printed on the label}

