

81584-1

2/2/2005

1/11



UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 2, 2005

Karen Obenshain
Keller & Heckman, LLP
1001 G Street, NW
Washington, DC 20001

Subject: **Tetra Algae Eliminator**
EPA Registration No. 81584-1
Application Dated: January 4, 2005
Receipt Date: February 2, 2005

Dear Ms. Obenshain:

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

Proposed Notification:

- Change Primary Brand Name from: "Tetra Algae Eliminator to: "Tetra Algae Control"
- Add Alternate Brand Names: **Tetra AlgaeBan, TetraPond Algae Control, TetraPond Algae Ban**
- Addition and Deletion of non-public health claims
- Clarification of use directions

General Comment:

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

The notification is acceptable. A copy of the notification has been inserted in your file for future reference.

2/11

-2-

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Stacey Grigsby at (703) 305-6440.

Sincerely,



d/

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

Enclosure

3/11

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-05

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
		<input checked="" type="checkbox"/> Amendment	
		<input checked="" type="checkbox"/> Other	

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 Eliminator™	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(o)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 8709-8 Product Name <u>AlgaeFix</u>	

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 checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Not subject to PRIA (no fee category)

Notification for change of primary brand name, addition of alternate brand names, addition/deletion of non-public health claims, and clarification of use directions 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 type="checkbox"/> Plastic
	If "yes," Unit Package wgt. 4 - 28 lbs	No. per container 4 - 36	If "yes," Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted.				Other (Specify) _____	
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 checked="" 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 Catherine Kirkpatrick	Title Regulatory Compliance Associate	Telephone No. (Include Area Code) (540) 951-5508
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 Regulatory Compliance Associate	
Typed Name Catherine Kirkpatrick	5. Date 4 Jan 05	

KELLER AND HECKMAN LLP
SERVING BUSINESS THROUGH LAW AND SCIENCE®

1001 G STREET, N. W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TEL 202.434.4100
FAX 202.434.4646
WWW.KHLAW.COM

WRITER'S DIRECT ACCESS

January 4, 2005

Karen R. Obenshain
(202) 434-4118
obenshain@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 Eliminator*™ (EPA Reg. No. 81584-1)

Dear Mr. Heyward:

On behalf of our client, Tetra Holding (US), Inc. (Tetra), we are submitting a notification request to 1) change the primary brand name; 2) add alternate brand names; 3) add or delete non-public health claims; 4) clarify use directions; 5) add the California Proposition 65 notice; and 6) add miscellaneous marketing features to the Master Label for *Tetra Algae Eliminator*™, an algacide for ornamental freshwater fish aquaria and ponds. These changes are discussed in detail below.

Change Primary Brand Name

As per P.R. Notice 98-10, Section II(A), we request that the primary brand name of the currently registered product, *Tetra Algae Eliminator*™, be changed to *Tetra Algae Control*.

Add Alternate Brand Names

As per P.R. Notice 98-10, Section II(A), we request that the following alternate brand names be added to the Master Label:

Tetra AlgaeBan™

TetraPond Algae Control

TetraPond AlgaeBan™

5/11

Mr. Adam Heyward
January 4, 2005
Page 2

KELLER AND HECKMAN LLP

Deletion of Non-public Health Claims

As per P.R. Notice 98-10, Section II(B), we request the deletion of the following claims that appear on the currently registered Master Label:

- Eliminates algae blooms
- Eliminates suspended algae blooms
- Eliminates free floating algae blooms
- Effectively eliminates suspended algae blooms
- Effectively eliminates free floating algae blooms

Addition of Non-public Health Claims

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

- Effectively controls "green water" algal blooms (*Selenastrum*)/string or hair algae (*Spirogyra*)/blanketweed (*Oedogonium*)
- Safe for fish and plants
- Controls green water
- *TetraPond Algae Control* [*TetraPond AlgaeBan*[™]] effectively combats:
 - Algae blooms (green water, *Selenastrum*)
 - String & hair algae (*Spirogyra*)
 - Blanketweed (*Oedogonium*)

Clarification of Use Directions

As per our telephone conversation of December 20, 2004, the proposed modifications to the Use Directions for this product do not increase the rate or dosage of the product nor do these modifications result in increased exposure. Thus, these changes can be made through the notification process. The changes are highlighted on the attached label.

Mr. Adam Heyward
January 4, 2005
Page 3

6/11
KELLER AND HECKMAN LLP

Addition of California Proposition 65 Notice

Because the active ingredient used in this product contains substances that are included on the California Proposition 65 List, Tetra has chosen to include the following statement on all labels:

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

As per the Agency's guidance, the signal word (Notice) for the Proposition 65 statement does not conflict with the signal word (Caution) of the product.

Miscellaneous Marketing Additions

On all labels, Tetra proposes a graphic, which depicts the water clarity "Before" and "After" the use of their product. An example of this graphic is enclosed for your review. Tetra also proposes to add the following statement *only* to the 3L *TetraPond Algae Control* product:

"Sign up today! It's free! Get into the pond! Valuable tips for the pond enthusiast-delivered via e-mail. Sign up at www.tetrapond.com."

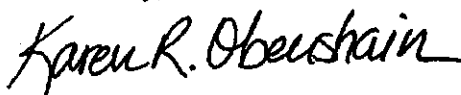
The following phrase may be used on the aquarium product labels and the smaller pond product labels:

"[Tetra Care] [Helps you care for your fish! tetrafish.com]"

We certify that no other changes have been made to the labeling (other than those listed above) or the confidential statement of formula. As per PR Notice 98-10, we will be able to market and distribute EPA Reg. No. 81584-1 using the new primary and alternate brand names, new claims, clarified use directions, and graphics upon receipt of the approval letter for this notification, within 30 days our submission of this request. We provide an example of the graphic label as well as a proposed modified master label (one label with all changes highlighted).

Please contact us if you have any questions or need additional information.

Sincerely,



Karen R. Obenshain
Staff Scientist

7/11

[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]

- [Algae Control]
- [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]
- [Safe for live plants and fish]
- [Safe for fish and plants]
- [Safe for ornamental plants and fish]
- [Safe for live ornamental plants and fish]
- [Safe for ornamental plants and fish in aquariums and ponds]
- [Safe for live ornamental plants and fish in aquariums and ponds]
- [Safe for ornamental plants and aquaria and pond fish]
- [Safe for 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]
- [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%

8/11

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)]

9/11

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

[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, Algae [Control / Ban™] is safe to use 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, Algae [Control / Ban™] is safe to use 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 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.

{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 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 Algae [Control / Ban™] in areas of high water agitation or by pre-diluting Algae [Control / Ban™] in a cup of aquarium water will help to distribute the active ingredient. For maximum effectiveness and safety to fish, 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]

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}

[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. 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™] effective 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 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, Algae [Control / Ban™] is safe to use 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.

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

Dedicate use of the measuring cup to algaecide 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. TREATMENT may be repeated if needed every three days up to [three, four] total doses. REMOVE DEAD ALGAE from pond.

11/11

[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}