

8959-51

6/25/2009

1 of 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUN 25 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Marianne Radtke
APPLIED BIOCHEMISTS
W175 N11163 Stonewood Drive / Suite 234
Germantown, WI 53022-4799

Subject: **Clearigate**
EPA Registration No.: 8959-51
Application Date: May 20, 2009
Receipt Date: May 29, 2009

Dear Ms. Radtke:

This acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Proposed Notification:

Minor Label Revisions: Update Medical Emergency Contact Information
Update per PR Notice 2007-4

General Comment:

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

The notification is unacceptable. Your First Aid and Precautionary Statements are not in agreement. Please reorder the First Aid Statement in appropriate order from most to least toxic route of exposure.

Should you have any questions or comments concerning this letter, Stacey Grigsby by telephone at (703) 305-6440.

Sincerely,

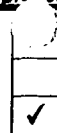
Tracy Lantz
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	7510P						
SURNAME	E. Mitchell						
DATE	6-25-09						



United States
Environmental Protection Agency
Washington, DC 20460



Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 8959-51	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CLEARIGATE	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) APPLIED BIOCHEMISTS W175 N1163 STONEWOOD DR. STE 234 GERMANTOWN, WI 53022 <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 checked="" 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.)

Update the Medical Emergency contact information
Required Certification Statement attached.

Update to comply with container regulations in 2007-4.
Required Certification Statement attached
PRIA fees are not required for these changes.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	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, 55, 275 Gal.		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product Sleeve and paper		<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 Marianne Radtke	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 800-558-5106 ext 528
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 <i>Marianne Radtke</i>	3. Title Regulatory Affairs Manager	
4. Typed Name Marianne Radtke	5. Date May 20, 2009	

Notification Statements For:

Product: Clearigate

EPA Reg. No. 8959-51

Registrant: Applied Biochemists

Certification Statement for 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 sections 12 and 14 of FIFRA.

Certification Statement for PR Notice 2007-4

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR Sections 156.10, 156.140, 156.144, 156.146 and 156.156. No changes have been made to the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR Sections 156.10, 156.140, 156.144, 156.146 and 156.156, 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.

Marianne Radtke

Regulatory Affairs Manager

May 17, 2009

Signature: Marianne Radtke

Handwritten marks and signatures in the bottom right corner.

APPLIED BIOCHEMISTS

W175 N11163 Stonewood Drive Suite 234
Regulatory Services
Marianne Radtke
Germantown, WI 53022-4799
262 255-4619 Fax
262 255-4449 ext. 328
E-mail -mradtke@advantistech.com

May 20, 2009

Office of Pesticide Programs (7504P)
Document Processing Desk (NOTIF)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Clearigate
EPA Reg. No. 8959-51
Application Date May 21, 2009

Applied Biochemists is submitting a Notification for the above subject product for:

- Update the Medical Emergency contact information
- Update to comply with container language as specified in PR Notice 2007-4.

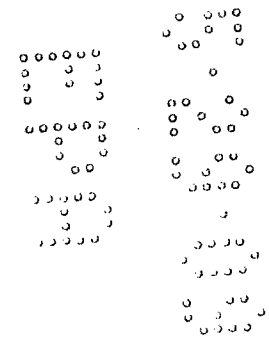
In support of this application for notification, enclosed are the following documents:

- A completed application for notification (EPA 8570-1) form with attached certification statements as required by PR 98-10 and PR Notice 2007-4.
- Two copies of the product labeling with changes highlighted.

If you have any questions please contact me at 800-558-5106 ext 328 or by e-mail at -mradtke@advantistech.com if there are any questions.

Sincerely,


Marianne Radtke
Regulatory Affairs Manager



CLEARIGATE

EPA Reg. No. 8959-51

Pat. # 5,407,899

EPA Est. No. 42291-GA-1

FOR USE IN CROP AND NON-CROP IRRIGATION CONVEYANCE SYSTEMS:
DITCHES, CANALS AND LATERALS; POTABLE WATER RESERVOIRS; LAKES; FARM, FISH, GOLF
COURSE, INDUSTRIAL AND SWIMMING PONDS

ACTIVE INGREDIENTS:

COPPER AS ELEMENTAL 3.825%

INERT INGREDIENTS 96.175%

TOTAL: 100.000%

From mixed Copper Ethanolamines in an Emulsified Formulation
Clearigate CONTAINS 0.31 LBS. OF COPPER PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes. Then continue
rinsing. Call Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call Poison Control Center or doctor for treatment advice.

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 by a Poison Control Center or
doctor.

IF INHALED: Move person to fresh air. If person is not breathing call 911 or an ambulance,
then give artificial respiration, preferably mouth-to-mouth, if possible.
Call Poison Control Center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for
treatment. If a medical emergency arises contact Arch Chemicals Emergency Action Network in the US call
1-800-654-6911 or outside the US call 423-780-2970. For help with a spill, leak, fire or exposure involving
this material call CHEMTREC 1-800-424-9300.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
Measures against circulatory shock as well as oxygen and measures to support breathing manually or
mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous
injection of a short-acting barbiturate drug.

See Additional Precautions on Back Panel

NET CONTENTS:

____ **390405** 5 GALLONS

____ **390430** 30 GALLONS

____ **390476** 275 GALLONS

ab applied biochemists

GERMANTOWN, WISCONSIN 53022

1-800-558-5106

www.appliedbiochemists.com

GENERAL GUIDELINES:

Clearigate is a chelated copper formulation containing an emulsified surfactant / penetrant for highly effective control of coarse (thick cell-walled) filamentous algae, muscilaginous (colonial) planktonic algae, Chara and a variety of emergent, floating and submerged aquatic plants. Vegetation controlled includes: Cladophora, Pithophora, Lyngbya, Microcystis, Hydrilla, pondweeds, water milfoil, naiad and other species having a sensitivity to copper absorption in conjunction with a penetrant.

FOR OPTIMUM EFFECTIVENESS:

Apply **CLEARIGATE** early in the day under bright or sunny conditions when water temperatures are at least 60°F (15.5°C).

Apply when growth first begins to appear or create a nuisance.

Apply in a manner which will ensure even distribution of product within treatment area.

Repeat application, as needed, if regrowth begins to appear and seasonal control is desired. Allow one to two weeks between consecutive treatments.

DIRECTIONS FOR USE:

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

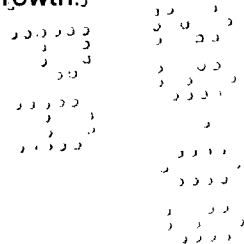
Read entire label. Use strictly in accordance with precautionary statements and directions and with applicable State and Federal Regulations.

STATIC WATER TREATMENT SURFACE SPRAY / INJECTION APPLICATION

For effective control, proper chemical concentration contact should be maintained for a minimum of three hours. Application rates in the chart below are based upon static or minimum flow situations in lakes, ponds, reservoirs and inactive irrigation conveyance systems or drainage systems. Where significant inflow occurs (greater than 10% of total water volume in 24 hours), it is recommended that flow be stopped for 24 hours during and following treatment. If this is not possible, treat inflowing water in accordance with Flowing Water Treatment instructions.

Due to the potential toxicity to fish at dosages in excess of 0.5 ppm copper, the use of **CLEARIGATE** above this level is suggested only by experienced applicators. In areas where fish are not present or where some fish kill is not objectionable, total volume treatments can be made. In all other areas, treatments above 0.5 ppm copper should not exceed 1/3 to 1/2 of the entire water body, allowing one to two weeks between consecutive treatments.

Select dosage rate based upon species/type of plants being controlled. Choose a dilution which will allow relatively even application throughout the intended treatment area with the type of equipment being used. Avoid drift by using coarse spray droplets, applying close to the water surface and/or injecting solution below the water surface through submersed hoses for treatment of submerged growth.



Aquatic Vegetation Type or Species	Dosage PPM	Rates Gallons Per Acre- Foot	Dilution % Spray Solution V/V	Treatment Comments
ALGAE				
Planktonic	0.1 -0.5	0.9 - 4.4	1.5%- 5%	Apply lower dosage rates on light infestations. Use higher rates on heavy blooms and where algae masses are clumped and accumulated.
Filamentous	0.2- 0.6	1.8 - 5.3	5%- 10%	Apply lower dosage rates on early season, light infestations or treatment of regrowth. Apply higher rates on surface mats and coarse species such as Pithorpha, Cladophora Lyngbya.
Chara/Nitella	0.4- 0.8	3.6- 7.1	10%- 15%	Apply lower dosage rates on new infestations or early season growth. Apply higher rates on older, established calcified plants. Apply as close to top of plant growth as possible.
SUBMERGED PLANTS				
<i>Egeria densa</i> (Brazilian Elodea)	0.6-1.0	5.4- 8.7	10% - 20%	Apply lower dose on early season, low density growth. Apply higher rates in thicker stands of plants. Product should be applied as close to the top of the plants as possible. Underwater injection is recommended when plants are more than one foot below water surface.
<i>Elodea canadensis</i>	0.8-1.0	7.1 - 8.7	10% - 20%	
<i>Hydrilla verticillata</i>	0.4-1.0	3.6 - 8.7	10% - 20%	
<i>Myriophyllum spp.</i> (Water Milfoil)	0.8-1.0	7.1 - 8.7	10% - 20%	
<i>Najas spp.</i> (Naiad)	0.5-1.0	4.4 - 8.7	10% - 20%	
<i>Potamogeton spp.</i> (Pondweeds)	0.5-1.0	4.4 - 8.7	10% - 20%	
		Gallons per Surface Acre		
FLOATING PLANTS				
<i>Lemna spp.</i> (Duckweed)		4.4 - 8.7	20% - 25%	Apply lower rates to shallow (less than 1ft.) infestations. Use higher rates for large infestations in deeper water (1foot or greater). Use a fine spray and wet plants thoroughly. Do not disturb with motor wake or paddles after treatment.
<i>Eichornia crassipes</i> (Water Hyacinth)		4.4 - 8.7	20% - 25%	

FLOWING WATER TREATMENT DRIP SYSTEM/METERING PUMP APPLICATION

Effective aquatic plant control in flowing water (canals, ditches, laterals, etc.) is dependent upon maintaining suitable contact time with sufficient chemical concentrations. Other factors to consider include: type of growth present, degree of infestation, water temperature and weather conditions during and following treatment. Fish may be killed at dosages in excess of 0.5 ppm copper in flowing water. Use dosages over 0.5 ppm only in areas where some fish kill is not objectionable or where fish have access to downstream avoidance of these concentration levels.

1. Prior to treatment, it is important to accurately determine water flow rates. In the absence of weirs, orifices or similar devices which provide accurate water flow measurements, volume of flow may be estimated via the following formula:

$$\text{Average Width (ft.)} \times \text{Average Depth (ft.)} \times \text{Velocity* (ft/sec)} \times 0.9 = \text{Cubic Feet per Second (CFS)}$$

*Velocity is the time it takes a floating object to travel a given distance. Dividing the distance traveled (ft) by the time (seconds) will yield velocity (ft/sec). Repeat measurement at least 3 times at the intended application site and use the average of these measurements.

2. Calculate volume of ditch, canal, lateral or receiving pond in cubic feet based upon water levels at the time of treatment by using the following formula:

$$\text{Length (ft)} \times \text{Average width (ft)} \times \text{Average depth (ft)} = \text{Cubic Feet of Water}$$

3. Calculate turnover time (the amount of time it takes for the water in the system to be replaced by new water). Convert to hours using the following formula:

$$\frac{\text{Canal Volume (ft}^3\text{)}}{\text{Flow Rate (CFS)}} \div 3600 = \text{Turnover Time (hrs.)}$$

4. Select dosage rate from the chart below and calculate total **CLEARIGATE** requirements by using the formula following the chart.

AQUATIC VEGETATION TYPE	PPM COPPER	DOSAGE RATE QT. PER CFS/HOUR*
PLANKTONIC ALGAE	0.1 - 0.5	0.3 - 1.4
FILAMENTOUS ALGAE	0.2 - 0.6	0.6 - 1.7
CHARA/NITELLA	0.4 - 0.8	1.2 - 2.3
SUBMERGED WEEDS	0.5 - 1.0	1.4 - 2.8

NOTE: Use higher dosage range in cooler water (60°F - 70°F), under conditions of heavy growth and/or on matured plant growth. Lower dosage ranges may be used on maintenance control treatments, young plants and/or under minimal growth conditions in warmer waters (>70°F).

CLEARIGATE Required (qts) = Dosage Rate (qt/CFS/hr) x Flow Rate (CFS) x Turnover Time (hrs)*
NOTE: If turnover time is less than 3 hrs., substitute 3 hrs. into this calculation.

5. For ditches, canals and laterals determine the number of drip/metering application sites required (based upon turnover time) by referring to the chart below:

TURNOVER TIME (Hrs) NUMBER OF DRIP/METERING SITES

Less than 4.5	1
4.6 - 7.5	2
7.6 - 10.5	3
10.6 - 13.5	4
13.6 - 16.5	5

Etc.

Sewage treatment ponds and other sites where water is stored for a calculated retention time and are fed by a single input source will require a single dripper/metering system. Inflowing water should be treated at the appropriate dosage rate from the chart in #4 for the duration of the entire turnover time calculated in #3.

6. Calculate distance between drip/metering sites by using the following formula:

$$\frac{\text{Canal/Ditch/Lateral Length (ft)}}{\text{No. of Drip/Metering Sites}} = \text{Distance Between Drip/Metering Systems (ft)}$$

7. Calculate amount of **CLEARIGATE** required per drip/metering site by using the following formula:

$$\frac{\text{Total CLEARIGATE Required (qts)}}{\text{No. of Drip/Metering Sites}} = \text{CLEARIGATE Required Per Site (qts.)}$$

8. Calculate drip/metering duration per site by using the following formula:

$$\frac{\text{CLEARIGATE Required Per Site (qts)}}{\text{Dosage Rate (qt/CFS/hr)} \times \text{Flow Rate (CFS)}} = \text{Drip Metering Duration (hrs) Per Site}$$

9. Calculate Drip/Metering Rate by using the following formula to convert to oz./min or ml/min.

$$\text{Flow Rate (CFS)} \times \text{Drip Rate (qt/CFS/hr)} \times 0.533^* = \text{Drip Rate (oz/min.)}$$

NOTE: 0.533 is a constant used to convert qt/hr to oz/min

METRIC CONVERSION: Drip Rate (oz/min) x 29.57 = Drip Rate (ml/min)

Calibrate drip system, metering pump or similar dosage device to establish output rate determined in Step No. 9. This can be done using a watch with a second hand and a calibrated measuring cup, graduated cylinder or similar vessel.

If possible, calibrate all drip/metering devices prior to beginning actual treatment. Turn them on as simultaneously as possible, beginning with the device furthest upstream.

Begin with only the amount of product required at each site or record your start-up time and shut down drip/metering systems after the drip/metering duration time period determined in Step No. 8.

Remove containers from application sites following treatment. Triple rinse application equipment. Dispose of empty containers in accordance with container disposal instructions on this label. Partially used containers should be resealed with original closures and stored in accordance with storage instructions on this label.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

CORROSIVE. Causes skin burns and irreversible eye damage. May be fatal if absorbed through skin. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Wear protective clothing, protective eyewear, and rubber gloves. Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENT HAZARDS

Fish toxicity is dependent upon hardness of water. May be toxic to trout and other species of fish in soft water. Do not use in waters containing trout, koi, goldfish or other sensitive species if the carbonate hardness of the water is less than 50 ppm. Fish may be killed by dosage in excess of 0.5ppm copper in flowing water or systems where total water volume treatments are made.

Avoid contact with drift to desirable plants or crops as injury may result. Clean out application equipment after each operation. Do not apply under conditions of high wind or wave action.

Treatment of dense weed growth and algae blooms in static ponds and lakes can result in oxygen loss from decomposition of dead vegetation. This loss can cause fish suffocation. Therefore, treat only 1/3 to 1/2 of the dense growth at a time and wait one to two weeks between treatments.

Some states may require permits for application of this product to public water. Check with local authorities.

PHYSICAL/CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE & DISPOSAL:

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Keep container closed when not in use. Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Do not reuse or refill container. Do not contaminate feed, feedstuffs, or drinking water. Do not store or transport near feed or food. Store at temperatures above 32°F. Do not store near heat or flame.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

(For <5gallon non-refillable containers only):

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

(For >5gallon non-refillable containers only):

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ with water and recap. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

(For 275Gallon refillable container only):

CONTAINER DISPOSAL: Refillable container. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill container about 10 percent full with water. Agitate vigorously or recirculate water with pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat rinsing procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

Warranty

To the extent consistent with applicable law neither the manufacturer nor the seller makes any warranty, expressed or implied concerning the use of this product other than indicated on the label.

To the extent consistent with applicable law buyer assumes risk of use of this material when such use is contrary to label instructions. Read and follow the label directions.