

3377-61

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

08/05/2003

1/8

August 5, 2003

Ann M. Oxford
Manager, Regulatory Affairs
Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801

Subject: Clearbrom 1021 Biocide
EPA Registration No. 3377-61
Application Date: July 3, 2003
Receipt Date: July 8, 2003

Dear Ms. Oxford:

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

Proposed Notification

- minor label clarification to Directions for Use Statement

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6345.

Sincerely,

Wanda Mitchell
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL	7510C	7510C					
SURNAME	E. B. ...	Mitchell					
DATE	8/06/03	8/5/03					

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

Application for Pesticide - Section I

1. Company/Product Number <p style="text-align: center;">3377-61</p>	2. EPA Product Manager <p style="text-align: center;">Robert Brennis</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> <input type="checkbox"/> Restricted
3. Company/Product (Name) <p style="text-align: center;">Clearbrom 1021 Biocide</p>	PM# <p style="text-align: center;">32</p>	
5. Name and Address of Applicant (Include ZIP Code) Albemarle Corporation 451 Florida Street Baton Rouge, LA 70801 <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
<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.

Notification: Use additional Page(s) if necessary. (For section I and Section II)
 Notification of a minor label clarification. The word "if" has been removed from the decorative fountain directions for use. The statement "If using a dispensing device, adjust the device feed rate to assure a constant treatment level between 0.5 and 5 ppm residual bromine" is now "Using a dispensing device, adjust the device feed rate to assure a constant treatment level between 0.5 and 5 ppm residual bromine." 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 the 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:													
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <table style="width:100%; border-collapse: collapse;"> <tr> <td style="font-size: small;">If "Yes"</td> <td style="font-size: small;">No. per</td> </tr> <tr> <td style="font-size: small;">Unit Packaging wgt.</td> <td style="font-size: small;">Container</td> </tr> <tr> <td style="font-size: small;">½ and 1 lb</td> <td style="text-align: center;">12</td> </tr> </table>	If "Yes"	No. per	Unit Packaging wgt.	Container	½ and 1 lb	12	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <table style="width:100%; border-collapse: collapse;"> <tr> <td style="font-size: small;">If "Yes"</td> <td style="font-size: small;">No. Per</td> </tr> <tr> <td style="font-size: small;">Unit Package wgt.</td> <td style="font-size: small;">Container</td> </tr> </table>	If "Yes"	No. Per	Unit Package wgt.	Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
If "Yes"	No. per												
Unit Packaging wgt.	Container												
½ and 1 lb	12												
If "Yes"	No. Per												
Unit Package wgt.	Container												
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 12 - 1/2 to 1 lb packets, 1.5 - 2.0 lb tubs, 5 lb pails, 50 lb pails	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 checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Other <u>plastic sleeve</u> <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 Ann M. Oxford	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (225) 388-8111
Certification		6. Date Application Received (Stamped)
I certify that the statements which I have made on this form and all attachments 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.		
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Ann M. Oxford	5. Date July 3, 2003	

3/8

CLEARBROM™ 1021 BIOCIDES

For Use In Disinfection of Pools, Spas and Hot Tubs and to Control Microbial Growth in Decorative Waters

~~For Use in the Disinfection of Salon Foot Spas~~ *delete*

Active Ingredient	
1,3-dibromo-5,5-dimethylhydantoin	99.4%
Other Ingredients	0.6%
Total	100.0%

Available bromine: 111%

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 eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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 a 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Registration No. 3377-61
EPA Est. 66397-OK-1, 58401-IL-1



451 Florida Street
Baton Rouge, LA 70801

In case of emergency endangering life or property involving this product, call collect (225) 344-7147

Net Contents _____

JAN 10 2003

3377-61

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

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

ENVIRONMENTAL HAZARDS [for 50 pound packages and larger]

This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Do not mix with other chemicals. Mix only with water. Never add water to product, always add product to large quantities of water. Use clean dry utensils. Do not add this product to any dispensing device containing remnants of any other product. Such use may cause a violent reaction leading to fire or explosion. Contamination with moisture, organic matter, or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases and possible generation of fire and explosion. In case of contamination or decomposition, do not reseal container. If possible, isolate container in open air or well ventilated area. Flood with large volumes of water, if necessary.

STORAGE AND DISPOSAL

STORAGE: Keep this product dry in original tightly closed container when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, or if decomposition occurs, isolate container and flood area with large amounts of water to dissolve all material before discarding this container.

CONTAINER DISPOSAL

(small plastic jugs or pails) Do not reuse container, place in trash collection. Rinse thoroughly before discarding in trash.

(tear open pouches) Do not reuse bag. Discard in trash.

(plastic pails or drums 50 lb and larger) Triple rinse (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Note: Buyer assumes all responsibility for safety and use not in accord with directions.

JAN 10 2003

3377-61

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with the labeling. Read entire label and use strictly in accord with precautionary statements and Directions for Use.

DISINFECTING SPAS AND HOT TUBS

When used as directed, CLEARBROM 1021 BIOCIDE is an effective disinfectant for your spa or hot tub water, keeping it clean, clear and free of odor. CLEARBROM 1021 BIOCIDE gives the effectiveness of chlorine without the chlorine odor.

To start up a new spa or one recently drained, clean all surfaces, back flush or clean the filter, chemically balance the calcium hardness and total alkalinity, treat for iron, copper and manganese, if present. Adjust the pH to 7.2 - 7.8, prior to initiating treatment with CLEARBROM 1021 BIOCIDE.

Place CLEARBROM 1021 BIOCIDE in suitable feeder. Adjust the feeder according to the manufacturer's directions to maintain an active bromine level between 2 - 4 ppm in residential spas and 3 - 6 ppm in commercial spas. Check your feeder regularly and add additional product as needed. Maintenance of residual is dependent on water temperature, light intensity and bather load, and requires frequent checks with a test kit. Use a reliable test kit for the bromine measurements. The pump and filter should be operated at least three hours every day regardless of use. Outdoor hot tubs and spas may require more frequent cleaning and treatment with CLEARBROM 1021 BIOCIDE.

To maintain clear, clean water and insure performance of your spa or hot tub chemicals, water should be drained and spa or hot tub refilled with fresh water every 60 days.

DISINFECTION OF SWIMMING POOLS

Initial Application

Ensure all equipment is working properly. Backwash the filter system following the manufacturer's directions. Chemically balance the calcium hardness to 200 ppm and total alkalinity to 100 - 150 ppm. Adjust the pH to 7.2 - 7.8. Fill suitable feeder with CLEARBROM 1021 BIOCIDE. Adjust the flow of water into the feeder according to the manufacturer's directions to maintain an active bromine residual between 1 - 4 ppm as Br₂ in the pool (approximate use rate of 0.5 ounces per 1000 gallons of water). Maintenance of residual is dependent on ambient temperature, light intensity and bather load, and requires frequent checks with a test kit. Use a reliable test kit to measure bromine residual. The pump and filter should be operated at least eight hours every day regardless of use. Outdoor pools may require longer filtering and consume higher amounts of CLEARBROM 1021 BIOCIDE.

Continued Application

Check the feeder weekly and refill with additional product. Adjust the flow of water into the feeder according to the manufacturer's directions to maintain an active bromine level between 1 - 4 ppm as Br₂ in the pool. Use a reliable test kit for the bromine measurement. The pump and filter should be operated at least eight hours every day regardless of use. Outdoor pools may require longer filtering and consume higher amounts of CLEARBROM 1021 BIOCIDE.

Superoxidation: Water soluble, non-filterable wastes can accumulate in spa, hot tub and pool water causing dull or cloudy water and stimulating algae growth. Superoxidation or superchlorination with a suitable oxidizing shock treatment should be done on a regular basis to remove these wastes and maintain clear sparkling water. A suitable oxidizing agent is: **[ONE OR MORE OF THE FOLLOWING WILL APPEAR ON THE LABEL.]**

- ◆ Calcium hypochlorite *[alternatively a trade name may be substituted.]*
- ◆ Lithium hypochlorite *[alternatively a trade name may be substituted.]*

JAN 10 2003

6/8

- ◆ Sodium dichloroisocyanurate *[alternatively a trade name may be substituted.]*
- ◆ Sodium hypochlorite *[alternatively a trade name may be substituted.]*
- ◆ Potassium peroxymonopersulfate *[alternatively a trade name may be substituted.]*

When using other products as outlined in directions for this product, always follow directions on those products.

Do not directly mix this product in concentrated form with any other chemicals. Do not add other chemicals in the feeder when using this product. A violent reaction leading to fire and/or explosion could result.

Treatment levels of CLEARBROM 1021 BIOCIDE can best be measured with test kits for either bromine or chlorine. Tests should be conducted immediately after drawing samples from the pool. Use test kits according to directions.

1. When a bromine test kit is used, results can be read directly as ppm bromine
2. When a chlorine test kit is used, results can be expressed in terms of bromine by multiplying chlorine values by the conversion factor 2.25.

After application, ensure that the bromine level is below 7.5 ppm before reentering the spa, hot tub or pool.

To determine pool capacity: Rectangular Pools - Length times width times average depth (in feet) times 7.5 equals gallons. Round and Oval Pools - long diameter times short diameter times average depth (in feet) times 5.9 equals gallons.

Do not broadcast into pool.

DECORATIVE WATERS

When used as directed, this product effectively controls algal, bacterial, and fungal slime in lakes, ponds, ornamental ponds and fountains that do not contain fish or other aquatic fauna. To control microbial growth add a sufficient amount of this product to achieve and maintain a bromine residual 0.5 - 5 ppm or as needed to obtain control of the system. ~~If the using a dispensing device, adjust the device feed rate to assure a constant treatment level between 0.5 and 5 ppm residual bromine. Regular use of a test kit is necessary to maintain an appropriate bromine residual in the system.~~

delete
extra
word

JAN 10 2003

3377-61

DISINFECTING SALON FOOT SPAS

To start up a new spa or one recently drained, clean all surfaces. Fill the spa with water. Adjust the pH to 7.2 - 7.8 prior to initiating treatment with CLEARBROM 1021 BIOCIDE. Add a 2-gram scoop of CLEARBROM 1021 BIOCIDE to a 5 to 8 gallon foot spa water to achieve 4 ppm bromine. After each use, empty and clean spa surfaces.

[Alternate statement to replace above paragraph]: To start up a new spa or one recently drained, clean all surfaces. Adjust the pH to 7.2 - 7.8 with [specific product name such as "Spa Balance"] prior to initiating treatment with CLEARBROM 1021 BIOCIDE. Add a 2-gram scoop of CLEARBROM 1021 BIOCIDE to a 5 to 8 gallon foot spa water to achieve 4 ppm bromine. After each use, empty and clean spa surfaces.

[Alternate directions if using a feeder rather than directly adding product to spa water. May or may not appear on the label.]

Foot Spa Feeder Instructions:

To start up a new spa or one recently drained, clean all surfaces. Fill the spa with water. Adjust the pH to 7.2 - 7.8 prior to initiating treatment with CLEARBROM 1021 BIOCIDE. Place CLEARBROM 1021 BIOCIDE in suitable feeder. Adjust the feeder according to the manufacturers directions to maintain an active bromine level of 4 ppm. Check your feeder regularly and add additional product as needed.

[alternate] Foot Spa Feeder Instructions:

To start up a new spa or one recently drained, clean all surfaces. Fill the spa with water. Adjust the pH to 7.2 - 7.8 with [specific product name such as "Spa Balance"] prior to initiating treatment with CLEARBROM 1021 BIOCIDE. Place CLEARBROM 1021 BIOCIDE in suitable feeder. Adjust the feeder according to the manufacturers directions to maintain an active bromine level of 4 ppm. Check your feeder regularly and add additional product as needed.

*Rejected use
product performance
data are
required per DIS/TSS
16*

3377-01

8/8

CLEARBROM 1021 BIOCID
EPA Reg. No., 3377-61

Optional marketing statements

The following statements may or may not appear on the label, or may appear in combination

For Use with Vinyl Lined Pools
 For Use in All Pools
 For above-ground and in-ground pools
 Ideal for all pool surfaces
 Ideal for all pool and spa surfaces
 Ideal for all pool, spa and hot tub surfaces
 Ideal for all spa and hot tub surfaces
 Ideal for above-ground pools
 Ideal for vinyl pool surfaces
 Safe for all pool surfaces
 Safe for all spa surfaces
 Safe for all pool and spa surfaces
 Safe for all pool, spa and hot tub surfaces
 Safe for all spa and hot tub surfaces
 For all pool surfaces
 For Spas & Hot tubs

For use in all pool types (This statement alerts consumer to the fact they may use this product in above ground, in ground, indoor, outdoor, plaster, vinyl, and fiberglass pools)

Easy to use
 Easy and convenient
 Convenient to use
 Easy, single-step bromine disinfectant

Non-foaming
 Non-staining
 No heavy metals

Oxidizes and clarifies for beautiful water
 Oxidizes and clarifies for clean, clear water
 Clarifies
 For routine disinfection and clarification
 Keeps water clear
 Provides Crystal Clear Water
 For Clear, Clean Water
 No more algae stains
 Sparkling, clear water
 Restores water sparkle
 Clear, clean water
 Disinfects, clarifies, and protects

For application in feeders and floaters

Suitable for use with alternative devices such as ionizers, electrolysis and mineral feeders

Bromine disinfectant
 Bromine disinfectant and clarifier
 Disinfectant and algistat
 Disinfectant and algaecide
 Bromine technology
 Single step
 One step disinfecting system

Patented
 Patents pending

For commercial use

Slow dissolving nuggets

100% chlorine-free
 Chlorine-free
 Contains no chlorine
 No chlorine odor
 No chlorine smell
 No chloramines

Low odor

Kills E. coli and Enterococcus faecium
 Kills E. coli
 Kills Enterococcus faecium
 Kills bacteria such as E. coli and Enterococcus faecium

~~Suitable for use in all salon foot spas~~
~~For salons that care about their customers~~

} delete

JAN 10 2003