



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 10 2003

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Anne M. Oxford  
Albermarle Corporation  
451 Florida Street  
Baton Rouge, LA. 70801

SUBJECT: October 28, 2002 Amendment  
Clearbrom 1021 Biocide  
EPA Registration 3377-61

Dear Ms. Oxford:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is conditionally acceptable provided the following changes are made:

All references to the Salon Foot Spa disinfectant use must be deleted since it is not supported by the Bromine RED and as new use with Public Health implications, product performance data are required.

On page 2, add the word "separately" to last sentence of first paragraph so sentence reads: "Remove contaminated clothing and wash clothing separately before reuse."

On page 4, delete extra word (*the*) from second to last sentence in Decorative Waters section.

The proposed use of your product as a Salon Foot Spa disinfectant requires the generation of product performance data based on your end use label. According to Section 3 (c) (5) of FIFRA, as amended, and the provisions of 40 CFR 163.8, products bearing claims for control of microorganisms which pose a threat to human health require specific efficacy data to support such claims and patterns of use.

Based on a review of DIS/TSS 16, the following criteria are utilized to determine whether or not the labeling of an antimicrobial pesticide bears uses of human health significance:

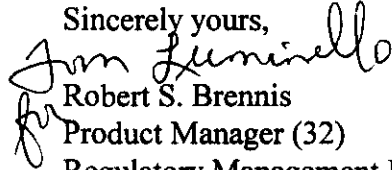
Products bearing claims for control of microorganisms infectious for man will be considered as directly related to human health and will require specific and complete efficacy data to support such claims and patterns of use.

Unqualified and non-specific claims for products as sterilizers, disinfectants, or sanitizers will be considered to include or imply effectiveness against microorganisms infectious for man. Antimicrobial products recommended for use in hospital or medical environments, including sickrooms in public or private dwellings, will be similarly considered as human health-related. Such claims or recommendations must be expressly qualified or deleted in order to remove implications of human health significance.

Since elimination or significant reduction in numbers of microorganisms (sterilization, disinfection, sanitization) must be demonstrated before a product is considered acceptable for claims against microorganisms infectious for man, or for use in medical or sickroom environments, products bearing claims for effectiveness at the bacteriostatic level (inhibition of growth) will not be accepted for such situations. Bacteriostatic claims will only be permitted for products expressly recommended for control of microorganisms of economic or aesthetic significance (e.g. slime-forming bacteria, odor-causing bacteria).

When no pesticidal purpose or function is known or shown to exist for a proposed claim or pattern of use for an antimicrobial product, registration will not be considered.

In summary, your request to make minor changes to the pool chemistry parameters is acceptable. A copy of your conditionally approved label is enclosed. Please resubmit, two copies of your finished label including these revisions. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,  
  
for Robert S. Brennis  
Product Manager (32)  
Regulatory Management Branch II  
Antimicrobial Division (7510-C)

Enclosure

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# CLEARBROM™ 1021 BIOCID

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 \_\_\_\_\_

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WITH COMMENTS  
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**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.

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**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 BIOCIDES is an effective disinfectant for your spa or hot tub water, keeping it clean, clear and free of odor. CLEARBROM 1021 BIOCIDES 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 BIOCIDES.

Place CLEARBROM 1021 BIOCIDES 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 BIOCIDES.

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 BIOCIDES. 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 Br<sub>2</sub> 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 BIOCIDES.

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 Br<sub>2</sub> 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 BIOCIDES.

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.]

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 In the letter dated  
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- ◆ 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

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**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 BIOCID. Add a 2-gram scoop of CLEARBROM 1021 BIOCID 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 BIOCID. Add a 2-gram scoop of CLEARBROM 1021 BIOCID 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 BIOCID. Place CLEARBROM 1021 BIOCID 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.

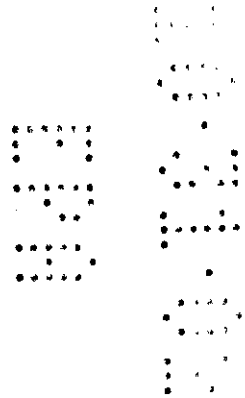
**[alternate] Foot Spa Feeder Instructions:**

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 BIOCID. Place CLEARBROM 1021 BIOCID 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*

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**CLEARBROM 1021 BIOCIDES**  
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

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

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)

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

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

Low odor

Non-foaming  
Non-staining  
No heavy metals

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

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

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

} delete

For application in feeders and floaters

REGISTERED  
EPA REG. NO. 3377-61  
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JAN 10 2003  
Federal Insecticide,  
Fungicide and Rodenticide Act  
EPA REG. NO. 3377-61  
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