

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 6 2004

Mr. Mark Jernigan
Bio-Lab
P.O. Box 1489
Decatur, GA 30031

Subject: BioGuard Master 10
EPA Registration No. 5185-130
Amendment Date: April 9, 2003
EPA Receipt Date: April 11, 2003

Dear Mr. Mark Jernigan,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with following conditions.

- Response to Agency letter dated March 31, 2003

Conditions

Revise the label as follows:

- 1) Add the statement, "Use only with pools that have a water re-circulating system (pump) and filter." It must appear on the front panel and in the directions for small vinyl swimming pools.
- 2) Since this product is corrosive to the skin, you must revise the 4th statement under the "Precautionary Statements" to read "Wear goggles or safety glasses, *protective clothing*, and rubber gloves when handling this product."
- 3) Under the "Precautionary Statements," delete the statement, "irritating to nose and throat." Since your product chose the cite-all option for the acute inhalation data requirement, the product was classified as category IV. If you would like to add additional statements, you must submit a justification for the additional labeling.

Risk Assessment Summary

An evaluation of non-dietary residential exposures was conducted as a screening level assessment on representative scenarios: dermal and inhalation exposures for adult handlers during open-pour applications of product to small vinyl pools, and post-application dermal, inhalation, and incidental oral ingestion exposures for children wading/swimming in treated pools. The Agency is generally not concerned with a calculated MOE greater than or equal to

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the target MOE. A target MOE of 100 was selected for oral, inhalation, and long-term dermal exposures, and a target MOE of 300 was selected for short-and intermediate dermal exposures. All scenarios evaluated yielded margin of exposure (MOE) non-cancer risk estimates well above the 100 and 300 targets for levels of concern. Therefore, it has been determined that there is no anticipated adverse exposure concerns associated with the use of this product in accordance with the label's use rate, re-entry directions, and handling precautions.

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

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{All text in brackets [xxx] is optional and may or may not be included on a final label.}
{All text in braces {xxx} is administrative and will not appear on a final label.}

BIOGUARD
MASTER 10

{Optional marketing statements that may be used with swimming pool algaecide.}

- [Controls Algae]
- [For fast algae control]
- [For control of algae growth.]
- [A swimming pool algaecide.]
- [Economical 10% algae preventative.]
- [Keeps pool water clear and free of visible algae.]
- [Controls algae and algal slime growth in swimming pools.]

{Optional marketing statements that may be used with winter swimming pool algaecide.}

- [Winter Algae Preventative]
- [Economical 10% winter algae preventative.]
- [For control of algae growth.]
- [Controls algae and algal slime growth in swimming pools.]
- [A swimming pool algaecide.]

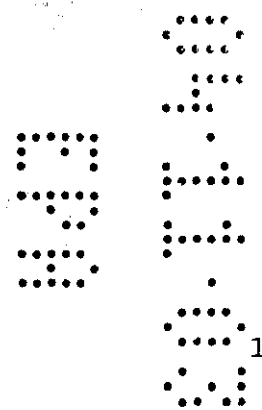
{Optional marketing statements that may be used with swimming pool algaecide for small volume pools}

- [For use with small pools]
- [For small pools]
- [For small vinyl pools]
- [Treats pools up to 10,000 gallons]
- [Controls Algae]
- [For fast algae control]
- [For control of algae growth.]
- [A swimming pool algaecide for small pools.]
- [Economical 10% algae preventative.]
- [Keeps pool water clear and free of visible algae.]
- [Controls algae and algal slime growth in small swimming pools.]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 5185-130



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ACTIVE INGREDIENT:

Alkyl (C₁₄, 58%; C₁₆, 28%; C₁₂, 14%)
dimethyl benzyl ammonium chloride 10.0%

OTHER INGREDIENTS: 90.0%

TOTAL INGREDIENTS: 100.0%

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 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 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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [IN CASE OF MEDICAL EMERGENCY, CALL [1-303-623-5716] [1-877-800-5553] [telephone number supplied by supplemental registrant].]

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

See [back] [side] panel for additional precautionary statements.

BIOLAB, INC.
PO BOX 1489
DECATUR, GEORGIA

EPA REG. # 5185-130
EPA EST. # 5185-GA-1

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WITH COMMENTS
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{Directions to be used for swimming pool algaecide.}

SWIMMING POOL ALGAE PREVENTATIVE

This economical product is formulated to complement swimming pool water being treated with traditional chlorine or bromine systems. It is effective in preventing most common algae growth and aids in maintaining pool water clarity. This product may foam and therefore should not be used for spa treatment or in pools with attached spas or jetted returns.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions.

Ensure all pool equipment is working properly. Backwash the filter system following manufacturer's directions. Adjust pH to between 7.2-7.6. In outdoor chlorine treated pools, add stabilizer to establish a minimum stabilizer level of 30-40 ppm to reduce the degradative effects of sunlight upon the chlorine residual. Check for metals and if present add a stain and scale inhibitor to prevent staining of pool surface due to metal. Maintain sanitizer residual in accordance with label directions found on your sanitizer. When using other products as outlined in directions for this product, always follow directions on those products.

INITIAL APPLICATION: For an initial application, pour directly into pool at a rate of 13 fluid ounces of this product per 5,000 gallons of water (this will provide 2 ppm of this product in the water). More rapid distribution will be achieved by pouring a portion of the specified amount into several areas of the pool until all of the required quantity has been added. Recirculation will assure rapid dispersion. Wait at least 15 minutes after application before entering pool.

MAINTENANCE: Pour directly into pool at a rate of 3.2 fluid ounces per 5,000 gallons of water every 5-7 days depending on weather and use factors (this will provide 0.5 ppm of this product in the water). After each rain of consequence, add 3.2 fluid ounces per 5,000 gallons of water. Even when the pool may not be in use for periods of time, algicide additions should be made since a heavy accumulation of algae growth may be difficult to remove. The appropriate amount of this product should be added by pouring a portion of the specified amount into several areas of the pool until the required quantity has been added. Recirculation will assure rapid dispersion. Wait at least 15 minutes after application before entering pool.

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{Directions to be used for winter swimming pool algaecide.}

WINTER ALGAE PREVENTATIVE FOR SWIMMING POOLS

This economical product aids in the prevention of algae in swimming pools during the winter months, when the pool is not in use. This product may be used in pools sanitized with chlorine or bromine. This product may foam and therefore should not be used for spa treatment or in pools with attached spas or jetted returns.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions.

Ensure all pool equipment is working properly. Backwash the filter system following manufacturer's directions. Adjust pH to between 7.2-7.6. Check for metals and if present, add a stain and scale inhibitor to prevent staining of pool surface due to metals. Superchlorinate the pool using a recommended winter shock treatment according to label directions. When using other products as outlined in directions for this product, always follow directions on those products.

Pour this product directly into the pool water along the edges of the pool at a rate of 1 gallon per 25,000 gallons of water (this will provide 4 ppm of this product in the water) and allow to circulate 2-4 hours. Clean pool water line and filter. In areas with severe freezing, drain pool equipment and plumbing lines or use an antifreeze recommended for swimming pool plumbing and equipment. Pools without covers or with mesh covers, may need a second treatment of this product in mid-winter or just prior to freezing.

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{Directions to be used for swimming pool algaecide for small volume pools}

[SMALL] [VINYL] SWIMMING POOL ALGAE PREVENTATIVE

This economical product is formulated to complement [small] [vinyl] swimming pool water being treated with chlorinating products. It is effective in preventing most common algae growth and aids in maintaining [small] [vinyl] pool water clarity. This product may foam.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions.

Ensure all pool equipment is working properly. Adjust pH to between 7.2-7.6. Establish a minimum stabilizer level of 30 ppm to reduce the degradative effects of sunlight upon the chlorine residual. Check for metals and if present add a stain and scale inhibitor to prevent staining of pool surface due to metal. Maintain sanitizer residual in accordance with label directions found on your sanitizer. When using other products as outlined in directions for this product, always follow directions on those products.

INITIAL APPLICATION: For an initial application, pour directly into pool at a rate of 2 ½ tablespoons* per 500 gallons of water (this will provide 2 ppm of this product in the water). More rapid distribution will be achieved by pouring a portion of the specified amount into several areas of the pool until all of the required quantity has been added. Recirculation will assure rapid dispersion. Wait at least 15 minutes after adding this product or as long as directed by the labels of other products used as outlined in the directions for this product before entering the pool.

{Optional table of alternate dosage rates per gallons to be treated.}

Quick Reference Table for Initial Application Dosage for Common Pool Sizes

Pool Capacity in Gallons	250	500	1000	1500	2000	2500	3000	3500	5500
BioGuard Master 10									
Initial Dose	4.0 tsp.	2.5 tbs.	2.6 fl oz.	4.0 fl oz.	5.0 fl oz.	6.5 fl oz.	7.7 fl oz.	9.0 fl oz.	14.0 fl oz.

MAINTENANCE: Pour directly into pool at a rate of 2 teaspoons* per 500 gallons of water every 5-7 days depending on weather and use factors (this will provide 0.5 ppm of this product in the water). After each rain of consequence, add 2 teaspoons per 500 gallons of water. Even when the pool may not be in use for periods of time, algicide additions should be made since a heavy accumulation of algae growth may be difficult to remove. The appropriate amount of this product should be added by pouring a portion of the specified amount into several areas of the pool until the required quantity has been added. Recirculation will assure rapid dispersion. Wait at least 15 minutes after adding this product or as long as directed by the labels of other products used as outlined in the directions for this product before entering the pool.

*If you use a measuring spoon, use a clean, dedicated spoon to dose the appropriate amount of product into the pool. Keep the dosage spoon stored out of reach of children.

{Optional table of alternate dosage rates per gallons to be treated.}

Quick Reference Table for Maintenance Dosage for Common Pool Sizes

Pool Capacity in Gallons	250	500	1000	1500	2000	2500	3000	3500	5500
BioGuard Master 10									
Maintenance Dose	1.0 tsp.	2.0 tsp.	4.0 tsp.	1.0 fl oz.	1.3 fl oz.	1.6 fl oz.	2.0 fl oz.	2.25 fl oz.	3.5 fl oz.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 6 2004

Product is not for sale in California.
EPA Registration No. 5785-130
EPA Reg. No. 5785-130

{Containers one gallon or less}

STORAGE AND DISPOSAL Keep this product in original tightly closed container when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. **CONTAINER DISPOSAL:** Do not reuse container, but place in trash collection. Rinse thoroughly before discarding in trash.

{Containers greater than one gallon}

Storage and Disposal
Do not contaminate food, feed or water by storage or disposal.
Storage: Keep product in original tightly closed container in locked storage area inaccessible to children and persons unfamiliar with its use. Store in cool, dry, well ventilated area away from heat or open flame.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal or 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 Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
Container Disposal: Do not reuse container. Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS KEEP OUT OF REACH OF CHILDREN. DANGER: Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or safety glasses and rubber gloves when handling this product. Irritating to nose and throat. Avoid breathing fumes. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS: Do not mix with other chemicals.

{Environmental hazards statement for end-use products in containers of less than 5 gallons (liquid) or less than 50 pounds (solid, dry weight).}

[ENVIRONMENTAL HAZARDS This pesticide is toxic to fish and aquatic organisms.]

{Environmental hazards statement for end-use products in containers of equal to or greater than 5 gallons (liquid) or equal to or greater than 50 pounds (solid, dry weight).}

[ENVIRONMENTAL HAZARDS This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other 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 local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.]

ACCEPTED
with COMMENTS
in EPA Letter 2/2/04

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NOTE: Buyer assumes all responsibility for safety and use not in accordance with directions.

{The following is optional text to be used at BioLab's discretion with swimming pool use directions. This information is non-essential and will be provided only as a courtesy. Will not appear on all swimming pool products.}

TO DETERMINE POOL CAPACITY: Rectangular Pools - length times width times average depth (in feet) times 7.5 equals gallons. Round and Oval Pools - average diameter times average diameter times average depth (in feet) times 5.9 equals gallons.

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