

5185-474

05/19/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Bio-Lab Inc.
PO Box 300002
Lawrenceville, GA 30049

MAY 19 2008

Attention: Mark Jernigan
Regulatory Manager

Subject: BioGuard Banish
EPA Reg. No. 5185-474
Amendment Application Date: February 15, 2008
EPA Received Date: February 19, 2008

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

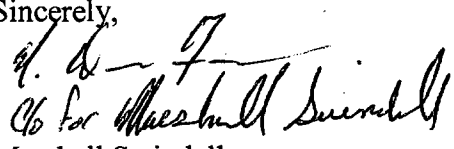
- For all references that state "**Non-Staining**", add the following statement: "**provided that proper labeling instructions are followed to detect metals prior to pool maintenance treatment**". The symbol "†" does not provide the purchaser of this product an adequate advisement pertaining to the possible effects of staining in case an inhibitor (used to treat these cases of staining) is not used in the maintenance treatments. A notation on page 12 of your label states that "Metals from...poorly sequestered **algaecides** have the potential to stain pool surfaces". Since your product has claims as an algaecide, treatment should be forthright to alert the consumer of applicable procedures to avoid potential staining.
- For references listed in marketing statements that states "**All of Types of Algae or All Algae Types**", delete the words "All" and "Types". This claim implies a greater range of effectiveness than what is labeled.
- For all references where the word "**Algae, Algaecide or Algicide**" is stated alone in a marketing statement (except where it clearly states a specific type of algae i.e., black, mustard...or where it specifies particularly that it will be used in a swimming pool), insert the word "**Pool**".

- For all references that state this product is to be used as part of a **“BioGuard Care System”**, that language (and all language that accompanies references to the **BioGuard Care System**) needs to be deleted. The proposed marketing statements for this process are ambiguous. Specific language that defines this system, details of the use directions, and a list the products that would be used in this process needs to be addressed and outlined.
- For all claims in the label that states this product **“kills”** or **“destroys”**, or the product is an **“algaecide”** or **“algicide”**, the following language needs to be inserted: **“when used as directed”**. Language used in various instances throughout this labeling implies that this product acts as a **“preventative treatment”** in conjunction with other products to kill algae. The Agency considers **“preventative”** as a term to control the pre-emergence of a pest, which is different than the word **“kill”**, which eliminates existing pests upon contact. Unless data is submitted to support that BioGuard® Banish kills algae as a stand alone product in the presence of visible algae, then the aforementioned language must be inserted.
- On page 1, in the statement **“Results in 24 hours”**, insert the word **“Potential”** and the wording **“when used as directed”**.
- On page 2, in the marketing claim that states **“Results in 24 hours”**, insert the word **“Potential”** at the beginning, and add the wording **“when used as directed”**.
- On page 2, in the marketing claim that states **“Kills Most Pool Algae Types in 24 hours”**, delete the words **“Most”** and **“Types”**. In addition, insert the word **“Potentially”** at the beginning of the wording **“when used as directed”**.
- On page 2, in the statement **“Kills Pool Algae in 24 hours”**, insert the word **“Potentially”** at the beginning, and add the wording **“when used as directed”**.
- On page 3, after the statement **“Works in sanitized pools”**, add the following language: **“not treated with biguanides or pools treated with hydrogen peroxide”**.
- On page 3, in the marketing statement **“An Algicide with clarifiers...”** delete the wording **“with clarifiers”** and **“clears cloudy water”**.
- On page 4, the product name, **“BioGuard® Banish”**, needs to be added to the label.
- On page 6, in the **PRIOR TO APPLICATION** section, add the following statements: **“If metals testing indicates a need to use a stain and scale inhibitor, apply that product per label instructions”** and **“Establish and maintain proper chlorine or bromine levels”**.

- On page 8, in the **PRIOR TO APPLICATION** section, add the following statements: **“If metals testing indicates a need to use a stain and scale inhibitor, apply that product per label instructions”** and **“Establish and maintain proper chlorine or bromine levels”**.
- On page 9, in your **Optional Marketing Statement B** section, in the wording **“When you use [This product][BioGuard® Banish] you will see results in 24 hours”** delete the words **“you use”** and in its place, insert **“used as directed”**. In addition, add the word **“potential”** just before the word **“results”**.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

not for d w/ bromides or pools treated w/ hydrogen peroxide 7/16

[Works in sanitized pools]
[Convenient and easy to use with results in 24 hours]

[No mixing or predissolving needed]
[An algicide ~~that kills algae and~~ - when used as directed]

[Long lasting, simple treatment for algae]
[Non-Staining Copper Pool Algicide] - when used as directed
[Long Lasting, Non-Staining Algicide]

[Kills Algae] - when used
[PATENTED FORMULA] as directed

~~Prevents algae growth when the pool is not in use~~

~~Prevents algae growth during winter months~~

[[Use] [As Needed]]
[Long lasting, simple treatment for algae]
[Ideal for use with BioLab UV system]
[Compatible with BioLab UV system]
[BioLab UV system approved.]

~~The BioLab UV System below may be used with this product~~

{Optional marketing statements that may be used with winterization.}

[Provides Winter Protection against [Unightly] Algae]
[Prevents Algae Growth During Winter Months]
[Treats 12,000 gallons] {[This statement will only be used when sold in pint bottles for Winterization]}
[Treats 24,000 gallons] {[This statement will only be used when sold in quart bottles for Winterization]}
[Treats 48,000 gallons] {[This statement will only be used when sold in half gallon bottles for Winterization]}
[For clear water at spring opening]

[One application will protect your pool water from algae through the winter months]
[No mixing or pre-dissolving needed]
[Prevents algae growth when the pool is not in use]
[Controls algae during winter months]

[Winter algicide] - when used as directed
[Works in brominated and chlorinated pools]
[Works in bromine and chlorine based sanitizer systems]
[Prevents algae growth during winter months]
[Long lasting winter protection against algae]

[An algicide ~~that kills algae and maintains~~ clears water through the winter months] when used as directed

[Closing]
[Winter]
[Off Season Care]
[Off Season]
[Winter Care]

~~Prevents algae growth when the pool is not in use~~



Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide registered under EPA Reg. 40 CFR 152.101

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All text on this page new.

{Directions to be used for prevention and treatment of algae}

Swimming Pool Algaecide and Algae Preventative

{Optional Marketing Statement A}

[BioGuard® Banish®] [algaecide] [This product] is a highly effective, patented, non-staining [algaecide] [algicide] that kills and controls all types of algae in swimming pools. [BioGuard Banish] [algaecide] [This product] is especially recommended for killing and controlling green, blue-green (frequently called black or spot algae) and mustard algae growths. [BioGuard Banish] [algaecide] [This product] can be used as a remedy for visible algae or to prevent algae from occurring. See use directions for Prevention of Algae or Treatment of visible algae for proper application of [BioGuard Banish] [algaecide] [this product]. This product is formulated for use in chlorine or bromine sanitized swimming pools of all surface and filter types.

{Optional Marketing Statement B}

The BioGuard Care System has three important parts that help you maintain crystal blue sparkling water.

- ~~Substrate to remove contaminants~~
- ~~Shock to destroy contaminants~~
- ~~Preventative algaecide to stop algae before it starts~~

All parts of the BioGuard Care System are vital to achieving sparkling water.

BioGuard® Banish® [This product] is a non-foaming algae preventative for the BioGuard Care System. Weekly use of [BioGuard® Banish®][this product] prevents algae before it starts. [This product] [BioGuard Banish®] is formulated to complement most swimming pool sanitizers. [This product] [BioGuard Banish®] is a highly effective algae killer and algae preventative. [This product] [BioGuard Banish®] is effective and non-staining when used as directed. [This product] [BioGuard® Banish®] kills and prevents all types of algae; black algae, green algae, and mustard algae. [This product] [BioGuard® Banish®] provides a residual effectiveness that protects your pool against algae formation while keeping your pool water sparkling clear. [This product] [BioGuard® Banish®] is non-foaming and can be used in pools with attached spas or jetted returns.

[Use [BioGuard® Banish®] [this product] weekly when using the BioLab UV system to prevent algae.]

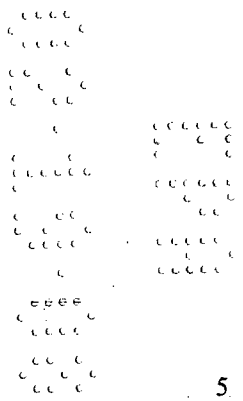
IMPORTANT NOTES:

1. Do not use in pools sanitized with biguanides or pools treated with hydrogen peroxide.
2. Prior to the initial application of this product, test pool water for the presence of metals. If metals are present, apply a metal stain preventative per label directions.
3. When using other products, always follow label directions for those products.
4. [† In use dilution, this product is non-staining to pool surfaces and equipment.] {or} [† Full strength product will stain porous pool surfaces.]

ACCEPTED
With COMMENTS
 to EPA Letter Dated
MAY 19 2008

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

5185-474



All text of this page new.

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.

PRIOR TO APPLICATION:

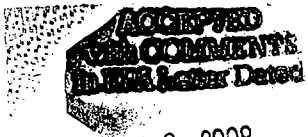
1. Ensure all equipment is working properly. If necessary, clean the filter system.
2. Adjust pH between 7.2-7.6.
3. Establish and maintain proper chlorine or bromine levels. In chlorine-treated pools, add stabilizer to establish a minimum level of 30-40 ppm of cyanuric acid to reduce the degrading effects of sunlight on chlorine residual.
4. Vacuum leaves and any other foreign debris from pool. *add language on 4 of 6 regarding metals*
5. Brush visible algae thoroughly from the pool's surface with a surface-compatible brush.

TO PREVENT ALGAE: *Language regarding chlorine or bromine levels*

1. Initially apply 8 fluid ounces of this product per 10,000 gallons of pool water with pump and filter operating.
2. Thereafter, for weekly application intervals, add 1.5 fluid ounces per 10,000 gallons of pool water. For two week application intervals, add 3 fluid ounces per 10,000 gallons of pool water every other week. Apply more often if pool volume is diluted by heavy rain, frequent backwashing or partial drain/refill.
3. Wait at least 15 minutes after application before entering pool.

TREATMENT OF VISIBLE ALGAE:

1. Add 1 lb. of [BurnOut WP] {or} [BurnOut Extreme] {or} [granular calcium hypochlorite] per 10,000 gallons of pool water or 1 lb. of [BurnOut 35] {or} [granular lithium hypochlorite] per 6,000 gallons of pool water or 1 lb. of BioGuard Smart Shock per 12,000 gallons of pool water. Follow application directions on these products.
2. Allow to circulate for 1 hour.
3. With pump and filter operating, apply 16 fluid ounces of [BioGuard Banish] [algacide] [this product] per 10,000 gallons of pool water directly to the pool water in areas of heaviest algae growth. *pool*
4. Continuously circulate pool water for 24 hours.
5. The next day, thoroughly brush pool surfaces.
6. Prior to re-entry, test chlorine level. Do not enter pool until chlorine level is between 1 - 4 ppm.
7. In cases of persistent algae, repeat brushing and product application after 2-4 days.
8. [The use of a filter aid will enhance filter efficiency and algae removal.]
9. [Chemically cleaning the filter is recommended 3 to 4 days after treatment.]



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All text on the page new.

{Directions to be used for prevention of algae}

Prevention of Algae

{Optional Marketing Statement A}

[BioGuard® Banish®] [algaecide] [This product] is a highly effective, patented, non-staining [algaecide] [algaecide] that controls all types of algae in swimming pools. [BioGuard Banish] [algaecide] [This product] is especially recommended for controlling green, blue-green (frequently called black or spot algae) and mustard algae growths. This product is formulated for use in chlorine or bromine sanitized swimming pools of all surface and filter types.

{Optional Marketing Statement B}

~~The BioGuard® Care System has three important parts that help you maintain crystal blue sparkling water.~~

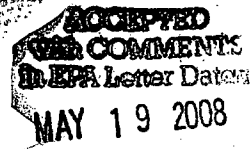
~~1. BioGuard® Banish® [algaecide] [This product] is a highly effective, patented, non-staining [algaecide] [algaecide] that controls all types of algae in swimming pools. [BioGuard Banish] [algaecide] [This product] is especially recommended for controlling green, blue-green (frequently called black or spot algae) and mustard algae growths. This product is formulated for use in chlorine or bromine sanitized swimming pools of all surface and filter types.~~

BioGuard® Banish® [This product] is a non foaming algae preventative for the BioGuard Care System. Weekly use of [BioGuard Banish®][this product]prevents algae before it starts. [This product] [BioGuard Banish®] is formulated to complement most swimming pool sanitizers. [This product] [BioGuard Banish®] is a highly effective algae preventative. [This product] [BioGuard Banish®] is effective and non-staining when used as directed. [This product] [BioGuard® Banish®] kills and prevents all types of algae; black algae, green algae, and mustard algae. [This product] [BioGuard® Banish®] provides a residual effectiveness that protects your pool against algae formation while keeping your pool water sparkling clear. [This product] [BioGuard® Banish®] is non-foaming and can be used in pools with attached spas or jetted returns.

[Use [BioGuard® Banish®] [this product] weekly when using the BioLab UV system to prevent algae.]

IMPORTANT NOTES:

1. Do not use in pools sanitized with biguanides or pools treated with hydrogen peroxide.
2. Prior to the initial application of this product, test pool water for the presence of metals. If metals are present, apply a metal stain preventative per label directions
3. [† In use dilution, this product is non-staining to pool surfaces and equipment.] {or} [† Full strength product will stain porous pool surfaces.]
4. This product is designed to prevent the growth of algae. If visible growth is already present, it will be necessary to use a treatment product to kill the visible algae.



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

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ACCEPTED
with COMMENTS
in EPA Letter Dated
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
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pool
{Directions to be used for treatment of visible algae}

pool
Treatment of Visible Algae

{Optional Marketing Statement A}

when used as directed
when used as directed
[BioGuard® Banish®] [algaecide] [This product] is a highly effective, patented, non-staining pool algaecide that kills ~~all types of~~ algae in swimming pools [and clears pool water when used as directed]. [BioGuard Banish] [algaecide] [This product] is especially recommended for killing green, blue-green (frequently called black or spot algae) and mustard algae growths. This product is formulated for use in chlorinated or brominated swimming pools of all surface and filter types.

{Optional Marketing Statement B}

~~BioGuard® has a wide variety of products that solve specific pool situations. These products are designated as "Remedy".~~

when used as directed
~~BioGuard® Banish® is a highly effective fast acting Algae destroyer. [This product] [BioGuard® Banish®] kills all types of algae; black algae, green algae, and mustard algae. [This product] [BioGuard® Banish®] is formulated to complement most swimming pool sanitizers. [This product] [BioGuard Banish®] is effective and non-staining when used as directed. When you use [this product] [BioGuard® Banish®] you will see results in 24 hours. [This product] [BioGuard® Banish®] is non-foaming and can be used in pools with attached spas or jetted returns.~~

~~[Use [BioGuard® Banish®] [this product] when using the BioLab UV system to destroy algae.]~~ *potential*

used as directed
IMPORTANT NOTES: 1. Do not use in pools sanitized with biguanides or pools treated with hydrogen peroxide. 2. Prior to the initial application of this product, test pool water for the presence of metals. If metals are present, apply stain and scale inhibitor (chelating agent) per label directions. 3. † In use dilution, this product is non-staining to pool surfaces and equipment [and clears water].

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.

PRIOR TO APPLICATION: Ensure all equipment is working properly. If necessary, clean the filter system, adjust pH between 7.2-7.6, and establish a minimum level of 30-40 ppm of [stabilizer] [cyanuric acid] in chlorinated pools. Vacuum leaves and any other foreign debris from pool. If metals testing indicates a need to use a stain and scale inhibitor, apply that product per label directions. Brush visible algae thoroughly from the pool's surface with a surface-compatible brush. Establish and maintain proper chlorine or bromine levels.

TREATMENT OF VISIBLE ALGAE: Add 1 lb. of [BurnOut WP] {or} [BurnOut Extreme] {or} [granular calcium hypochlorite] per 10,000 gallons of pool water or 1 lb. of [BurnOut 35] [granular lithium hypochlorite] per 6,000 gallons of pool water or 1 lb. of BioGuard Smart Shock per 12,000 gallons of pool water. Follow application directions on these products. Allow to circulate for 1 hour. With pump and filter operating, apply 16 fluid ounces of [BioGuard Banish] [algaecide] [this product] per 10,000 gallons of pool water directly to the pool water in areas of heaviest algae growth. Continuously circulate pool water for the next 24 hours. Afterwards, thoroughly brush pool surfaces. Prior to re-entry, test chlorine level. Do not re-enter pool until chlorine level is between 1 - 4 ppm. In cases of persistent algae, repeat brushing and application after 2-4 days. A filter aid may be used to enhance filter efficiency. [Chemically cleaning the filter is recommended 3 to 4 days after treatment.]

deleted text

{The following is optional text to be used at BioLab's discretion with swimming pool use directions for determination of pool capacity. 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 - Long diameter times short diameter times average depth (in feet) times 5.9 equals gallons.]

STORAGE AND DISPOSAL: Keep this product in its original tightly closed container when not in use. Store in a cool, dry, well ventilated area. Do not contaminate food or feed by storage or disposal. **PRODUCT DISPOSAL:** Securely wrap original container in several layers of newspaper and discard in trash. **CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. ← new text

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: CAUTION: Harmful if swallowed. Causes moderate, but temporary, eye irritation. Avoid contact with eyes or clothing. Wear protective eye wear (safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

← First Aid moved front panel

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 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].]**

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).}
[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).}

[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.]

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