

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 6, 2004

MEMORANDUM

Subject: Efficacy Review for BioGuard® Crystal Blue Mineral Cartridge, EPA Reg. No.5185-
UOI; DP Barcode: D303633

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510C)

Thru: Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Portia Jenkins / Marshall Swindell
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: BioGuard
Bio-Lab Inc.
1735 North Brown Road
Lawrenceville, GA 30049

Formulation from the Label:

| <u>Active Ingredient(s)</u> | <u>% by wt.</u> |
|--------------------------------|-----------------|
| Metallic Silver**..... | 63.5 % |
| <u>Inert ingredients</u> | 36.5 % |
| Total..... | 100.0 % |

**From silver nitrate

(1)

I. BACKGROUND

The product, *BioGuard® Crystal Blue Mineral Cartridge* (EPA File Symbol 5185-UOI), is a new product that contains silver nitrate in material within a cartridge, capable of delivering silver ions into a pool. The cartridge containing the silver media is placed into a filter unit of a pool. As water flows through the cartridge, silver is dissolved into the pool water to establish an initial concentration of approximately 70ppb. The applicant requested to register the product as a disinfectant and algaecide for pools and considered this product a competitive product to *Nature2 AG* (EPA Reg. No. 67712-5). Disinfection and algaecidal effectiveness is based on the maintenance of 10ppb - 80ppb silver ions (Ag^+) and 0.3ppm - 0.5ppm chlorine in the circulating pool's water. The product is an essential component of the new *Crystal Blue System* from *BioGuard®*. Studies were conducted at *BioLab, Inc.*

This data package contained a letter from the applicant's representative to EPA (dated March 22, 2004), EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID Nos. 462322-05 through 462322-07), Statements of No Data Confidentiality Claims for all three studies, Raw data on all five pools of the field study (received on Sept. 23, 2004), and the proposed label.

MRID 462300-05 "Efficacy of *BioGuard® Crystal Blue System* (Silver Ion/Low Chlorine Sanitizing System) in a 250-Gallon Simulated Swimming Pool tested according to American National Standards Institute/NSF-50-2000 Test Method for the Evaluation of Process Equipment", by Richard J. Muller Jr.; Study conducted at *Biolab, Inc.* Study completed on February 24, 2004. This study was conducted in compliance to American National Standard Institute (ANSI)/NSF-50-2000 acceptance criteria for disinfectant efficacy of process equipment, and will not be reviewed.

II. USE DIRECTIONS

The product is designed to be used for feeder application or for skimmer application. The product is described as an effective sanitizer for pool when used with an EPA registered source of chlorine at 0.5ppm residual chlorine. Directions on the proposed label provided the following information regarding initial installation, replacement, and use of the product:

Change this cartridge every six months. Make sure all pool equipment is working properly, including pump, filter, skimmer[s] and heater. Backwash filter following manufacturer's directions. Check alkalinity, pH and calcium hardness with a test kit. Adjust alkalinity to 125 -150ppm. Adjust pH to 7.4 -7.6. Adjust calcium hardness to 175 -275. When using other products as outlined in directions for this product, always follow directions on those products.

For Initial Installation: 1. Install the *BioGuard Crystal Blue Housing* into the circulation system of the pool. 2. Insert *Crystal Blue Sanitizer Cartridge* following that product's label directions. 3. Connect *Mineral Cartridge (A)* to *Water Polishing tube (B)* by aligning arrows on each piece. Push together to connect. 4. Insert completed piece from step 3 into open slot in housing. 5. Turn circulation system on. 6. Refer to *Sanitizer Cartridge* label direction for further instructions.

For Installation of Replacement Cartridge: 1. Turn off circulation system. 2. Open lid of *Crystal Blue*

Housing. 3. Remove the connected BioGuard Crystal Blue Mineral Cartridge and Water Polishing tube from housing by pulling straight up and dispose of entire piece in trash. 4. Connect Mineral Cartridge (A) to Water Polishing tube (B) by aligning arrows on each piece. Push together to connect. 5. Insert completed piece from step 4 into open slot in housing. 6. Turn circulation system on.

Swimming may resume after 15 minutes of circulation time. (Not compatible with biguanide systems)

For Use in skimmers: 1. Make sure skimmer is free of debris. No other chemicals should be fed through the skimmer during the first 12 hours following addition of the Mineral Cartridge to the skimmer. 2. Place Mineral Cartridge into skimmer basket. Do not touch wetted cartridge unless wearing household gloves. 3. Operate circulation system for a minimum of 2 hours after placing Mineral Cartridge in skimmer. 4. Test chlorine residual: a. If less than 0.5ppm, shock the pool using a chlorine based product. b. If 0.5 to 0.3ppm, swimming may resume 15 minutes after Mineral Cartridge application. c. If greater than 3.0ppm, allow chlorine residual to drop below 3.0ppm before resuming swimming. 5. Replace cartridge every (6) six months. (Not compatible with biguanide systems)

III. AGENCY STANDARD FOR PROPOSED CLAIMS

Disinfectants for Water in Swimming Pools, Spa, Hot Tubs, Whirlpools, and Jacuzzis

Swimming pool (and spa) water disinfection presents a unique combination of variables, including the number of swimmers/bathers, the frequency of use, the frequency with which the water is changed, general environmental conditions, and the type/degree of organic contamination of the water by the swimmers/bathers (e.g., suntan lotions and oils) and by various debris. As a result, both laboratory testing and confirmatory field testing are required.

The effectiveness of swimming pool and spa additives may be substantiated with data derived from the AOAC Disinfectants (Water) for Swimming Pools Method, 17th Edition, 2000, against both *Escherichia coli* (ATCC 11229) and *Enterococcus faecium* (ATCC 6569). The method may be modified, such as for pH. An initial bacterial suspension count of 2×10^8 is desired. Time zero bactericidal concentrations must be in the range of 9.9×10^5 to 1.5×10^6 . Available chlorine at time zero in the NaOCl test control must be within ≥ 0.58 to ≤ 0.62 . Results in the NaOCl control test must show complete kill of *E. coli* within 0.5 minutes, and *E. faecium* in 2 minutes. Test results must show the absence of colony growth on dilution plates and the absence of growth in all 5 lactose or thioglycolate tubes to demonstrate complete kill of the test organisms. **Performance standard:** The lowest concentration of the test germicide providing results equivalent to those of the sodium hypochlorite control is the lowest concentration of the product that can be considered effective. These Agency standards are presented in DIS/TSS-12 and the AOAC test method Disinfectants (Water) for Swimming Pools.

Confirmatory field testing must take place in at least two swimming pools (or spas), under Experimental Use Permit, lasting for an entire swimming season (4 to 12 months). Reports must include at least the following data regarding the test pools:

- The design of the pool, the re-circulation and filter systems, and the water capacity.
- The daily bather load.

- The amount and identification of all chemicals added daily (specifying time, site and method).
- The range of chemical characteristics of the water, such as pH, nitrogenous substances, metal and hardness.
- The physical characteristic of the water, including temperature and clarity, determined at least daily.
- Daily meteorological data, including air temperature, rainfall, and number of hours of sunlight for outdoor pools.
- Bacteriological monitoring should be conducted daily, in accordance with the suggested Ordinance and Regulations Covering Public Swimming Pool of the American Public Health Association. Water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remotely as possible from the inlets, preferably at the midpoints between inlets. A minimum of 144 samples should be taken during the test period. Samples should be taken just below the surface of the water, and preferably at such times when the number of persons using the pool during the preceding hour has been at least 50% of the maximum bather load of the pool, and the number of persons in the pool water at the time the samples are collected is at least equal to 25% of the maximum bather load of the pool. Pertinent chemical characteristics of the pool water at the sampling site should be determined at the time of sampling.
- The concentration of the antimicrobial agent in the water monitored daily at the same time-intervals that the bacteriological assay samples are obtained.
- The method that the product user will employ for monitoring the level (ppm) of antimicrobial agent in the water.

Performance standard: Field test results must show that 85% of the samples collected meets the following indices (i.e., or that not more than 15% of the samples collected fail the following indices): (1) The standard plate count at 35°C shall exceed 200 colonies/1.0 ml; (2) The most probable number of coliform bacteria shall be less than 2.2 organisms/100.0ml. When the membrane filter test is used, there shall be no more than 1.0 coliform organism/50ml; and (3) The most probable number of enterococcal organisms shall be less than 2.2/organisms/100.0 ml. When the membrane filter test is used, there shall be no more than 1.0 enterococcal organism/50ml. These Agency standards are also presented in DIS/TSS-12.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 462322-06 "Field Efficacy Test For BioGuard® Crystal Blue" by Geoffrey A. Brown. Study conducted at Biolab, Inc., Technology and Development Department, P.O. Box 30002 Lawrenceville, GA 30049-1002. Study completion date – February 9, 2004. Project Number 03-007.

This study was conducted in compliance with 'Good Laboratory Practice' as described in 40CFR 160. Five outdoor, in-ground, residential pools were used for this study. Four pools utilized the BioGuard® Crystal Blue System (One of which had a canister containing silver chloride in addition to silver nitrate), and one served as a control. All test pools were located in Grand Cayman, BWI and the study lasted 197 days (July 28, 2003-February 9, 2004). A total of 418 samples were collected for water and microbiological analyses. Daily bather load and swimmers in the pool were recorded by study personnel and study director at the time of sampling. Water analyses (concentrations of calcium hardness, total alkalinity, and pH) were performed before and

during the study. Records of maintenance and chemical additions by employees of Hew's Pool Services and study personnel were provided. Tests for chlorine, pH, temperature, turbidity, silver ion concentrations (Inductively coupled plasma method), nitrate and phosphate were performed before starting the study, during, and at periods throughout the study. Physical characteristics were recorded and meteorological data (air temperature, rainfall, and the number of hours of sunlight, length of day) were purchased from the Cayman Weather Service. Water samples were taken same time, for determination of antimicrobial agent (hypochlorous acid and silver ion), and for bacteriological analysis (taken at opposite sides of the pool at midpoints just below the surface of the water). Water samples designated for bacteriological assay were collected separately and immediately inactivated with a solution capable of neutralizing chlorine and silver ions. Bacteriological results were presented as pass or fail the efficacy requirement set in the Agency's DIS/TISS-12. The study was broken into two distinct phases. Phase I data were collected when chlorine residuals were high and bathers were not present. The second phase of testing used chlorine residuals of about 0.5ppm total available chlorine in the presence of active bathers. Chlorine levels were adjusted to ca. 0.5ppm total available chlorine by adding 35% hydrogen peroxide (H₂O₂) directly to the pools. Data summaries are presented in the results section of the review.

3. MRID 462322-07 "Presumptive Efficacy Test for GioGuard® Crystal Blue System", by Delores Murphy; Project number: 03-015. Study conducted at Biolab, Inc., Antimicrobial Laboratory located at 114 New Street, Decatur, GA 30030. Study completion date – February 24, 2004.

This study was substantiated with data derived from AOAC Official Method 965.13 Disinfectants (Water) for Swimming Pools against *Escherichia coli* (ATCC 11229) and *Enterococcus faecium* (ATCC 6569) (copy provided). A ~10-ppb silver ion with ~0.5ppm chlorine test solution was made in phosphate buffer using 100ppm stock silver solution prepared by adding ca. 0.157g silver nitrate to ~1000ml deionized water, and the pH adjusted to pH=7.5. A ~0.6ppm chlorine solution was used as control. The neutralizing blank contained ca. 1.46g sodium thiosulfate and ca. 1.3ml mercaptoacetic acid (thioglycolic acid) per 1000ml. A 199 ml aliquot of test sample was then inoculated with 1 ml of either *E. faecium* or *E. coli* suspension. The average concentrations 1.0 x 10⁶ and 1.8 x 10⁶ CFU/ml for *E. coli*; 0.25 x 10⁵ and 0.9 x 10⁶ CFU/ml for *E. faecium*. Following contact times of 0.5, 1, 2, 3, 4, 5, and 10 minutes samples of the microorganism/test sample mixture were neutralized and surviving microorganisms quantitated. Five lactose tubes for *E. coli* and five thioglycolate tubes for *E. faecium* were also inoculated from each neutralized tube. Controls were treated in the same manner. Following incubation, the plates were enumerated and broth tubes scored visually for growth. As defined by the AOAC, absence of colony growth on dilution plates and absence of growth in all 5 broth tubes is necessary to show complete kill of the test organism.

Note: Even though there is not a significant (big) difference between 0.6ppm of chlorine in the control and 0.5ppm chlorine in the test, the efficacy was demonstrated. The ideal situation would be to demonstrate that 0.5ppm chlorine was not as effective as 0.6ppm chlorine.

V. RESULTS

MRID 462322-06

| Pool Identifier | Approximate Gallonage | Filter Type | Pump | | | Silver Ion Source | Pump Run Time (hr) |
|-----------------|-----------------------|-------------|-------------|-------------|------------|--------------------------|--------------------|
| | | | Brand | Model # | Horsepower | | |
| M. Stafford | 8,600 | Sand | GE Motor | 5KC38PN | 3/4 | AgNO ₃ | 6 |
| C. O'Dea | 9,700 | Sand | Hayward | C48L2134B1 | 1½ | AgNO ₃ | 5 |
| J. Elliot | 20,000 | Sand | Hayward | C48J2N13B | 1¼ | AgNO ₃ | 11 |
| N. Perton | 14,000 | Sand | Hayward | C48K2N143B1 | 3/4 | AgNO ₃ / AgCl | 12 |
| R. Jenkinson | 14,300 | Sand | Smith Corp. | 648L2N134K1 | 1½ | None | 12 |

MRID 462322-06 Phase I

| Pool Identifier | Average Total available Chlorine (ppm) | Average Silver (ppb) | Samples Taken | No. of Samples Passing Efficacy Test | Pass Rate (%) |
|--|--|----------------------|---------------|--------------------------------------|---------------|
| M. Stafford | 14.9±7.7 | 50.8±5.96 | 56 | 51 | 91 |
| C. O'Dea | 25.8±30.5 | 42.9±10.5 | 52 | 43 | 83 |
| J. Elliot | 20.8±9.7 | 40±18.4 | 50 | 48 | 96 |
| N. Perton | 8.9±5.17 | 19.5±5 | 56 | 50 | 89 |
| R. Jenkinson | 5.9±1.8 | <10 | 12 | 7 | 58 |
| Total (with BioGuard Crystal Blue System) | - | - | 214 | 192 | 90 |
| Total (control) | - | - | 12 | 7 | 58 |

MRID 462322-06 Phase II

| Pool Identifier | Silver Present | Samples Taken | Number Passing | Number Failing | Pass Rate (%) |
|-----------------------------|----------------|---------------|----------------|----------------|---------------|
| C. O'Dea | Yes | 128 | 117 | 11 | 91.4 |
| J. Elliot | Yes | 96 | 85 | 17 | 88.5 |
| N. Perton | Yes | 16 | 2 | 14 | 18.8 |
| R. Jenkinson | No | 30 | 15 | 15 | 50 |
| Total with Silver | - | 240 | 204 | 42 | 85 |
| Total without Silver | - | 30 | 15 | 15 | 50 |

| MRID 46232 2-07 | Run # | | Subcultures | 0-Minute chlorine level (ppm) | Contact Time (minutes) | | | | | | | | |
|----------------------------|----------|-------------|----------------|--|---------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| | | | | | 0 | 0.5 | 1 | 2 | 3 | 4 | 5 | 10 | |
| <i>E. coli</i> | 1 | Cont rol | Plate (CFU/ml) | 0.58 | 1.8 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | | Test | Plate (CFU/ml) | 0.517 | 1.8 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | 2 | Cont rol | Plate (CFU/ml) | 0.601 | 1.0 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | | Test | Plate (CFU/ml) | 0.496 | 1.0 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| <i>E. faeciu m</i> | 1 | Cont rol | Plate (CFU/ml) | 0.58 | 0.25 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | | Test | Plate (CFU/ml) | 0.517 | 0.25 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | 2 | Cont rol | Plate (CFU/ml) | 0.613 | 0.9 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |
| | | Test | Plate (CFU/ml) | 0.526 | 0.9 x 10 ⁶ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | Tubes | | | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 | 0/5 |

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 462322-06) **support** the use of the product, BioGuard® *Crystal Blue Mineral Cartridge* as an effective disinfectant for pool when used with an EPA registered source of chlorine at 0.5ppm residual chlorine.
2. The submitted efficacy data (MRID 462322-07) **support** the use of the product, BioGuard® *Crystal Blue Mineral Cartridge* as an effective disinfectant for pool when used with an EPA registered source of chlorine at 0.5ppm residual chlorine.

VII. RECOMMENDATION

The proposed label claims that the product, BioGuard® *Crystal Blue Mineral Cartridge* as an effective disinfectant for pool when used with an EPA registered source of chlorine at 0.5ppm residual chlorine, **are supported** by the applicant's data.