

670-2

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Sunburst Chemicals, Inc.
220 W. 86th Street
Minneapolis, MN 55420

NOV 28 2000

Subject: BioClean
EPA Registration No. 670-2
Amendment Date: 5/23/00
EPA Receive Date: 6/05/00

Attention: Ms. Jacqueline Hogue

The amendment, referenced above, submitted in connection with registration under FIFRA to add the organism, *Pseudomonas aeruginosa*, to the label to support a hospital disinfectant claim is acceptable provided you address the following recommendations before this product is released for shipment.

Efficacy

The submitted data in MRID No. 451470-01 demonstrates Bio Clean's effectiveness as a disinfectant against *Pseudomonas aeruginosa* (ATCC 15442) when diluted at 1 oz to 3 gallons of water at 20°C in 5% fetal bovine serum for ten minutes.

Labeling Recommendations

- 1. Since this product is recommended for use in operating rooms on hard, non-porous surfaces, the following paragraph from PR Notice 94-4 must be added to this label.

This product is not to be used as a terminal sterilant/ high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization/ high-level disinfection.

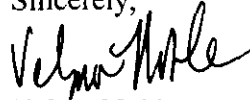
CONCURRENCES

| | | | | | | | |
|---------|----------|--|--|--|--|--|--|
| SYMBOL | 7510C | | | | | | |
| SURNAME | Campbell | | | | | | |
| DATE | 11/28/00 | | | | | | |

2. According to DIS/TSS 15, separate cleaning and deodorizing directions will need to be added to the label. You may want to revise the Disinfection heading to state "Cleaner/Deodorizer/Disinfectant"

A stamped label is enclosed for your records. Please submit a copy of the final printed label before this product is released for shipment.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

Bio Clean

CLEANER
DETERGENT

DETERGENT/DISINFECTANT
DEODORIZER
VIRUCIDE*

DISINFECTANT
MILDEWSTAT (on hard
nonporous surfaces)

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl
benzyl ammonium chlorides 7.95%

Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl
ammonium chlorides 7.95%

INERT INGREDIENTS

TOTAL 84.10%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements.

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 min. Get medical attention. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF SWALLOWED: Call a doctor or get medical attention. Drink 1 or 2 glasses of water and induce vomiting by touching back of the throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of 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 the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse empty container with water. Plastic containers may be disposed of in a sanitary landfill, incinerated or, if allowed by local authorities, burned. If burned, stay out of smoke.

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 goggles or face shield, rubber gloves, and protective clothing when handling. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product 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.

FOR CHEMICAL SPILL INFORMATION
DIAL: 1-800-424-9300

FOR EMERGENCY MEDICAL
INFORMATION DIAL: 1-800-228-5635

Contains no phosphorus.
NJ-TSRN: 5000-5022
PA: Identification of specific ingredients is being withheld as a trade secret.

Manufactured by:
Sunburst Chemicals, Inc.

220 W. 86th Street Minneapolis, MN 55420
(612) 884-3144

EPA Reg. No. 670-2 EPA Est. No. 670-MN-01

NET CONTENTS: 6 lbs. Lot #:

ACCEPTED
with COMMENTS
in EPA Laboratory

NOV 28 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act amended, for the pesticide registered under EPA Reg. No. 670-2

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

BIO CLEAN is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, and other institutions such as schools, offices, hotels, motels, cafeterias, restaurants, grocery stores, and apartment buildings, where housekeeping is of prime importance in controlling the hazard of cross-contamination. BIO CLEAN, when used as directed, is formulated to disinfect inanimate, hard nonporous surfaces such as walls, floors, sink tops, tables, and chairs. For larger areas such as operating rooms, patient care facilities, and restrooms, BIO CLEAN is designed to provide both general cleaning and disinfection. BIO CLEAN deodorizes those areas that generally are hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas that are prone to odors caused by microorganisms.

DISINFECTION - To disinfect hard, nonporous surfaces, follow the steps below. The dispenser will automatically deliver a solution that contains 1 oz. of Bio Clean to 1-2 gallons of hot water.

1. Remove cap. Place the Bio Clean container upside down in the dispenser. 2. Place the dispenser outlet tube into the sink or drain. Turn on the hot water to the dispenser and turn the dispenser dial to the WATER position. Run water into the drain until water is hot coming out of the dispenser outlet tube. 3. Transfer the dispenser outlet tube to the receptacle (mop bucket, pail, pan, jug, trigger sprayer, etc.) and turn the dispenser dial all the way to the CLEANING SOLUTION position where it stops. Fill receptacle to the desired level then turn the dial to OFF. 4. Use the Quat Test Strips provided in each case of Bio Clean to be sure the concentration is at least 620 ppm Quat. If less than 620 ppm, push the button in the center of the handle to add more Bio Clean and hold the button in for 10 seconds. Mix and retest. Repeat if necessary until concentration exceeds 620 ppm. Remove dispenser outlet tube. 5. Apply this solution with a mop, sponge, trigger sprayer, or cloth so as to thoroughly wet all surfaces. Allow to remain wet for 10 minutes and then let air dry.

Prepare a fresh solution for each use. For heavily soiled areas, a pre-cleaning step is required. If BIO CLEAN is used on direct food contact surfaces such as countertops, tables, picnic tables, appliances, and/or stovetops, thoroughly rinse these surfaces with potable water. This product must not be used on the following food contact surfaces: utensils, glassware, and dishes.

BACTERICIDAL ACTIVITY - At the stated Disinfection dilution rate, this product exhibits effective disinfectant activity against the organisms *Pseudomonas aeruginosa* PRD-10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Brevibacterium ammoniagenes*, *Enterococcus faecalis*, *Shigella dysenteriae*, *Staphylococcus aureus*, and *Enterobacter aerogenes* and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard nonporous surfaces, use BIO CLEAN at the stated dilution rate for Disinfection. Apply solution with a cloth, mop, sponge, or hand pump trigger sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

EFFICACY TESTS HAVE DEMONSTRATED THAT BIO CLEAN IS AN EFFECTIVE BACTERICIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

***VIRUCIDAL ACTIVITY** - BIO CLEAN, when used on environmental, inanimate, hard nonporous surfaces at the Disinfectant dilution rate with a contact time of 10 minutes, exhibits effective virucidal activity against HIV-1, Influenza A₂, Parainfluenza Type 1 (Sendai), Canine Distemper, Feline Pneumonitis, Vaccinia Virus, and Herpes Simplex Type 1.

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS where there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye covering.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of BIO CLEAN.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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