

670-2

05/14/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 14 2013

Ms. Karen E. Warkentien
Sunburst Chemicals Inc.
220 west 86th Street
Minneapolis MN 55420

Subject: **Bio Clean**
EPA Registration Number 670-2
Application Dated February 25, 2013
EPA Received Date February 25, 2013

Dear Ms. Warkentien:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

- Deletion of Clostridium difficile (C. diff.) and vegetative C. diff

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,
Drusilla Copeland
for Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label

CONCURRENCES

SYMBOL	SURNAME	DATE						

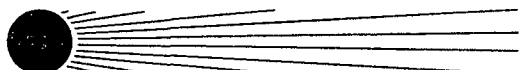
LABEL WITH CHANGES HIGHLIGHTED

2/3

ACCEPTED

MAY 14 2013

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



SUNBURST CHEMICALS

BIO CLEAN

HOSPITAL DISINFECTANT/DETERGENT

CLEANER DETERGENT	DEODORIZER VIRUCIDE*	DISINFECTANT MILDEWSTAT (on hard non-porous surfaces)
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ACTIVE INGREDIENTS:

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides,	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	7.95%

INERT INGREDIENTS: 84.10%

TOTAL: 100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See side panel for additional precautionary statements.

FIRST AID

EYES: Hold eyelids open and flush with a steady gentle stream of 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 or advice. **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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

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 50F or higher than 120F.

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: Nonrefillable container. Do not refill or reuse container. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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.

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

**FOR EMERGENCY MEDICAL
INFORMATION**
DIAL: 1-866-303-6943

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

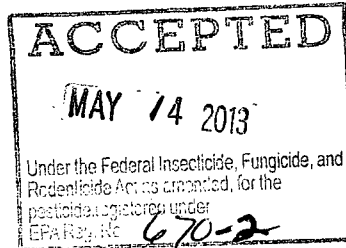
Manufactured by:
Sunburst Chemicals, Inc.
220 W. 86th Street
Minneapolis, MN 55420
(952) 834-3144
EPA Reg. No. 670-2
EPA Est. No. 670-MN-01

Covered under U.S. Patents including #5,977,183

NET CONTENTS: 4.5 lbs.

Lot#:

ESL042709 REV042909



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 made of stainless steel, chrome, porcelain, glass, vinyl or plastic on 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 which generally are hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms. BIO CLEAN is not to be used 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. BIO CLEAN may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high level disinfection.

CLEANING/DEODORIZING/DISINFECTING: To clean/deodorize/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 water. 1. Remove cap. Place the Bio Clean container upside down in the dispenser. 2. Turn on the water to the dispenser. 3. Put the dispenser outlet tube to the receptacle (mop bucket, pail, jug, trigger sprayer, etc.) and turn the dispenser dial all the way to the SOLUTION position. 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, add concentrate. Mix and retest. Repeat if necessary until the 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. If sprayed, use a coarse spray. Allow to remain wet for 10 minutes and then let air dry.

Prepare a fresh solution for each use. For heavily soiled areas, a precleaning step is required. For heavy duty cleaning, use BIO CLEAN at 2 oz per gallon of water which can be achieved by adding with the dial in the CONCENTRATE position. If BIO CLEAN is used on direct food contact surfaces such as countertops, tables, appliances, and/or stove tops, 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 choleraesuis*, *Salmonella enterica*, *Brevibacterium ammoniagenes*, *Enterococcus faecalis*, *Shigella dysenteriae*, *Staphylococcus aureus*, and *Enterobacter aerogenes*, *Staphylococcus aureus*-MRSA, *Enterococcus faecalis* Vancomycin Resistant, *Clostridium difficile* (vegetative) and meets all requirements for hospital use.

MILDEWSTAT: To control mold and mildew on precleaned, 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. If sprayed, use a coarse spray. 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, Hepatitis B (HBV) Influenza A2, Parainfluenza Type 1 (Sendal), Canine Distemper, Feline Pneumonitis, Vaccinia Virus, and Herpes Simplex Type 1. Effective against Hepatitis B when used at 1 oz. per gallon of water (1240 ppm Quat) following disinfection directions above.

KILLS HIV-1 and HBV ON PRECLEANED 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) and HBV.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 and HBV 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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* DELETED TEXT