

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 28 2006

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

Subject: **Bio Clean**
EPA Registration Number 670-2
Application Dated March 29, 2006
Received Date March 30, 2006

Dear Ms. Warkentien:

The following label revisions submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

Proposed Amendment:

- Additional of two new pathogens; Hepatitis B and Clostridium difficile

Labeling Comments:

1. The proposed label claims are acceptable regarding the use of Bio Clean, as a disinfectant against Clostridium difficile (vegetative) on hard, non-porous surfaces in the presence of 5% serum for a contact time of 10 minutes at a dilution of 1 ounce product per 1-2 gallons water. For clarity time of 10 minutes at a dilution of 1 ounce product per 1-2 gallons water. For clarity, "vegetative" should follow Clostridium difficile on the proposed label; as this product was not subjected to the rigors of sporicidal testing.

Note: The designation of "Salmonella choleraesuis" has been changed to "Salmonella enterica", effective immediately. This change must be reflected on this current submission, and any future label submissions.

2. The proposed label claims are acceptable regarding the use of Bio Clean as a disinfectant against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 10 minutes at a dilution of 1 ounce product per gallon water. Data provided

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

supports this claim. The Special Directions For Use" section, provided for efficacy against HIV must be expanded to include HBV. Please modify the label accordingly.

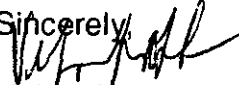
3. In accordance with DIS/TSS-15, label direction regarding use of antimicrobial pesticides on hard surfaces must include a description of the composition of surfaces on which the product may be used (e.g., stainless steel, chrome, glass, vinyl).
4. Please make the following change, as appropriate:

On page 2 of the proposed label, change "picnic table" to read "non-wooden picnic tables."

General Comments:

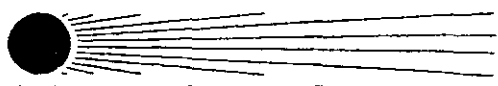
A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,


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

Enclosure Efficacy Review Dated June 28, 2006



SUNBURST CHEMICALS

BIO CLEAN

DETERGENT/DISINFECTANT

CLEANER
DETERGENT

DEODORIZER
VIRUCIDE*

DISINFECTANT
MILDEWSTAT
(on hard non
porous 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

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: 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, by burning. 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.

<p>FOR CHEMICAL SPILL INFORMATION DIAL: 1-800-424-9300</p> <p>FOR EMERGENCY MEDICAL INFORMATION DIAL: 1-866-303-6943</p>
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Manufactured by
Sunburst Chemicals, Inc
220 W 86th Street
Minneapolis, MN 55420
(952) 884-3144
EPA Reg No 670-2
EPA Est No 670-MN-01

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

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

NET CONTENTS: 6 lbs.

Lot#:

Rev 9/05

ACCEPTED
with COMMENTS
JUL 28 2006

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

4/4

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 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 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, 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 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. If BIO CLEAN is used on direct food contact surfaces such as countertops, tables, picnic 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 scholtzmuetteri*, *Salmonella choleraesuis*, *Brevibacterium ammoniagenes*, *Enterococcus faecalis*, *Shigella dysenteriae*, *Staphylococcus aureus*, *Clostridium difficile*, and *Enterobacter aerogenes* 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, Influenza A2, Parainfluenza Type 1 (Sendai), 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 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).

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.

