# UN. 2D STATES ENVIRONMENTAL PROTECT AN AGENCY

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



# **SEPA** United States Environmental Protection Office of Pesticide Programs

JUL 1 6 2009

Mrs. Karen E. Warkentien, Lewis & Harrison (Agent for Sunburst Chemicals, Inc.) 122 C. Street, N.W., Suite 740 Washington, D.C. 20001

Subject:

Product Name:

Bio Clean

EPA Reg. No.:

670-2

Notification Date:

June 25, 2009

EPA Receipt Date:

June 26, 2009

Dear Mrs. Warkentien,

This letter acknowledges receipt of your notification submitted under the provision of the Federal Insecticide, Fungicide and Rodenticide Act. (FIFRA) section 3(c)9 and PR Notice 98-10.

## **Proposed Notification**

Application for Pesticide Notification, Addition of Container Disposal Language per PRN 2007-4

### **General Comments**

Based on a review of the submitted materials, your application for pesticide notification of the product "Bio Clean", EPA Reg. No. 670-2 is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

> Product Manager, Team 31 Regulatory Management Branch

SYMBOL SURNAME EPA Form 1320-1A (1/90) Printed on Recycled Paper

20f6

| Please read instructions on reverse before co tring form.   | For   | m Appro NOMB N   | o. <b>2070-006</b> 0                | D. Approval expires 2-28-9                       |  |
|---|---|--|-------------------------------------|--|--|
| United States Environmental Protection Washington, DC 20  | • .   | <del></del>  | tration<br>dment                    | OPP Identifier Number                            |  |
| Application for Pesticide - Section I   |   |  |                                     |  |  |
| 1. Company/Product Number<br>670-2  | ₹   | 2. EPA Product Manager  Velma Noble  3. Proposed Classification  ✓ None Restricted |                                     |  |  |
| 4. Company/Product (Name)<br>Bio Clean  | <b>PM#</b> 31   | PM#  |                                     |  |  |
| 5. Name and Address of Applicant (Include ZIP Code)   | 6. Expedited  | 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)                      |                                     |  |  |
| Sunburst Chemicals Inc. 220 West 86th Street Minneapolis MN 55420  Check if this is a new address   | to:<br>EPA Reg. N   | EPA Reg. No.   |                                     |  |  |
|   | Section - II  |  |                                     |  |  |
| Amendment - Explain below.  Resubmission in response to Agency letter dated 5/2   | Final p   | Final printed labels in repsonse to  |                                     |  |  |
| Notification - Explain below.   | Other   | Other - Explain below.   |                                     |  |  |
| Notification of Label Change per PR Notice 2007-4: This notification regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and Formula for this product. I understand that it is a violation of 18 US amended label is not consistent with the requirements of 40 CFR § FIFRA and I may be subject to enforcement action and penalties ur | 156.156. No other changes<br>C § 1001 to willfully make ar<br>§ 156.10, 156.140, 156.144, | have been made to the<br>ny false statement to EF<br>, 156.146, and 156.156        | labeling or the<br>PA. I further un | e Confidential Statement of derstand that if the |  |
| Section - III   |   |  |                                     |  |  |
| 1. Material This Product Will Be Packaged In:   | ·   |  |                                     | <del></del>                                      |  |
| Child-Resistant Packaging Unit Packaging  |   |  | f Container  Metal                  |  |  |
| Yes Yes No  | Yes   |  | Plastic                             |  |  |
| * Certification must be submitted   If "Yes"   No. per Unit Packaging wgt.   Container  |   | per<br>Itainer   | Glass Paper Other (Sp               | pecify)  |  |
| 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions   |   |  |                                     |  |  |
| Label Container   |   |  |                                     | ر ز د د  |  |
| 6. Manner in Which Label is Affixed to Product Lithograph Other   |   |  |                                     | 3313   |  |
| Stenciled   |   |  |                                     | 3 ) 10<br>3                                      |  |
|   | Section - IV  |  |                                     | , ,,,,,,,  |  |
| 1. Contact Point (Complete items directly below for identification  |   | cted, if necessary, to   | I                                   |  |  |
| Name Karen E. Warkentien  |   |  |                                     | No.a(include Area Códa)                          |  |
| Certifica I certify that the statements I have made on this form and I acknowledge that any knowlingly false or misleading sta both under applicable law.   | all attachments thereto ar  |  | omplete.                            | 6. Dete Application "Received (Stamped)          |  |
| 2. Signature  | 3. Title  Consultant to Sunburst Ch   | itle unsultant to Sunburst Chemicals Inc.  |                                     |  |  |
| 4. Typed Name   | 5. Date   |  |                                     |  |  |
| Karen E. Warkentien   | 25 June 2009  |  |                                     |  |  |

# LEWIS & HARRISON

122 C Street, N.W., Suite 740 Washington, D.C. 20001 telephone 202.393.3903

fax 202.393.3906

Consultants in Government Affairs

25 June 2009

Via Hand Delivery

Ms. Velma Noble, PM #31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 Crystal Drive
Arlington VA 22202

SUBJECT:

Bio Clean, EPA Reg. No. 670-2 Application for Pesticide Notification Addition of Container Disposal Language per PRN 2007-4

Response to Your Letter Dated 27 May 2009

Dear Ms. Noble:

On behalf of our client, Sunburst Chemicals Inc. (Sunburst), Lewis & Harrison, LLC, submits herewith the following documents in support of amended registration for Bio Clean, EPA Reg. No. 670-2:

Volume I: Administrative Materials

- Application for Pesticide Notification (EPA Form 8570-1)
- Draft label (two copies, one with highlighted changes)

This resubmission is made in response to PR Notice 2007-4 and your letter dated 27 May 2009. A copy of your letter is enclosed.

### Notification of Label Change per PR Notice 2007-4

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC § 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties funder sections 12 and 14 of FIFRA.

Ms. Velma Noble, PM #3. )
Page 2 of 2

This submission is NOT subject to processing under the Pesticide Registration Improvement Act (PRIA) and should be categorized as a notification.

Should you have any questions concerning this submission, please contact me by phone at (202) 393-3903 x22 or via email at <a href="mailto:kwarkentien@lewisharrison.com">kwarkentien@lewisharrison.com</a>.

Sincerely,

LEWIS & HARRISON, LLC Consultant to Sunburst Chemicals Inc.

Karen E. Warkentien

**Enclosures** 

cc: Bill Scepanski, Sunburst



HOSPITAL DISINFECTANT/DETERGENT

CLEANER DETERGENT

DEODORIZER VIRUCIDE\*

MILDEWSTAT (on hard non-porous surfaces)

**ACTIVE INGREDIENTS:** 

Alkyl (60%  $C_{14}$  , 30%  $C_{16}$  , 5%  $C_{12}$  , 5%  $C_{18}$  ) dimethyl benzyl ammonium chlorides 7.95% Alkyl (68%C<sub>12</sub>, 32%C<sub>14</sub>) dimethyl ethylbenzyl ammonium chlorides

**INERT INGREDIENTS:....** 

84.10%

**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 pastric 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) 884-3144 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

Date Reviewed: Reviewed By:

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, frigger sprayer, etc.) and turn the dispenser diat all the way to the SCILUTION 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 soray. Allow to remain wet for 10 minutes and then let air dry.

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: utensits, glassware, and dishes.

BACTERICIDAL ACTIVITY: At the stated disinfection dilution rate, this product exhibits effective disinfectant activity against the organisms Pseudomonas aeruginosa PRD-10, Escherichla coli, Klebsiella pneumonlae, Salmonella scholtmuelleri, Salmonella enterica, Brevibacterium ammoniagenes, Enterococus faecalis, Shigella dysenteriae, Staphylococcus aureus, and Enterobacter aerogenes, Staphylococcus aureus and Enterobacter aerogenes, Staphylococcus aureus are un control of the control

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, Vaccionia 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

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 Immunodeliciency 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 8 body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

F F

TC

trea pler SW, glas doct

EYE

Prol

. . . . . .