

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

51267-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



SEP - 8 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Kate Warner
Regulatory Affairs Administrator
Bioserv, Inc
P.O. Box 248
Hiwassee, GA 30546

Subject: BIO-CLEAN
EPA Registration No. 51267-1
Amendment Dated: May 1, 2003
EPA Received Date: June 10, 2003

Dear Ms. Kate Warner,

The following amendment submitted in connection with registration under section 3(c)(7)(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable with the following conditions.

Proposed Amendment

- Update First Aid Statements in compliance with PR Notice 2001-1

Conditions

Revise the label as follows:

- Delete the following sites "animal housing of various types and kennels. You have neglected to provides specific direction for use for these sites
- Add the following phrase to the Storage and Disposal instructions. **Wrap and** discard in the trash.
- The Precautionary Statement should read as follows:

Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) Maybe fatal if absorbed through the skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and was before reuse.

CONCURRENCES

SYMBOL							
IRNAME							
DATE							

General Comments

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above conditions are not compiled with, the registration will be subject to cancellation in accordance with FIFRA section (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these condition.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510c)

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its 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) contact 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 preclean or decontaminate critical or semi-critical medical devices prior sterilization or high-level disinfections.

This product is a cleaner, disinfectant, deodorizer for use in hospitals, nursing homes, hotels, motels, animal housing of various types, surgical, mortuary, and laboratory work areas, and institutions where housekeeping will be of prime importance in controlling the hazard of cross contamination of environmental surfaces.

This product can provide the assurance that, when used as directed, a marked reduction in the microbe population will result in and on such environment.

This product, when mixed at 1 ounce to a gallon of water, will clean, deodorize and disinfect floors, walls, bathroom fixtures, tile, sinks, garbage pails, restrooms, bed-side tables, hospital halls, operating rooms, bed-pans, kennels, tables or any hard surface such as stainless steel, formica, plastic, or aluminum.

Remove gross filth or heavy soil. Preclean all surfaces prior to application of the product. Thoroughly wet all surfaces to be cleaned with a mop, cloth, sponge or spray for a contact time of at least 10 minutes at a temperature of 20° C or higher. A fresh solution should be prepared for each use.

This product is effective against Staphylococcus aureus, Salmonella, Pseudomonas, Mycobacterium tuberculosis subsp. bovis (BCG). Pathogenic fungi, as well as Herpes simplex Type 2 virus and Influenza A2/Hong Kong virus. It controls odors by destroying odor-producing microorganisms on environmental surfaces. Do not use for food storage areas.

This product when mixed at 2 ounces to a gallon of water is effective against Mycobacterium tuberculosis subsp. bovis (BCG) when applied to inanimate hard non porous surfaces for a contact period of 5 minutes at 20°C or higher.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals.

DANGER. Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. May be fatal if swallowed. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

STORAGE AND DISPOSAL


Store in original container in areas inaccessible to children and persons unfamiliar with the product.

Do not reuse container. Discard in the trash.

EPA REG. NO. 51267-1

EPA EST. NO. 8155-OH-1

Manufactured By:
BIOSERV, INC.
P.O. Box 248 • Hiawasee, GA 30546



BioCLEAN OTQ/1000

**CLEANER /
DISINFECTANT
DEODORIZER**

ACTIVE INGREDIENTS	
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethyl benzyl ammonium chloride	5.0%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	5.0%
Bis (tributyltin) oxide	1.0%
INERT INGREDIENTS	69.0%
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID

IF IN EYES: Flush eyes with water for at least 15 minutes. Get medical attention immediately.

IF ON SKIN OR CLOTHING: Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.

IF SWALLOWED: Do not induce vomiting. Drink water or milk. Get medical attention immediately.

IF INHALED: Move to fresh air. Get medical attention immediately.

NOTE TO PHYSICIAN: See back panel for additional precautionary statements.

Net Contents: 32 Fl. Oz. (1 U.S. Qt.) 946 ml

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 8 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 51267-1

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