

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

Subject:

BIO-CLEAN

EPA Registration No. 51267-1

May 1, 2003 Amendment Dated: 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 2.
- The Precautionary Statement should read as follows: 3.

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.

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PA Form 1320-1A (1/90)			Printed on Recycled Paner					OFFICIAL FILE COPY	

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.

Manufactured By: BIOSERV, INC. P.O. Box 248 • Hiawasee, GA 30546 This product is effective against Staphylococcus aureus, Salmonella, Pseudomonas, Mycobacterium tuberculosis subsp. bovis (BCG). Pathogenic fungi, as well a 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.

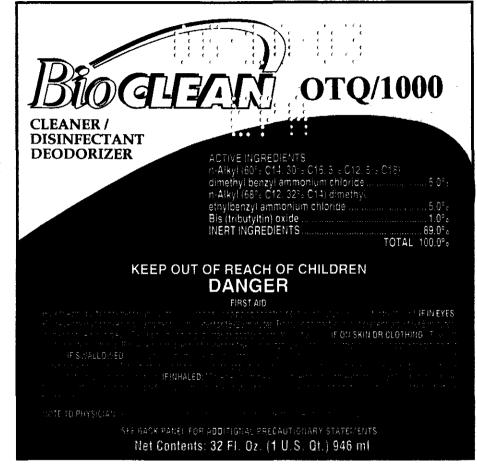
DANGER. Keep out of reach of children. Corrosive Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. May be fatal if swallowed. Harmful if absorbed through the skin. Wash thoroughly with soap and water 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. 8155-0H-1



ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 8 - 2083

Under the Federal Insecticide, Pungicide, and Rodenticide Actas amended, for the posticide, registered under EPA Reg. No. 5/267-/