

87492-1

8/4/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

AUG 04 2011

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

David Swain, Agent for Strategic Resource Optimization, Inc.
c/o Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN. 46725

Subject: Electro-Biocide
EPA Registration Number 87492-1
Application Date: March 9, 2011

Dear Mr. Swain:

The Agency has reviewed your submission in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the action to be acceptable with the following comments. Revise the label accordingly:

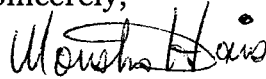
- Change "hard, non-porous surfaces" to "pre-cleaned hard, non-porous surfaces"; and,
- Change "porcelain" and "ceramic" to "glazed porcelain" and "glazed ceramic"; and,
- Under Disposal of Infectious Material, change "should" to "must".

In summary, your request to revise the basic Confidential Statement of Formula (CSF) and add an alternate #1 CSF has been reviewed and determined to be acceptable. The new basic and alternate #1 CSFs dated March 9, 2011 will supersede and replace the previously accepted basic CSF. A copy of our chemistry review, D387743, is enclosed. We have confirmed the optional precautionary language and signal word status of the revised CSFs. Our review of the acute toxicology profile for the alternate #1 CSF, D387745, is also enclosed.

In addition, you have conducted acceptable confirmatory product performance data for the pathogens previously approved as well as two new microorganisms, *Acinetobacter baumannii* and *Klebsiella pneumoniae*. A copy of our efficacy review, D387746, is also enclosed.

A stamped copy of the accepted with comments labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling. If you have any questions, please contact Tom Luminello by telephone, (703) 308-8075, or by e-mail at luminello.tom@epa.gov.

Sincerely,



Monisha Harris
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510 P)

3076

ELECTRO-BIOCIDE

[Electro-Biocide is a multi-purpose, bactericidal and virucidal cleaner that disinfects hard, non-porous surfaces]

pre-cleaned

ACTIVE INGREDIENT:	
Chlorine Dioxide.....	0.02%
OTHER INGREDIENTS:	99.98%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 87492-1
EPA Est. No. 85056-CO-001

Net Contents: 1 gallon

Manufactured for:

Strategic Resource Optimization Inc. (SRO)
289 Elk Creek Drive
Bailey, CO 80421

[PRODUCT OF THE USA]

Expiration Date: See sticker attached to container for expiration date.
{*Expiration Date is 15 days from date of manufacture*}

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ACCEPTED
with conditions
in EPA Reg. No. 87492-1

AUG 04 2011

Under the Federal Insecticide, Fungicide and Rodenticide Act, this product is registered under FIFRA Act.

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Note to Agency: Text appearing in parenthesis () or brackets [] is optional text. {Bracketed text} is for administrative purposes only and will not appear on final printed label.

Recommended Use (Locations):

Electro-Biocide is a multipurpose bactericidal and †virucidal cleaner that disinfects hard non-porous surfaces such as stainless steel, chrome, glass, plastic, vinyl, porcelain, ceramic, plastic laminate, sealed terrazzo or granite, linoleum, metal, and finished wood.

glazed

glazed

Recommended for use in:

- | | |
|-----------------------|-----------------|
| Hospitals | Schools |
| Nursing Homes | Universities |
| Health Care Settings | Gymnasiums |
| Hotels & Motels | Locker Rooms |
| Cruise Ships | Restrooms |
| Dormitory Rooms | Fitness Centers |
| Temporary Housing | |
| Households | |
| Public Transportation | |

Recommended Use (Surfaces):

Electro-Biocide disinfects and is bactericidal and †virucidal on the following hard nonporous surfaces such as stainless steel, chrome, glass, plastic, vinyl, porcelain, ceramic, plastic laminate, sealed terrazzo or granite, linoleum, metal, and finished wood when used as directed:

glazed

glazed

- | | |
|-----------------|-------------------|
| Call bell | Patient Equipment |
| Over bed tables | Restroom Fixtures |
| Side tables | Trash cans |
| Closets | |
| Shelves | |
| Drawers | |
| Telephone | |
| TV remote | |
| Floors | |
| Walls | |

ACCEPTED
with COMMENTS
in Full Label Dated:

AUG 04 2011

Under the Federal Insecticide,
Fungicide and Rodenticide Act
registered for use as a disinfectant,
EPA Reg. No.

87492-1

For Use as a Disinfectant and †Virucide:

Disinfectant: Electro-Biocide, when [used as directed] is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Staphylococcus aureus* (MRSA) and *Enterococcus faecalis* (VRE) with a 10 minute contact time on hard non-porous inanimate surfaces.

†Virucidal: Electro-Biocide, when [used as directed] is effective against Rhinovirus Type 37, Influenza Type A (H1N1) Virus, Hepatitis A Virus and Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS virus] with a 10 minute contact time on hard non-porous inanimate surfaces.

pre-cleaned

pre-cleaned

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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 blood stream 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

TO DISINFECT:

- 1) Only trained applicators are permitted to apply this product.
- 2) Handlers applying chlorine dioxide in an occupational setting must wear gloves.
- 3) Pre-clean all hard, non-porous surfaces with Electro-Biocide or detergent prior to disinfection
- 3) Spray from 4-6 inches all hard, non-porous surfaces until surface is thoroughly wet
- 4) Allow surfaces to remain wet for 10 minutes
- 5) Allow surfaces to air dry

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[NOTE: Pre-treat a small, inconspicuous area of surface being disinfected for colorfastness.]

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / 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 [AIDS Virus] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of Electro-Biocide.

Contact Time: Allow surface to remain wet for 10 minutes to kill HIV-1. Use a 10 minute contact time for all other organisms claimed.

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Disposal of Infectious Material: Blood / body fluids ^{MUST} should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE:

Store this product in a cool, dry area, away from direct sunlight or heat. Always store pesticides in the original container. In case of leaking container, wrap product in secondary container and follow pesticide disposal instructions. In case of spill, contain and flush with water and dispose of waste on site.

PESTICIDE DISPOSAL:

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Call your local solid waste disposal agency or 1-800-CLEANUP for disposal instructions.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or dispose in trash.

ACCEPTED
WITH COMMENTS
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