

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 20 2001

Diana Hoffmann
CEO
EnviroSystems, Inc.
1754 Technology Drive
Suite 106
San Jose, CA 95110

Subject: Eco Tru™
EPA Registration No. 70791-1
Submission Dated December 19, 2001

Dear Ms. Hoffmann:

The Agency sent a letter dated December 6, 2001 to EnviroSystems, Inc. requesting that you change the contact times for certain microorganism on your proposed label. This amendment was submitted in support of the proposed changes.

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below.

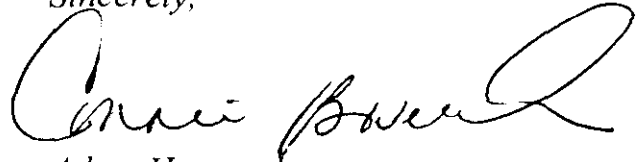
1. The submitted label has *Staphylococcus aureus* and *Salmonella choleraesuis* at 10 minutes and *Pseudomonas aeruginosa* at 2 minutes. The three main microorganisms *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* have been accepted for 2 minutes for each, this change was made on the stamped label.
2. Reference should be made to the surfaces in description being hard non-porous surfaces.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

A stamp copy of your labeling is enclosed for your records. Submit one copy of the final printed label prior to release for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward". The signature is fluid and cursive, with a large initial "A" and a long, sweeping tail.

Adam Heyward

Product Manager - Team 34

Regulatory Management Branch II

Antimicrobials Division (7510C)

EcoTru®

(master label – Revised 12/12/01)

- Hospital Disinfectant/Cleaner
- Instrument Presoak
- Disinfectant/Decontaminant Cleaner
- Institutional Disinfectant/Decontaminant Cleaner
- Dental Decontaminant/Cleaner
- Veterinary Disinfectant/Decontaminant Cleaner
- Medical Decontaminant/Cleaner
- Surface Disinfectant/Decontaminant Cleaner
- Laboratory Surfaces Decontaminant/Cleaner
- Household Disinfectant
- Commercial Facility Disinfectant

BACTERICIDAL – VIRUCIDAL - FUNGICIDAL – TUBERCULOCIDAL - PSEUDOMONACIDAL

Ready To Use

Active Ingredients:

Parachlorometaxylenol.....	0.20%
Other ingredients.....	99.80%
Total.....	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Reg. No. 70791-1

EPA Est. No. 73462-CA-001

Effective against:

- *Pseudomonas aeruginosa* * (ATCC 15442) - 2 minutes contact time
- *Salmonella choleraesuis* * (ATCC 10708) - 2 minutes contact time
- *Salmonella typhimurium* ** (ATCC 6539)
- ✓ *Escherichia coli* OH157 ** (ATCC 43888)
- ✓ *Campylobacter jejuni* *** (ATCC 29248)
- ✓ *Legionella pneumophila* *** (ATCC 33153)
- ✓ *Listeria monocytogenes* ** (ATCC 19111)
- ✓ *Streptococcus pyogenes* ** (ATCC 8669)
- *Staphylococcus aureus* *** (ATCC 6538) - 2 minutes contact time
- ✓ *Mycobacterium bovis* ** (ATCC 35743, TMC 1028)
- ✓ *Trichophyton mentagrophytes* ** (ATCC 9533)
- ✓ *Candida albicans* ** (ATCC 10231)
- ✓ HIV-1 ** (Zepto Metrix Corporation, Buffalo, NY)
- ✓ Herpes simplex Type 1 ** (ATCC VR-260)
- ✓ Herpes simplex Type 2 ** (ATCC VR-734)
- ✓ Influenza A2 *** (ATCC VR-100)
- ✓ Rhinovirus 39 *** (ATCC VR-340)
- ✓ Hepatitis B ** (DHBV)

- (* 2 minutes contact time)
- (** 5 minutes contact time)
- (***10 minutes contact time)

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70791-1

DESCRIPTION:

EcoTru™ is a multi-purpose, broad spectrum, ready to use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. It is especially useful in patient care areas, laboratories, non-food contact surfaces in food preparation areas, health club facilities, daycare centers, schools, households, and areas where environmental control of cross contamination is important. EcoTru will effectively disinfect, when used as directed, such items as counter tops, exterior toilet surfaces, sinks, tubs, showers, floors, walls, handrails, door knobs, bed railings, veterinary care surfaces, dental operator surfaces, dental countertops, dental chairs, light lens covers, sinks, drain boards, cabinets, faucets, appliances, and other inanimate objects.

DIRECTIONS FOR USE:

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

EcoTru™ Hospital Disinfectant/Cleaner & Instrument Presoak is designed for effective disinfection, cleaning and deodorizing of hard inanimate surfaces such as walls, sink tops, tables, chairs, telephones and bed frames, and for the decontamination of instruments prior to sterilization. When using strong cleaners and disinfecting agents, it is always advisable to first test in an inconspicuous area.

TO DISINFECT CONTAMINATED SURFACES AND OBJECTS [Healthcare facilities]:

Mix by inversion. For heavily soiled areas, or surfaces or objects soiled with blood or body fluids, a precleaning step is required. Use a clean sponge or lint-free cloth. On precleaned surfaces, apply EcoTru DAILY with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Note contact time for individual microorganism on this label.

INSTRUMENT PRESOAK – TO DECONTAMINATE INSTRUMENTS PRIOR TO STERILIZATION:

Completely immerse instruments for 10 minutes prior to preparation for sterilization. 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) 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

EcoTru inactivates HIV-1 on precleaned environmental surfaces and objects previously soiled with blood or body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces or objects with blood or body fluids, and in which the surfaces and objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus (HIV-1)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON HARD INANIMATE SURFACES AND/OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

Personal Protection: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks and/or eye coverings.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of EcoTru with a mop, cloth, sponge or mechanical sprayer so as to thoroughly wet precleaned surfaces. DO NOT DILUTE. Allow surfaces to remain wet for two minutes to ensure total inactivation of HIV virus. This contact time will not control other common types of viruses and bacteria. For example, a five-minute contact time is required to control Mycobacterium tuberculosis at 20°C.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

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[Households and Commercial Establishments]

DIRECTION FOR USE: Ready-to-use. Mix by inversion. Use through the house or commercial facility on hard, non-porous non-food contact surfaces. **To Clean and Sanitize:** Spray surfaces until wet. Leave surfaces wet for 30 seconds before wiping. **To Disinfect:** Spray surfaces until wet. For bactericidal, tuberculocidal, and fungicidal disinfection, let stand for 5 minutes before wiping. For virucidal and Staph disinfection, let stand for 10 minutes before wiping. To control and prevent mold and mildew and their odors: spray surfaces until wet. Repeat application as necessary. To deodorize: Spray on surfaces as needed.

STORAGE AND DISPOSAL:

Storage: Store in a cool place.

Disposal: Wastes resulting from use of this product may be poured down the drain. No special handling is required.

EnviroSystems, Inc.

1754 Technology Drive, Suite 106
San Jose, CA 95110-1320
Telephone: 1-800-622-2888 or 1-408-501-0890

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