



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 30, 2002

Ms. Diana Hoffman, Chief Executive Officer
EnviroSystems, Inc.
1754 Technology Drive, Suite 106
San Jose, CA 95110-1320

Subject: Notification in Accordance with PR Notice 98-10
Eco Tru®
EPA Registration Number 70791-1
Application dated September 16, 2002

Dear Mr. Jones:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification:

- Add the statement "Eco Tru® has successfully met all of the requirements of AMS 1453: Disinfectant Cleaner for Aircraft Interiors to Master Label."

General Comments:

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable with the following comments: .

Since this product is being used in hospitals, the following statement must be added to the master 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 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 Maybe used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection

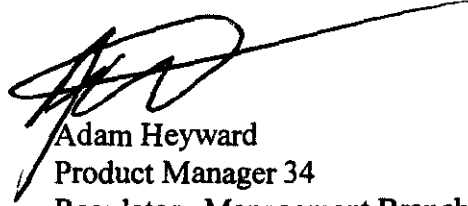
2 3 6

For detailed information concerning this statement, refer to PR Notice 94-4.

A copy of the notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

376



Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
--	---	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number EnviroSystems, Inc./ No. 70791-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EcoTru	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) EnviroSystems, Inc. 1754 Technology Drive, Suite 106 San Jose, CA 95110-1320 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>70791-1</u> Product Name <u>EcoTru</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section II. The purpose of this submission is to add to the master label that the product meets the requirements of AMS 1453: Disinfectant Cleaner for Aircraft Interiors. AMS 1453 is a requirement of the aircraft industry to ensure that the product will not cause harm to the aircraft. The results of this testing (not required for EPA) are included. The label is a master label that is not substantially different from the current registered label, except for the expanded AMS 1453 claims.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. from 8oz to 55 gal	No. per container n/a	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container various: 8oz, 16oz, 22oz, 1gal, 55gal		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Diana Hoffman	Title Chief Executive Officer	Telephone No. (Include Area Code) (408) 501-0890
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Diana Hoffman</i>	3. Title Chief Executive Officer	5. Date September 16, 2002
4. Typed Name Diana Hoffman		

4 8 6

EcoTru®

(master label – revised 09/12/02)

- 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

NOTIFICATION
 Date Reviewed: 9-24-02
 Reviewed By: E. W. Tucker

BACTERICIDAL – VIRUCIDAL – FUNGICIDAL – TUBERCULOCIDAL - PSEUDOMONACIDAL

Ready To Use

Active Ingredients:

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Reg. No. 70791-1

EPA Est. No. 70791-CA-001

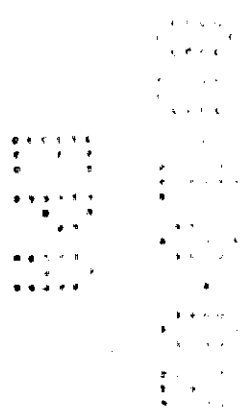
Effective against:

- Pseudomonas aeruginosa* (ATCC 15442)
- Salmonella choleraesuis* (ATCC 10708)
- 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)
- Mycobacterium bovis (TB)** (ATCC 35743, TMC 1028)
- Trychophyton mentagrophytes** (ATCC 9533)
- Candida albicans** (ATCC 10231)
- HIV-1** (Zepto Metrix Corporation, Buffalo, NY)
- Herpes simplex Type I** (ATCC VR-260)
- Herpes simplex Type II** (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)



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, day care 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 operatory surfaces, dental countertops, dental chairs, light lens covers, sinks, drain boards, cabinets, faucets, appliances, and other inanimate objects. EcoTru® has successfully met all of the requirements of AMS 1453: Disinfectant Cleaner for Aircraft Interiors.

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 disinfectant 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 five minutes to ensure total inactivation of HIV virus. This contact time will not control other common types of viruses and bacteria. For example, a ten-minute contact time is required to control Influenza A2.

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

[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