

70791-2

08-15-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 15, 2007

David Swain
SRC Scientific & Regulatory Consultants
Agent for
EnviroSystems Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Notification in Accordance with PR Notice 98-10
EnviroTru
EPA Registration Number 70791-2
Application: July 16, 2007
Receipt Date: July 18, 2007

Dear Mr. Swain:

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

Proposed Notification:

Add "office buildings" as a use site

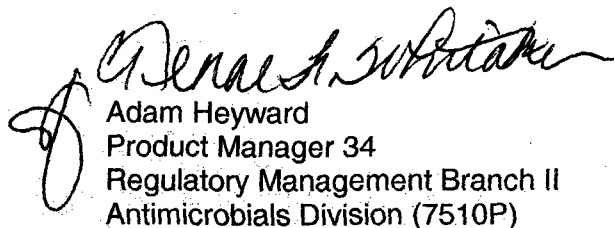
General Comment:

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

The notification application is acceptable. A copy has been inserted in the file for future reference.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov.

Sincerely,


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

SRSC
Scientific & Regulatory
Consultants, Inc.
July 16, 2007

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Mr. Adam Heyward, PM34
Office of Pesticide Programs (7504P)
Document Processing Desk (NOTIF)
EPA
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: EnviroTru
EPA Reg. No. 70791-2

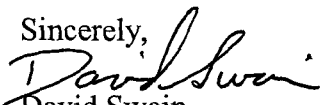
Dear Mr. Heyward:

Enclosed is a notification for the above product, submitted on behalf of our client EnviroSystems, Inc. The purpose of the notification is to add "office buildings" as a use site. "Office buildings" is consistent with the other types of indoor use sites which are already approved, including health club facilities, day care centers, schools and households.

The addition to the label is highlighted with red text on the enclosed label.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec, 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

In addition, we request that a stamped copy of the label be returned to aid in filing these additions to the states. If you have any questions regarding this submission, please contact me at 260-244-6270 or at dswain@srconsultants.com. Thank you for your assistance with this notification.

Sincerely,

David Swain
Agent for EnviroSystems Inc.

cc: L. Breedlove

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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 70791-2	2. EPA Product Manager A. Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EnviroTru	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) EnviroSystems, Inc. 116 Morlake Drive, Suite 201 Mooresville, NC 28817 <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. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input 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.)

Notification of text addition through PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please contact David Swain at dswain@srconsultants.com or at 260-244-6273 (fax) with any questions.

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 type="checkbox"/> Yes <input checked="" 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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 22 fl. oz., 1 gallon, 5 gallon, 55 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> 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 David M. Swain	Title Agent for EnviroSystems, Inc.	Telephone No. (Include Area Code) (260) 244-6270
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)
Signature <i>David M. Swain</i>	3. Title Agent for EnviroSystems, Inc.	
4. Typed Name David M. Swain	5. Date July 16, 2007	

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EnviroTru®

Disinfectant* [Deodorizer][Cleaner]

READY-TO-USE

Bactericide, Sanitizer

Active Ingredient:

Parachlorometaxlenol	0.2%
Other Ingredients.....	99.8%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

Net Contents: {insert package contents here}

EPA Reg. No. 70791-2

EPA Est. No. xxxxxx-xx-xxx

[Lot _____]

[Expiration Date _____]

Manufactured for:
EnviroSystems, Inc.
116 Morlake Drive, Suite 201
Mooresville, NC 28117
1 800 822 2888 www.EnviroSi.com

A wholly owned subsidiary of Anpath Group, Inc.

Note: Bracketed [] information is optional text. Text separated by a comma (,) denotes-and/or-options. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

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{This list of organisms is for informational purposes. The organisms and related claims may or may not be listed on the final printed label or on a reference sheet (See sample shown on page 7) and if listed may use a different format.}

EFFECTIVE AGAINST:

Campylobacter jejuni (ATCC 29428) **
Escherichia coli (ATCC 11229) *
Escherichia coli O157:H7 (ATCC 43888) *
Klebsiella pneumoniae (ATCC 23357) **
Legionella pneumophila (ATCC 33153) **
Pseudomonas aeruginosa (ATCC 15442) *
Salmonella enterica (ATCC 10708) *
Salmonella typhi (ATCC 6539) *
Shigella sonnei (ATCC 9290) *

Staphylococcus aureus (ATCC 6538) ***
Klebsiella pneumoniae (ATCC 4352) ***

* Disinfects in 5 minutes
** Disinfects in 10 minutes
*** Sanitizes in 5 minutes

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DESCRIPTION: EnviroTru is a multi-purpose, ready-to-use, effective limited disinfectant* [deodorizer] [deodorizing] [cleaner] for use on hard, non-porous, precleaned surfaces (e.g. stainless steel, chrome, glass, vinyl). EnviroTru will disinfectant precleaned surfaces, when used as directed on counter tops, walls, tables, chairs, exterior toilet surfaces, sinks, tubs, showers, floors, hand rails, door knobs, veterinary care surfaces, cabinets, faucets, appliances, and telephones. It is especially useful in laboratories, non-food contact surfaces in food preparation areas, health club facilities, office buildings, day care centers, schools and households. It can also be used on aircraft, trains, automotive forms of transportation, ships and boats, whether commercial or military. EnviroTru has passed AMS 1452A, AMS 1453 and Boeing D6-7127 specifications for non-corrosion and materials compatibility.

DIRECTIONS FOR USE:

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

MIX BY INVERSION. DO NOT DILUTE.

For Use as a Cleaner and/or Deodorizer:

[MIX BY INVERSION. DO NOT DILUTE.] Apply by mechanical sprayer, cloth, sponge, or mop to thoroughly wet surfaces.

For Use as a Disinfectant:

[MIX BY INVERSION. DO NOT DILUTE.] Preclean surfaces with EnviroTru, then apply by mechanical sprayer, cloth, sponge, or mop so as to thoroughly wet surfaces. Let stand for 5-10 minutes. Refer to list of organisms for appropriate contact time. Wipe dry.

Note – All food contact surfaces must be rinsed with potable water. Do not use on glassware, cookware, utensils, or dishes. If finish or restorer will be applied to floors, rinse the floor prior to applying coating.

For Use as a Non-Food Contact Sanitizer:

[MIX BY INVERSION. DO NOT DILUTE.] Preclean surfaces with EnviroTru then apply by mechanical sprayer, cloth, sponge, or mop so as to thoroughly wet surfaces. Let stand for 5 minutes. Wipe dry.

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{The following instructions for Animal Facilities may be placed in a package insert. }

[See Package Insert for Animal Housing Facility use instructions. {See page 8}]

Animal Housing Facilities (Including Veterinary Clinics, [Equine] Farms, Livestock, Swine and Poultry Houses):

For cleaning, deodorizing, and disinfecting the following hard nonporous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
Thoroughly clean all surfaces with [soap][detergent][EnviroTru] and rinse with potable water. Saturate surfaces by wiping, spraying or foaming with product for a period of 5-10 minutes. Refer to list of organisms for appropriate contact time. Wipe dry.
4. Immerse handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
5. Ventilate buildings and other closed spaces.
6. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with [soap][detergent][EnviroTru], and rinse with potable water before reuse.

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{For sizes 1 gallon or less}

STORAGE AND DISPOSAL

Store in original container. Keep securely closed. Do not reuse empty container. Rinse thoroughly. [Wrap and] Discard in trash. Dispose of unused product down the drain or in accordance with local regulations.

{For sizes over 1 gallon}

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in dry, well ventilated area away from chemicals, direct light, heat or open flame. Do not mix with other cleaning or disinfecting products.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office or the Manufacturer for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill; or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

{For containers of 5 gallons or 50 lbs. or more}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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{Additional Optional Antimicrobial Labeling :}

[Kills][Effective against] [{Insert any organism(s) listed on page 2}]
[Kills][Disinfects][Effective against] [bacteria]
[Antibacterial]
[Cleans] [and] [Sanitizes][Deodorizes][Disinfects]
[Bactericidal]
[Kills][Sanitizes][Reduces] >99.9% of Staph and Klebsiella [in 5 minutes]

{Additional Optional Labeling :}

[Compatible with surfaces][Suitable for surfaces]
A [gentle][mild] way to [disinfect][sanitize]
[Kind to][Gentle on][Mild to] surfaces
[Gentle][Mild] enough to use without gloves
[Gentle][Mild] enough for airplane surfaces
[Meets EPA requirements for Toxicity Category IV]
Requires no protective clothing or gloves
Requires no protective clothing, gloves or special ventilation
[Compatible with hard, non-porous surfaces]
Multi-Purpose Disinfectant* & Deodorizing Cleaner
Easy to Use
No [mixing] [or][measuring]
[Non-flammable]
[Pleasant Smell]
[No special shipping and handling requirements]

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{Additional Optional Labeling :}

[Requires no special ventilation]

[Does not require any breathing apparatus]

{The following is a sample reference sheet as described on page 2.}

EnviroTru (EPA Reg. No. 70791-2) Test Organism Reference List

EnviroTru (EPA Reg. No. 70791-2) has been shown effective against the following organisms in testing conducted in compliance with EPA Good Laboratory Practice (40CFR Part 160) by independent laboratories:

Campylobacter jejuni (ATCC 29428) **
Escherichia coli (ATCC 11229) *
Escherichia coli O157:H7 (ATCC 43888) *
Klebsiella pneumoniae (ATCC 23357) **
Legionella pneumophila (ATCC 33153) **
Pseudomonas aeruginosa (ATCC 15442) *
Salmonella enterica (ATCC 10708) *
Salmonella typhi (ATCC 6539) *
Shigella sonnei (ATCC 9290) *

Staphylococcus aureus (ATCC 6538) ***
Klebsiella pneumoniae (ATCC 4352) ***

* Disinfects in 5 minutes
** Disinfects in 10 minutes
*** Sanitizes in 5 minutes

12/12

{The following is a sample package insert as described on page 4.}

EnviroTru (EPA Reg. No. 70791-2)
Veterinary Housing Facilities Package Insert

Animal Housing Facilities (Including Veterinary Clinics, [Equine] Farms, Livestock, Swine and Poultry Houses):

DIRECTIONS FOR USE:

For cleaning, deodorizing, and disinfecting the following hard nonporous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
Thoroughly clean all surfaces with [soap][detergent][EnviroTru] and rinse with potable water. Saturate surfaces by wiping, spraying or foaming with product for a period of 5-10 minutes. Refer to list of organisms for appropriate contact time. Wipe dry.
4. Immerse handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
5. Ventilate buildings and other closed spaces.
6. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with [soap][detergent][EnviroTru], and rinse with potable water before reuse.

See EnviroTru label for additional instructions.