

70791-2

05/20/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

May 20, 2008

David Swain
Agent for
EnviroSystems, Inc.
P. O. Box 1014
102 ½ Chauncey Street
Columbia, IN 46725

Subject: Product Name: EnviroTru®
OPP Decision Number: D-389276
EPA Registration Number: 70791-2
Application Dated: January 31, 2008
Receipt Date: February 10, 2008

Dear Mr. Swain:

The following amendment, submitted in connection with registration under section 3(c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

- Add label claims for *staphylococcus aureus* MRSA and *Enterococcus faecalis* VRE

Acceptable Data

The submitted data (MRID #s 473375-01 and -02) supports the use of the product claim as a non-food contact sanitizer against *Staphylococcus aureus*-MRSA and *Enterococcus faecalis* Vancomycin Resistant on pre-cleaned hard, non-porous surfaces for a contact time 5 minutes at room temperature (20.0°C).

General Comments

The Agency is moving away from review of paper submitted registration Applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic

submissions, including label:

http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have any questions concerning electronic label submissions, a list of contacts is available at the following website: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

A stamped copy of the accepted labeling is enclosed for your records.

For detailed information and consideration, please refer to the enclosed EPA/AD Product Science branch review dated April 23, 2008.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov or Lisa McKelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



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

Enclosure: [Stamped labeling & efficacy review]

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EnviroTru®

Disinfectant* [Deodorizer][Cleaner]

READY-TO-USE

Bactericide, Sanitizer

Active Ingredient:

Parachlorometaxlenol0.2%
Other Ingredients.....99.8%
Total.....100.0%

KEEP OUT OF REACH OF CHILDREN

Net Contents: {insert package contents here}

EPA Reg. No. 70791-2

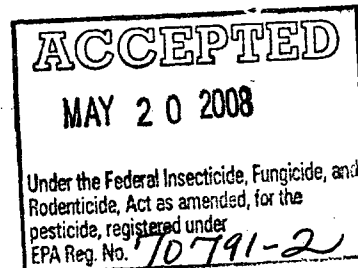
EPA Est. No. xxxxxx-xx-xxx

[Lot _____]

[Expiration Date _____]

Manufactured for:
EnviroSystems, Inc.
116 Morlake Drive, Suite 201
Mooresville, NC 28117
1 800 374 0017 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) ***
- [Methicillin Resistant] Staphylococcus aureus (MRSA) (ATCC 33592) ***
- Enterococcus faecalis [VRE] [Vancomycin Resistant] (ATCC 51299) ***

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

Note: Bracketed [] information is optional text. Text separated by a comma (,) denotes-and/or-options.
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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)]. [It can be used on aircraft, whether commercial or military, on surfaces such as lavatories, galleys, windows, tray tables, service trays, overhead bins, arm rests, bulkheads, walls and floors.] 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] [conforms to] 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.

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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{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.

{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]

[Kills] [Sanitizes] [Reduces] >99.9% of [Methicillin Resistant] Staphylococcus aureus (MRSA) [in 5 minutes]

[Kills] [Sanitizes] [Reduces] >99.9% of MRSA [VRE] [in 5 minutes]

[Kills] [Sanitizes] [Reduces] >99.9% of Staph, MRSA, Klebsiella, and VRE [in 5 minutes]

[Kills] [Sanitizes] [Reduces] >99.9% of Staph and MRSA [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]

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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[Non-flammable]

[Pleasant Smell]

[No special shipping and handling requirements]

{Additional Optional Labeling :}

[Requires no special ventilation]

[Does not require any breathing apparatus]

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{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) ***
[Methicillin Resistant] Staphylococcus aureus (MRSA) (ATCC 33592) ***
Enterococcus faecalis [VRE] [Vancomycin Resistant] (ATCC 51299) ***

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

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{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.