

84683-1

11-10-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

NOV 10 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J. Michael Kelley, PhD
Authorized Representative for OhSo Clean, Inc.
Toxcel
Toxicology & Regulatory Affairs
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

Subject: **Benefect® Broad Spectrum Disinfectant**
EPA Registration Number: 84683-1
Application: June 19, 2009
Receipt Date: June 19, 2009

Dear Mr. Kelley:

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 with comments.

Proposed Amendments

- Revised labeling
- Basic CSF dated 6/17/09 and Alternate CSFs (Alt #1) dated 10/13/09, (Alt #2) dated 6/17/09 and (Alt #3) dated 10/7/09 .

Acceptable Data

Efficacy

Data Requirement	Means of Support	Status
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> Genotype USA300	Submitted study, MRID 477867-01	Acceptable, contact time 10 minutes, with soil
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i>	Submitted study, MRID 477867-02	Acceptable, contact time 10 minutes, with soil

General Comments

The label deficiencies identified in Agency letter dated March 25, 2009 have been satisfied per submitted application dated June 19, 2009.

The revised basic CSF dated 6/17/09 supersedes all previously accepted basic formulas. Copies of the Alternate CSFs (Alt #1) dated 10/13/09, (Alt #2) dated 6/17/09 and (Alt #3) dated 10/7/09 have been placed in your file for future reference.

Should you wish to add/retain, a reference to the company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention, that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped label is enclosed for your records.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: carlisle.sharon@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email address at: mckelvin.lisa@epa.gov.

Sincerely,



ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Encloses: Stamped Label

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{All text in brackets [xxx] is optional & may or may not be included on a final label.}
{All text in braces {xxx} is administrative & will not appear on a final label.}

Benefect® Broad Spectrum Disinfectant

[Caution]

Keep Out of the Reach of Children

Active Ingredient:

Thymol (present as a component of Thyme Oil)	0.23%
Other Ingredients:	99.77%
Total	100%

EPA Reg. No. 84683-1 EPA Est. No. 075840-CAN-001

Net Contents _____

[Patented Internationally]
OhSo Clean, Inc.
3001 19th Street
San Francisco, CA 94110
[www.CleanWellToday.com]
[www.Terrachoice.com]

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.

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*The patented technology is proven to kill over 99.99% of: bacteria (specifically, *Salmonella enterica*, *Staphylococcus aureus*, MRSA [(Methicillin Resistant *Staphylococcus Aureus*)], *Pseudomonas aeruginosa*, and *Mycobacterium bovis* (TB)); & fungi (specifically *Trichophyton mentagrophytes* [(the Athlete's Foot fungus)] & HIV-1 (the AIDS virus) on hard, non-porous, inanimate surfaces.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labelling.

{Required language for labels with medical device use claims, as per PR Notice 94-4.}

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 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{Required language for labels with HIV-1 efficacy claims.}

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

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids, are disposable latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood & other body fluids must be thoroughly cleaned from surfaces & objects before application of the disinfectant.

Disposal of Infectious Material: Blood & other body fluids should be autoclaved & disposed of according to federal, state & local regulations for infectious waste disposal.

Contact Time: Leave surface wet for 10 minutes.

Pre-clean surfaces to remove soil prior to disinfection.

TO CLEAN: 1. Shake, apply product & wipe away.

TO DISINFECT [& DEODORIZE]: 1. Shake well and wet the surface with the [spray][product by sprayer, mop, brush, cloth or sponge] (test for surface compatibility on inconspicuous area first). 2. Leave for 10 minutes at room temperature; allow to air-dry, no rinsing or wiping is required (even on food contact surfaces).

STORAGE/DISPOSAL: Nonrefillable container. Store airtight at room temperature. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash.

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{Optional &/or interchangeable claims and marketing statements;}

Kills [over] 99.99% of [Germs*][MRSA]
[Hospital] Disinfectant [Cleaner]
Instrument PreSoak
Decontaminant
[5 minute] Tuberculocide
Tuberculocidal [in 5 minutes]
[Fungicide][Fungicidal][Fungistat]
[*Virucidal] [*Virucide]
[Bactericide][Bactericidal][Antimicrobial][Antibacterial][Bacteriostat]
Controls [Prevents] Cross-Contamination on treated surfaces
[Controls Odors]
[Deodorizer][Deodorizes]
Botanical
Lemon [& Clove] [& Spice] [& Herb] Scent
Ready To Use
[Part of our] Botanical Cleaning & Disinfection Solution
Made from plant extracts with pleasant [aromatherapeutic vapors] [botanical scent]. No synthetic fragrances, dyes, or bleach.
Proven to kill over 99.99% of the EPA's designated test microorganisms for broad-spectrum claims of [hospital] disinfectant effectiveness.

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SUITABLE FOR use in residential, & medical applications; including [insurance restoration (fire, water, sewage, trauma scene decontamination & remediation sites), health care & food preparation facilities, hospitals, nursing homes, medical, veterinary & dental offices, health professional, chiropractic & physiotherapy clinics, child care centers, nurseries, sickrooms, restaurants, kitchens, cafeterias, food storage areas, fitness gyms, spas, schools, offices, hotels, zoos, barns & kennels.

SUITABLE FOR disinfecting hard, non-porous surfaces (metals, glass, fiberglass, plastic, vinyl and similar polymers, glazed tiles, painted or sealed surfaces, finished woodwork, laminated surfaces, marble, and similar stone or stone-like composites), such as: walls & floors, countertops, sinks, food preparation surfaces, toilet seats, pet habitats, garbage cans, children's toys, highchairs, changing tables, remediation equipment, PPE (Personal Protective Equipment), boat, airplane & train surfaces & cavities, prostheses & orthotics, shoes & boot soles, foot spa surfaces, [accessible] coils & drain pans of [HVAC & R equipment] [air conditioning & refrigeration equipment & heat pumps], sports equipment such as jock cups & helmets & any other non-porous surface where bacteria or unpleasant odors are a concern.

Effectively [controls][eliminates] odors produced by odor causing bacteria, fungi & other odor-causing organisms [on concrete, wood framing & studding, trim, carpets, pads & subfloors].

Effectively [controls][eliminates] odors on concrete, wood framing & studding, trim, carpets, pads & subfloors.