

84683-1

08-04-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

AUG - 4 2011

Dr. J. Michael Kelley, Ph.D
Representative for OhSo Clean, Inc.
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Benefect® Broad Spectrum Disinfectant**
EPA Registration No.: 84683-1
Application Date: 05/23/2011
Receipt Date: 05/24/2011

Dear Dr. Kelley:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Optional "CleanWell™ Inside" logo

Conditions

Revise the label as follows:

1. Revise the 12th claim on page 3 to read "Botanically derived active ingredient."
2. Revise the 15th claim on page 3 by deleting the term, "botanical." An unqualified botanical claim is considered a false/misleading safety claim under 40 CFR 156.10(a)(5).

General Comments

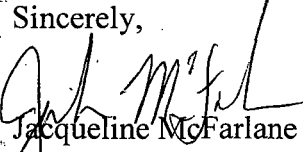
A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,


Jacqueline McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

3
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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 _____

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG - 4 2011

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

84683-1

[Patented Internationally]

OhSo Clean, Inc.

315 Pacific Ave

San Francisco, CA 94111

[www.CleanWellToday.com]

[www.Terrachoice.com]

*The patented technology is proven to kill over 99.99% of: bacteria (specifically, MRSA (Methicillin Resistant *Staphylococcus aureus*), *Salmonella enterica*, *Staphylococcus aureus*, , *Pseudomonas aeruginosa*, & *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.

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

5
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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.

SUITABLE FOR use in [residential, & medical applications] [restoration, decontamination & remediation sites (fire, water, sewage, trauma scene decontamination & remediation sites) including residential, schools, offices, hotels, 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, zoos, barns & kennels.

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

CleanWell™ Inside

