

84683-5

8/4/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

AUG - 4 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

J. Michael Kelley, Ph.D
Toxcel
7140 Heritage Village Plaza
Gainesville, VA 20156

Subject: **CleanWell Broad Spectrum Disinfectant**
EPA Registration No. 84683-5
Application Date: May 23, 2011
Receipt Date: May 24, 2011

Dear Dr. Kelley:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment:

- Adding Logo: CleanWell™ Inside

Conditions

Revise 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).

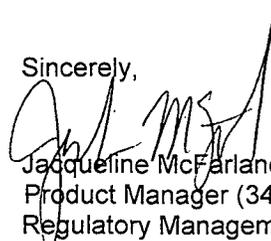
General Comment:

A stamped label with conditions is enclosed for your records. Submit a copy of the 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 during the hours of 8:00am to 4:00pm EST. 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)

Enclosure: EPA stamped accepted labeling

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

{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.}

CleanWell Broad Spectrum Disinfectant

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.

[Caution]
Keep Out of the Reach of Children

84683-5

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

EPA Reg. No. 84683-5 EPA Est. No. 075840-CAN-001
Net Contents _____

[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 preclean 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 and 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 and 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 and 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.

Disinfection of Animal Premises

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the disinfecting solution for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.

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 [(5 minutes for *Mycobacterium bovis* (TB))] at room temperature; allow to air-dry, no rinsing or wiping is required (even on food contact surfaces).

(Residential)

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

(Commercial, Industrial, Institutional)

Storage and Disposal

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

Pesticide Storage: Store airtight at room temperature away from persons unfamiliar with its use.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Offer empty container for recycling. If recycling is not available, puncture and dispose in a sanitary landfill or by other procedures approved by State and local authorities.

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

Kills [over] 99.99% of [Germs*][MRSA]

[Hospital] Disinfectant [Cleaner]

Decontaminant

[5 minute] Tuberculocide

Tuberculocidal [in 5 minutes]

[Fungicide][Fungicidal]

[*Virucidal] [*Virucide]

[Bactericide][Bactericidal][Antimicrobial][Antibacterial]

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 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

