

84683-5

05/04/2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 84683-5

Date of Issuance: MAY - 4 2011

Term of Issuance: Unconditional

Name of Pesticide Product:

CleanWell Broad Spectrum Disinfectant

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

OhSo Clean, Inc.
315 Pacific Avenue
San Francisco, CA 94111

Note: Changes in labeling, differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. D-442921) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Symbol to read, "EPA Reg. No. 84683-5".
b. Revise the "Personal Protection" statement under the HIV directions on page 2 by deleting the term, or, and stating "and."

Signature of Approving Official:

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

Date:

MAY - 4 2011

c. Revise the contact time under the "Disinfect [& Deodorize]" directions to indicate a 5 minute contact time against *Mycobacterium bovis* (TB)." Alternatively, you may revise the 4th and 5th claims on page 3 by deleting the phrase "[5 minutes]."

d. Since this product is used in barns, zoos, kennels, and veterinary offices, the following "Farm Premise" labeling requirements from DIS/TSS 18 must be added to the directions for use:

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.

e. Since the product is sold in residential as well as commercial, industrial, and institutional settings, then the "Storage and Disposal" instructions on page 2 must be revised to reflect the following:

(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 or 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.

f. Delete the third claim, Instrument Presoak, on page 3 because the label does not support directions on how to use this product in this manner.

g. Revise the 7th and 9th claims on page 3 by deleting the terms, "Fungistat" and "Bacteriostat." The label does not support directions on how to utilize this product to support these claims.

h. Revise the 18th claim on page 3 by deleting the phrase, "the EPA's designated."

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

A stamped copy of the label is enclosed for your records. Should you have any questions regarding this letter, please contact me at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby at (703) 305-6440 or by email at grigsby.stacey@epa.gov.

Sincerely,



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

Enclosure: Stamped label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

*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 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;}

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.