

84683-1

6/11/2012

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

JUN 11 2012

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: 05/25/2012
Receipt Date: 05/25/2012

Dear Dr. Kelley:

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Adding botanical and botanically derived claims

General Comments

Based on a review of the submitted materials, your notification for the addition of the botanical and botanically derived claims is acceptable. It is in compliance with PR notice 91-2 and in agreement with the label.

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 Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@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,

A handwritten signature in cursive script, appearing to read "Jacqueline McFarlane".

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

2046

| | | | |
|--|---|---|-----------------------|
|  | United States Environmental Protection Agency Washington, DC 20460 | <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other | OPP Identifier Number |
| | | | |

Application for Pesticide – Section 1

| | | |
|--|---|--|
| 1. Company/Product Number 84683-1 | 2. EPA Product Manager Jacqueline Campbell-McFarlane | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Benefect® Broad Spectrum Disinfectant | PM# 34 | |
| 5. Name And Address Of Applicant (Include ZIP Code) OhSo Clean, Inc. 315 Pacific Avenue San Francisco, CA 94111 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

Section II

| | |
|--|--|
| <input type="checkbox"/> Amendment – Explain below. | <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> Other – Explain Below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification to reinstate "Botanical" claims for Benefect Broad Spectrum Disinfectant (EPA Reg. No. 84683-1). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

| | | | |
|---|---|---|---|
| 1. Material This Product Will Be Packaged In: | | | |
| Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container 100x30; 12x120; 6x390; 4x4000ml | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(S) Retail Container 30/120/390/750/4,000/20,000ml | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled <input type="checkbox"/> Other _____ | | | |

Section IV

| | | | |
|--|---|--|------------------------------|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name J. Michael Kelley, PhD | Title: toXcel, LLC Authorized Representative for OhSo Clean, Inc. | Telephone No. (Include Area Code) 703-754-0248 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received |
| 2. Signature  | 3. Title Authorized Representative for OhSo Clean, Inc. | | |
| 4. Typed Name J. Michael Kelley, PhD | 5. Date May 25, 2012 | | |

30x6

toXcel

Toxicology & Regulatory Affairs

7140 Heritage Village Plaza

Gainesville, VA 20155-3061

Phone: (703) 754-0248

Fax: (703) 310-6950

HAND-DELIVER

May 25, 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Notification – Reinstate “Botanical” Claims on the Label for *Benefect® Broad Spectrum Disinfectant* EPA Reg. No. 84683-1

Dear Jacqueline Campbell-McFarlane:

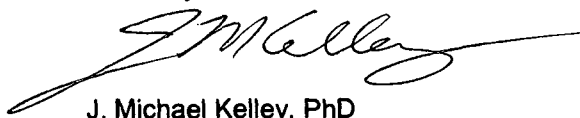
On behalf of OhSo Clean, Inc. of San Francisco, California, we are submitting this notification to reinstate “botanical” and “botanically derived” claims. Those claims were previously denied on August 4, 2011, based on the premise that they are false and misleading safety claims. This reversal of the latest stamped-accepted label decision follows a meeting with Dr. Steven Bradbury on April 13, 2012, in which he laid out the current policy allowing the registrant to continue using the currently approved wording regarding the origin of product ingredient on the labeling of its products until formal policy is developed. No other changes have been made to the label that was stamped-accepted by EPA on August 4, 2011.

The following documents are enclosed:

- 1) EPA Form 8570-1
- 2) One copy of the email correspondence, regarding the label language claim of “botanical” and “botanically derived”
- 3) One copy of current EPA stamped-accepted label (August 4, 2011)
- 4) One copy of the clean label
- 5) One copy of the Word “track-changes” label
- 6) One electronic (CD) copy of the label
- 7) Certification with Respect to Label Integrity form

We request to be informed of the acceptance of this notification letter on EPA letterhead to Mike.Kelley@toxcel.com. Such formal notice of acceptance will be required to obtain and maintain the required State registrations. Please contact me immediately if you have any questions regarding this label amendment.

Sincerely,



J. Michael Kelley, PhD
Authorized Representative for OhSo Clean, Inc.

cc: Larry Weiss
Sam DeAth

{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

NOTIFICATION
Date Reviewed: 6/11/17
Reviewed By: J. C. [Signature]

[Caution]

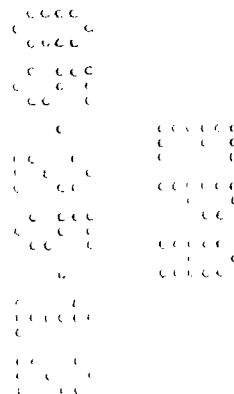
Keep Out of the Reach of Children

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.
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 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 must 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]
Kills [over] [99.9][9] % of [household germs] [kitchen germs] [bathroom germs] [germs*] [,] [botanically]
[on hard, non[-]porous surfaces]
[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

