

84683-1

11/26/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

NOV 26 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

J. Michael Kelley, PhD  
Agent for OhSo, Clean, Inc.  
ToXel  
7140 Heritage Village Plaza  
Gainesville, VA 20156

Subject: Benefect® Broad Spectrum Disinfectant  
EPA Reg. No. 84683-1  
Application Dated: October 27, 2010  
Receipt Date: October 27, 2010

Dear Mr. Kelly:

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

**Proposed Notification:**

- Grammatical error and sentence structure correction

**General Comments:**

Based on a review of the material submitted, your notification to correct grammatical errors and sentence structure is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact me at [Cambell-mcfarlane.jacqueline@epa.gov](mailto:Cambell-mcfarlane.jacqueline@epa.gov) or call (703) 308-6416

Sincerely,

*Jacqueline Campbell McFarlane*  
Jacqueline Campbell McFarlane  
Product Manager (34)

CONCURRENT Regulatory Management Branch II

Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

2/6



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide – Section 1

1. Company/Product Number <b>84683-1</b>	2. EPA Product Manager <b>Jacqueline Campbell-McFarlane</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Benefect® Broad Spectrum Disinfectant</b>	PM# <b>34</b>	
5. Name And Address Of Applicant (Include ZIP Code) <b>OhSo Clean, Inc. 315 Pacific Avenue San Francisco, CA 94111</b>  <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 of minor label changes 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	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	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) _____
* Certification must be submitted			
If "Yes" No. per Unit Packaging wgt. Container 100x30; 12x120; 6x390; 4x4000ml		If "Yes" No. per Unit Packaging wgt. Container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(S) Retail Container <b>30/120/390/750/4,000/20,000ml</b>	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 <b>J. Michael Kelley, PhD</b>	Title: toXcel, LLC <b>Authorized Representative for OhSo Clean, Inc.</b>	Telephone No. (Include Area Code) <b>703-754-0248</b>	
<b>Certification</b> 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 <b>Authorized Representative for OhSo Clean, Inc.</b>		
4. Typed Name <b>J. Michael Kelley, PhD</b>	5. Date <b>October 27, 2010</b>		

# toXcel

**Toxicology & Regulatory Affairs**  
**P.O. Box 363**  
**7140 Heritage Village Plaza**  
**Gainesville, VA 20156**  
**USA**

**Phone: (703) 754-0248**

**Fax: (703) 310-6950**

**HAND-DELIVER**

October 27, 2010

Jacqueline Campbell-McFarlane, PM-34  
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 of Minor Label Changes for Benefect® Broad Spectrum Disinfectant**  
**EPA Reg. No. 84683-1**

**Dear Ms. Campbell-McFarlane:**

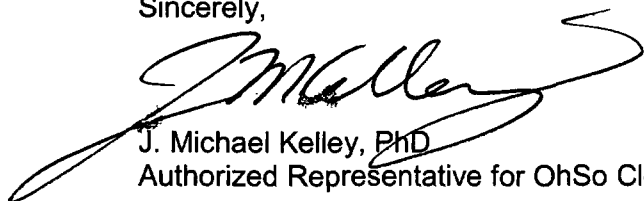
On behalf of OhSo Clean, Inc., we are submitting the enclosed notification of label wording changes for the above referenced product. The changes are grammatical and reorganization of the sentence structure to clarify instructions and highlight already approved use sites on the label. No additional uses have been added. No other changes have been made to the current label, which was approved by the Agency on November 10, 2009.

The following documents are enclosed:

- 1) An application (EPA Form 8570-1)
- 2) One copy of the revised label with highlighted changes (dated October 26, 2010)
- 3) Five clean copies of the revised label (dated October 26, 2010)

If you have any questions regarding this amendment, please contact me immediately by phone at 703-754-0248 or by e-mail at [Mike.Kelley@toxcel.com](mailto:Mike.Kelley@toxcel.com).

Sincerely,



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

cc: Sam DeAth

toXcel  
Toxicology & Regulatory Affairs  
P.O. Box 363  
7140 Heritage Village Plaza  
Gainesville, VA 20156  
USA  
Phone: (703) 754-0248  
Fax: (703) 310-6950  
www.toxcel.com

{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: 11/26/12  
Reviewed By: Dr. B. B. B.

[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]

Deleted: 3001 19<sup>th</sup> Street

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Deleted: November 10, 2009 CA revision  
20100929

\*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.

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**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 [Germ\*][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.

**Deleted:** , including (insurance restoration

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**Deleted:** schools, offices, hotels,

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.

**Deleted:** , glazed tiles, painted or sealed surfaces, finished woodwork, laminated surfaces, marble, and similar stone or stone-like composites

**Deleted:** remediation equipment, PPE (Personal Protective Equipment),

**Deleted:** shoes & boot soles,

**Deleted:** [accessible] coils & drain pans of [HVAC & R equipment] [air conditioning & refrigeration equipment & heat pumps],

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.

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