

84683-3

12/10/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 10 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J. Michael Kelley, PhD
Toxcel, LLC
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

Subject: **Benefect Botanical Daily Cleaner Disinfectant Spray**
EPA Registration No. 84683-3
Application Date: November 13, 2009
Receipt Date: November 13, 2009

Dear Dr. Kelley:

This acknowledges receipt of the notification identified above submitted under the provision section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Proposed Amendment:

- Add Influenza A H1N1 Claim

General Comment:

Based on a review of the material submitted, the following comment applies:

A copy of this accepted notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, you may contact Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epamail.epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	SURNAME	DATE					



United States
 Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number 84683-3	2. EPA Product Manager ShaRon Carlisle (acting)	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Benefect® Botanical Daily Cleaner Disinfectant Spray	PM# 34	
5. Name And Address Of Applicant (Include ZIP Code) OhSo Clean, Inc. 3001 19th Street San Francisco, CA 94110 <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

Amendment – Explain below. Final Printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification – Explain below. Other – Explain Below.

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

Label notification for *Benefect® Botanical Daily Cleaner Disinfectant Spray* EPA Reg. No. 84683-3 to add the H1N1 claim to the EPA stamped-accepted label (November 10, 2009). 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 100/30ml; 6/390ml; 4/4000ml	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 30/120/390/750/4000 ml	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 checked="" type="checkbox"/> Lithographed <input checked="" type="checkbox"/> Paper glued <input 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) 703-335-5670
2. Signature 		6. Date Application Received
3. Title Authorized Representative for OhSo Clean, Inc.		
4. Typed Name J. Michael Kelley, PhD		
5. Date November 13, 2009		

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toXcel

Toxicology & Regulatory Affairs

P.O. Box 363

7140 Heritage Village Plaza

Gainesville, VA 20156

USA

Phone: (703) 335-5670

Fax: (703) 310-6950

HAND-DELIVER

November 13, 2009

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 – The H1N1 claim on Latest Stamped-Accepted Label
(November 10, 2009) for *Benefect® Botanical Daily Cleaner Disinfectant
Spray*
EPA Reg. No. 84683-3

Dear ShaRon Carlisle:

On behalf of OhSo Clean, Inc. of San Francisco, California, we are submitting a label notification to add the H1N1 claim to the label, which already has the Influenza A claim. No other changes have been made to the label that was stamped-accepted by EPA on November 10, 2009.

The following documents are enclosed:

- 1) EPA Form 8570-1
- 2) One copy of current EPA stamped-accepted label (November 10, 2009)
- 3) Five copies of the label

We request to be informed of the acceptance of this notification by an email to Mike.Kelley@toxcel.com. 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

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative & will not appear on a printed label.}

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Benefect® Botanical Daily Cleaner Disinfectant Spray
{This is the product name approved by EPA for the Basic formulation}

[Benefect® Botanical Weekly Cleaner Disinfectant Spray
{This is the product name for the Alternative formulation (spray).}]

[Benefect® Botanical Monthly Cleaner Disinfectant Spray
{This is the product name for the Alternative formulation (foam).}]

NOTIFICATION
Date Reviewed: 12/10/09
Reviewed By: S. Grayby

[Caution]
Keep Out of the Reach of Children

Active Ingredients:

Thymol (present as a component of Thyme Oil).....0.05%
Other Ingredients:99.95%
Total.....100%

Net Contents _____

EPA Reg. No. 84683-3
EPA Est. No. 075840-CAN-001
[EPA Est. No. 84683-CA-01]

OhSo Clean, Inc.
3001 19th Street
San Francisco, CA 94110

*The patented technology is proven to] *Kill[s] [over] 99.9[9]% of household germs,
[specifically]: Influenza A [including][the Pandemic 2009][H1N1][Influenza A virus],
Rhinovirus [(type 37, the Common Cold virus)], Staphylococcus aureus, Salmonella enterica,
Pseudomonas aeruginosa, and Escherichia coli [on hard, non-porous, inanimate surfaces].
[Tested in the presence of 5% organic soil load].

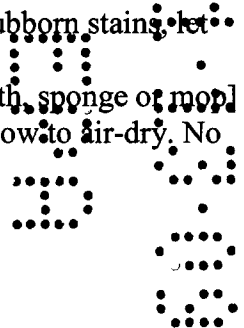
{Where medical devices are listed as applicable sites the following sites will be included as required by PR 94-4}

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 in 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.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labelling. For heavily soiled or greasy areas, pre-cleaning is required.

[TO CLEAN: 1. Wet the surface [with the spray] & wipe clean.][For stubborn stains, let stand for a few minutes.][Allow foam to penetrate, then wipe clean.]

TO DISINFECT [& DEODORIZE]: 1. Wet the surface [by sprayer, cloth, sponge or mop] [(spot test to check surface compatibility)]. 2. Leave for 10 minutes. Allow to air-dry. No rinsing [or wiping] is required [(even on food contact surfaces)].



TO SANITIZE: 1. Wipe the surface [spray surface] [(spot test to check surface compatibility)].
2. Leave for 30 seconds. 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:}

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NEW! {can be present on label for 6 months from date of first sale}

Kills [over] [99][.99]% of [household] germs*[,] [naturally] [botanically] on hard, non-porous surfaces

All Purpose Cleaner
A Better Way to Clean

Daily [Strength] Cleaner: {This designation will only apply to the Basic formulation.}

Streak-Free Spray for quick cleaning

Weekly [Strength] Cleaner: {This designation will only apply to the Alternate formulation (spray).}

Power Spray for thorough cleaning and tougher stains

Monthly [Strength] Cleaner: {This designation will only apply to the Alternate formulation (foam).}

[Deep Cleaning] [Penetrating] [Foam for intensive cleaning and stubborn stains]

Controls [Eliminates] Odors [Deodorizer][Deodorizes]

Botanical

[Light][Herbal] [Lemon] [Lemongrass] [&Thyme] [Thyme] [&Herb] [Citrus] [Scent]

[Bouquet] [&Clove] [Spice]

Ready To Use [RTU]

[Hospital] Disinfectant

Decontaminant

Controls [Prevents] Cross-Contamination on treated surfaces

Kills Influenza A Virus [Flu][, including][the Pandemic 2009][H1N1][Influenza A virus][(formerly called swine flu)], Rhinovirus (type 37 [the Common Cold virus])

Virucidal against Influenza A [Flu], Rhinovirus (type 37 [the Common Cold virus])

Kills over 99.99[9]% of bacteria in 30 seconds! [on food contact surfaces]

Food Surface Contact Sanitizer

Kills over 99.99% of the EPA's designated test microorganisms for broad-spectrum claims of [hospital] disinfectant effectiveness.

Bactericidal [Bactericide][Antibacterial][Antimicrobial]

[Part of our] Botanical Cleaning & Disinfection Solution

[Cuts grease and grime]

Benefect is a [sensible,][no compromise] botanical disinfectant [cleaner] [formula].

Truth is, you don't actually need a different cleaning product for every room in your home. Benefect cuts through the dirt in your life and the clutter under your sink.

Inspired by how people really clean, we developed the Benefect [Daily-Weekly-Monthly {This designation will only apply to the appropriate formulations.}] system to make short work of most household chores: from quick cleanups on countertops and glass; to routine messes on tabletops and highchairs; to stubborn stains on stovetops and tiles.

Don't let the pleasant smell fool you; and kills [over] 99.9[9]% of household germs (especially Influenza A and E. coli). A patented botanical disinfectant made from essential oils, it will not harm hard non-porous surfaces.

We set out to find a better way to clean,[and we're pretty happy with the results.] [and we hope you are too.] We hope you will be too.

Master Label – Spray 84683-3 – November 13, 2009

A better way to clean
Contains non-VOC emitting [ingredients] [and fragrance] [botanical essential oils].
No fine print.
To learn more, visit www.cleanwelldaily.com

Daily [Strength] Cleaner *{This designation will only apply to this Basic formulation.}*: A streak-free spray for quick and easy cleaning throughout the home on countertops, vanities, tabletops, chairs, sinks, mirrors, appliances, toys, changing tables, highchairs, cribs, windows and more

Weekly [Strength] Cleaner *{This designation will only apply to this Alternate spray formulation .}*: A power spray for thorough cleaning throughout the home and tougher stains on sinks, countertops, glazed tiles, stovetops, toilet seats, floors and more.

Monthly Strength Cleaner *{This designation will only apply to this Alternate foam formulation .}*: A penetrating foam for intensive cleaning throughout the home and stubborn stains on floors, stoves, ovens, microwaves, sinks, toilet seats, bathtubs, showers and more.

- Cleans, disinfects and deodorizes.
- Disinfects while you clean.
- Clean and disinfect in one easy step.
- More clean. Less time.
- Tough on dirt, easy on you.
- Clean easy, breathe easy.
- A cleaner home in minutes.

SUITABLE FOR use on hard, non-porous surfaces in residential, commercial [insurance restoration][fire, water, sewage & trauma scene remediation] or medical applications, including:

- | | |
|-----------------------------------------------------------|-----------------------------|
| Health care facilities | Food preparation facilities |
| Hospitals | Nursing homes |
| Medical, veterinary & dental offices | Day care facilities |
| Health professional, chiropractic & physiotherapy clinics | Nurseries |
| Kitchens, cafeterias, food storage areas | Sickrooms |
| Schools | Fitness gyms, spas |
| Zoos, barns & kennels | Hotels & motels |
| | Restaurants & bars |

SUITABLE FOR use on all hard, non-porous surfaces where bacteria or unpleasant odors are a concern including:

- | | |
|-------------------------------------------------------------------------------------------|--------------------------------------------|
| Countertops, Tables, | Food preparation surfaces |
| Pet habitats | Toilet seats |
| Sports equipment such as jock cups & helmets | Garbage cans |
| Children's toys | Highchairs |
| Remediation equipment & PPE (Personal Protective Equipment) | Changing tables |
| Sinks, Fixtures | |
| Non-porous construction materials such as water damaged [sewage contaminated] sheet metal | Boat, train & airplane surfaces & cavities |
| Floors, walls | Shoes & boot soles |
| Prostheses & orthotics | |
| Cabinets, Door knobs & handles | |

Effectively controls odors [produced by these microorganisms on non-porous surfaces].

Effectively [controls][eliminates] odors produced by odor causing bacteria, fungi & other odor-causing organisms [on concrete, finished woodwork, wood framing & studding, trim, bedding, mattresses, textiles, upholstered furniture, carpets, pads & subfloors].

Effectively [controls][eliminates] odors on concrete, finished woodwork, wood framing & studding, trim, bedding, mattresses, textiles, upholstered furniture, carpets, pads & subfloors.

Cleans and disinfects hard non-porous surfaces throughout the home.