

84683-3

1098



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 15 2011

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J Michael Kelley, PhD
Agent for OhSo Clean Inc
c/o toXcel
Toxicology & Regulatory Affairs
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, Va 20156

Subject:
EPA Registration No.84683-3
Application Date: January 24, 2011
Receipt Date: January 24, 2011

Dear Dr. Kelley,

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

Proposed Notification:

Adding optional icon "TO-GO" to master label for the CleanWell Company products.

General Comment:

Based on a review of the material submitted, the notification as referenced above is acceptable. A copy has been placed in our files for this product.

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 Glen McLeod by telephone at (703) 347-0181 or by e-mail at mcleod.glen@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,

Handwritten signature of Jacqueline Campbell-McFarlane
Jacqueline Campbell-McFarlane

CONCURRENT
Assistant Manager (34)

Regulatory Management Branch II
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

2098



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 Jacqueline Campbell-McFarlane	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. 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.)
Label notification for *Benefect® Botanical Daily Cleaner Disinfectant Spray* EPA Reg. No. 84683-3 to add optional icon (TO-GO) to the EPA stamped-accepted label (December 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:				2. Type of Container	
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	<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			
100/30ml; 6/390ml; 4/4000ml		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 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) 703-754-0248
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 January 24, 2011	

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

January 24, 2011

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 – Additional Optional Icon on Label for *Benefect® Botanical Daily Cleaner Disinfectant Spray* EPA Reg. No. 84683-3

Dear Jacqueline Campbell-McFarlane:

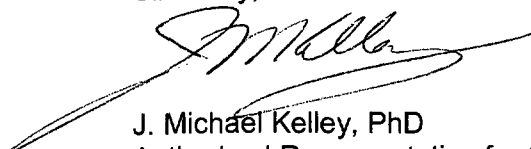
On behalf of OhSo Clean, Inc. of San Francisco, California, we are submitting this notification to add the optional icon "TO-GO" to the above referenced product label. The icon is an option to be used in conjunction with the existing label language and describes the size of the package the product is distributed in. The labels included with this submission are representative of a typical State final printed label and do not reflect all of the language found on the current EPA stamped-accepted master label. No other changes have been made to the label that was stamped-accepted by EPA on December 10, 2009.

The following documents are enclosed:

- 1) EPA Form 8570-1
- 2) One copy of the final printed state label with the additional icon

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

[Faint, illegible text, possibly a stamp or bleed-through]

{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.}

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).}]

[Caution]
Keep Out of the Reach of Children

NOTIFICATION
Date Reviewed: 2/11/11
Reviewed By: [Signature]

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)].

5098

TO SANITIZE: 1. Wet 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.

6028

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

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]



{This icon is optional and will only appear on the 30 ml container}

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.

Master Label – Spray 84683-3 – 20110201

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.

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 | |

Prostheses & orthotics
Cabinets, Door knobs & handles

Shoes & boot soles

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.