

84683-3

06/22/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUN 22 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J. Michael Kelley, Ph.D., Authorized Representative for
OhSo Clean, Inc.

ToXcel Toxicology & Regulatory Affairs
P.O. Box 363
Gainesville, VA 20156 USA

Subject: Response to Agency Letter dated May 15, 2009
Benefect® Botanical Daily Cleaner Disinfectant Spray
EPA Registration Number: 84683-3
Application Date: May 26, 2009
Receipt Date: May 26, 2009

Dear Dr. Kelley:

The alterations that you have made to your product labeling as a result of an Agency letter, dated May 15, 2009, are acceptable.

Proposed Notification:

Corrections made to submitted label as result of an Agency letter.

General Comments:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6415 or by e-mail at lantz.tracy@epa.gov or Killian Swift of my staff by telephone at (703) 308-6346 email address at: swift.killian@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 yours,

Lisa McKelvin

for Tracy Lantz
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section 1

1. Company/Product Number 84683-3	2. EPA Product Manager Tracy Lantz (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

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>May 15, 2009</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

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

Response to deficiency letter dated May 15, 2009, which addresses the April 22, 2009 Notification per PR Notice 98-10. Revision of the storage and disposal statement on the label in compliance with the May 15, 2009 deficiency letter.

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
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container 100/30ml; 6/390ml; 4/4000ml	If "Yes" Unit Packaging wgt. No. per Container	<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 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
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 26, 2009	

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{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.}

[A Better Way to Clean]

NOTIFICATION
Date Reviewed: 6/22/09
Reviewed By: KS

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).}]

[with Ingenium™]

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

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

All Purpose [Anti-Bacterial] Cleaner [+] [Disinfectant]

[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]

Botanical

[Herbal] [Lemon] [Lemongrass] [&Thyme] [Thyme] [&Herb] [Citrus] [Scent] [Bouquet]
[&Clove] [Spice]

Ready To Use [RTU]

Disinfectant

Decontaminant

Kills Influenza A Virus [Flu] [Virucidal against Influenza A [Flu]]

Bactericidal

[Part of our] Sustainable Botanical Cleaning & Disinfection Solution

[Cuts grease and grime] [with the best of them]

[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

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

[Benefect is [a] [an] [advanced] [sensible, no compromise] botanical disinfectant cleaner [formula]. *The patented technology is proven to] *Kill[s] [over] 99.9[9]% of household germs, [specifically]: Influenza A, Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, and Escherichia coli [on hard, non-porous, inanimate surfaces]. [Tested in the presence of 5% organic soil load].

[Truth is, you don't actually need a different cleaning product for every room in your home. Benefect with Ingenium 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). And with Ingenium, 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.]

[Benefect.] [A better way to clean] [Part of a sustainable solution.] [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.]

[Effectively controls odors [produced by these microorganisms on non-porous surfaces]. Made from botanically pure plant extracts [with pleasant] [aromatic], vapors.]

SUITABLE FOR use on hard, non-porous surfaces in residential and commercial 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 | Restaurants & bars |
| Schools | Fitness gyms, spas |
| Zoos & kennels] | Hotels & motels |

{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.]

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

- | | |
|---|--------------------------|
| Countertops | Walls |
| Food preparation surfaces | Toilet seats |
| Pet habitats | Garbage cans |
| Children's toys | Highchairs |
| Floors | Boat surfaces & cavities |
| Changing tables | Prostheses & orthotics |
| Sports equipment such as jock cups & helmets | Sinks |
| Non-porous construction materials such as water damaged sheet metal | |

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.

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

[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: 1. Wet the surface [spray surface] [(spot test to check surface compatibility)]. 2. Leave for 10 minutes. Allow to air-dry. No rinsing or wiping is required, except on direct food contact surfaces which require a potable water rinse after treatment.

STORAGE/DISPOSAL: Nonrefillable container. ~~[Leave containers out for convenient & easy access.]~~ Store airtight at room temperature. ~~[Waste resulting from the use of this product may be poured down the drain. No special handling is required.]~~ Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash. Please recycle empty container.