

84683-3

11-10-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

NOV 10 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J. Michael Kelley, PhD
Authorized Representative for OhSo Clean, Inc.
Toxcel
Toxicology & Regulatory Affairs
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

Subject: **Benefect® Botanical Daily Cleaner Disinfectant Spray**
EPA Registration Number: 84683-3
Application: June 19, 2009
Receipt Date: June 19, 2009

Dear Mr. Kelley:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendments

- Revised labeling
- Basic CSF (Daily) dated 10/7/09 and Alternates CSFs (Daily Alt 1, Daily Alt 2 and Weekly/Monthly) dated 10/13/09.

General Comments

The revised basic CSF (Daily) dated 10/7/09 supersedes all previously accepted Basic formulas. Copies of the Alternates CSFs (Daily Alt 1, Daily Alt 2 and Weekly/Monthly) dated 10/13/09 have been inserted in your file for future reference.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped label is enclosed for your records.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: carlisle.sharon@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email address at: mckelvin.Lisa@epa.gov.

Sincerely,



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

Enclosed: Stamped label

{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.}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 84683-3

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

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, 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. 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/DISPOS : 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;}

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], 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.

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

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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.

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

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

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