7/20/2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Dr. J. Michael Kelley, Ph.D Representative for OhSo Clean, Inc. P.O. Box 363 7140 Heritage Village Plaza Gainesville, VA 20156

JUL 20 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Subject: Benefect Botanical Daily Cleaner Disinfectant Spray EPA Registration No.: 84683-3 Application Date: 05/20/2011 Receipt Date: 05/20/2011

Dear Dr. Kelley:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

• Optional "CleanWellTM Inside" logo and scent stickers

Conditions

Revise the label as follows:

- 1. Delete the terms "botantically derived" when describing the product, the fragrance or its actions like disinfection because they are false and misleading. Note you may state that the active ingredient is botantically derived.
- 2. Delete the terms "essential oils" on page 3 and 4. This is false and misleading.

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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 <u>campbell-mcfarlane.jacqueline@epa.gov</u> or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at <u>carl.jaclyn@epa.gov</u>.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

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Sincerely,

Jacqueline Mcgarlane Product Manager (34) Regulatory Management Branch II Antimicrobials Division (7510P)

{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).*}] ACCEPTED with COMMEN EPA Letter De-JUL 2 0 2011

[Caution] Keep Out of the Reach of Children

Under the Federal Insection Fungicide, and Rodentics amended, for the pesticide registered under EPA Reg. No.

Active Ingredients:	84683-3
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. 315 Pacific Avenue San Francisco, CA 94111

*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. 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)].

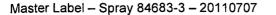
STORAGE/DISPOSAL: Nonrefillable container. Store airtight at room temperature. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash.

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{Optional &/or interchanged 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* 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]

Botanically-Derived Active Ingredient

[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 germs* for broad-spectrum claims of [hospital] disinfectant effectiveness.

Bactericidal [Bactericide][Antibacterial][Antimicrobial]

Part of and Dotanically Drived Cleaning & Disinfection Solution

[Cuts grease and grime]



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

Benefect is a botanically derived disinfastiont folgener] [fermulation

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 [botanically-derived].disinfector 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 wo.] We hope you will be too. A better way to clean Contains non-VOC emitting [ingredients] [and fragrance] [essential oils]. No fine print. To learn more, visit <u>www.cleanwelldaily.com</u>

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 nare facilities	Food, preparation, facilities
Hospitals	Nursing homes
Medical, veterinary & dental offices	Day care facilities
Health professional, chiropractic &	Nurseries
physiotherapy clinics	Sickrooms
Kitchens, cafeterias, food storage areas	Fitness gyms, spas
Schools	Hotels & motels
Zoos, barns & kennels	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)		
	Sinks, Fixtures	Changing tables
Non-porous construction materials such as water damaged [sewage contaminated] sheet metal		
	Floors, walls summer and the second s	 Boat, train & airplane surfaces & cavities
	Prostheses & orthotics	Shoes & boot soles
	Cabinets, Door knobs & handles	

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.

 $CleanWell^{TM}$ Inside



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