

84683-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAR 25 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

J. Michael Kelley, Ph. D
Vice President
ToXcel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20155

Subject: **Benefect Broad Spectrum Disinfectant**
EPA Registration Number: 74771-1
Application Letter Dated: December 22, 2006
Receipt Date: December 29, 2006

Dear Mr. Kelley:

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

Proposed Amendment:

Label revision in conjunction with petition # 6F7147 to establish an Exemption from the requirement of a Tolerance (as present in thyme oil).

- Deleted "potable water rinse" from the label

Label Deficiencies:


1. The registration no. must be changed from 74771-1 to 84683-1.
2. Remove "Kills 99.9% of Germs" on the front panel and page 2 of the label. This is a quantitative claim used for sanitizing claims not disinfection.
3. Product is not a sanitizer, therefore all food preparation, kitchens, cafeterias and food storage areas must be removed from the label unless areas are identified to be treated.
4. *Salmonella choleraesuis* must be changed to *Salmonella enterica*.
5. Change "Effectively controls odors produced by these microorganisms....." to read "Effectively controls odors produced by odor causing bacteria."
6. Floors and walls on page 2 must be removed unless the hard non-porous material is identified in these surfaces.
7. Add ATCC identification numbers to your microorganisms listed.

8. On the front panel, remove/clarify "Refill." Please refer to PR Notice 2007-4 for refillable container language.
9. 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.

General Comment:

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8583 or email address at: mitchell.emily@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email address at: mckelvin.lisa@epa.gov

Sincerely,



Emily Mitchell
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Label

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

Benefect® Broad Spectrum Disinfectant

[Kills 99.99% of Germs]
Controls Odors
Botanical
Lemon [& Clove] [Spice] Scent
Ready To Use
Refill
Hospital Disinfectant
Instrument PreSoak
Decontaminant
Disinfectant Cleaner
[5 minute] Tuberculocide [Tuberculocidal [in 5 minutes]]
Fungicide [Fungicidal]
*Virucidal

[Caution]
Keep Out of the Reach of Children

Active Ingredient:
Thymol (present as a component of Thyme Oil)0.23%
Inert Ingredients:99.77%
Total.....100%

EPA Reg. No. 74771-1 ^{→ transferred} EPA Est. No. 075840-CAN-001
Net Contents _____

Patented Internationally
Sensible Life Products (div of LBD Ltd)
34-7 Innovation Dr. ON, CA L9H 7H9
(800) 909-2813
www.Benefect.com
TerraChoice.com

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 25 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. 84683-1

Beneffect is the first botanical disinfectant cleaner. *The patented technology is proven to kill over 99.99% of bacteria including Salmonella choleraesuis, Staphylococcus aureus, Pseudomonas aeruginosa & Mycobacterium bovis (TB), fungi including Trichophyton mentagrophytes (the Athlete's Foot fungus) & HIV-1 (the AIDS virus) on hard, non-porous, inanimate surfaces. Effectively controls odors produced by these microorganisms on non-porous surfaces. Made from botanically pure plant extracts with pleasant aromatherapeutic vapors. No synthetic fragrances, dyes, ammonia or chlorine.

SUITABLE FOR use on hard, non-porous surfaces in residential, 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 |
| Restaurants & bars | Kitchens, cafeterias, food storage areas |
| Fitness gyms, spas | Schools |
| Hotels & motels | Zoos & kennels. |

SUITABLE FOR use on all hard, non-porous surfaces, including:

- | | |
|---|--------------------------|
| Countertops | Sinks |
| Food preparation surfaces | Toilet seats |
| Pet habitats | Garbage cans |
| Children's toys | Highchairs |
| Changing tables | Prostheses & orthotics |
| Sports equipment such as jock cups & helmets | Walls |
| Floors | Boat surfaces & cavities |
| Non-porous construction materials such as water damaged sheet metal | |
| Any other non-porous surface where bacteria or unpleasant odors are a concern | |

SUITABLE FOR control and inhibition of odors caused by bacteria, fungi & other odor-causing organisms.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labelling.

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 contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane 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.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURRFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids, are disposable latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood & other body fluids must be thoroughly cleaned from surfaces & objects before application of the disinfectant.

Disposal of Infectious Material: Blood & other body fluids should be autoclaved & disposed of according to federal, state & local regulations for infectious waste disposal.

Contact time: Leave surface wet for 10 minutes.

Pre-clean surfaces to remove soil prior to disinfection.

TO CLEAN: 1. Shake, apply product & wipe away.

TO DISINFECT: 1. Shake well and wet the surface with the spray (test for surface compatibility on inconspicuous area first). 2. Leave for 10 minutes at room temperature; allow to air-dry. No rinsing or wiping is required.

Storage / Disposal: Store airtight at room temperature. Recycle empty container.