



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 13, 2004

J. Michael Kelley, Ph. D.
toXcel, The agent for
Sensible Life Products
7545 Presidential Lane
Manassas, VA 20109

Subject: **Benefect Life products**
EPA Registration No. 74771-1
Application Date: October 6, 2004
Receipt Date: October 7, 2004

Dear Dr. Kelley:

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

Proposed amendment:

- Revised labeling:

Conditions:

The following label revisions must be made:

1. Delete the word "New" from the label. This product has been registered longer than six (6) months.
2. Since this product can be used in health care facilities, e.g., "Medical applications, including Health Care.", the following statement must be added to the label:

"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 human body, either into or 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."

Refer to PR Notice 94-4 for detailed information.

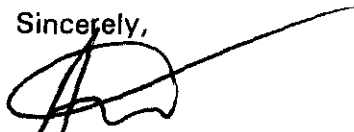
3. With respect to the term "Health Care," the label must be more specific as to the type of health care facilities, e.g., hospitals, nursing homes, etc. that this product will be used in.

General Comments:

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

enclosure:

{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.}

[Shake Well]

Benefect is the first Botanical disinfectant cleaner. The patented technology is proven to kill over 99.99% of bacteria (Salmonella choleraesuis, Staphylococcus aureus & Pseudomonas aeruginosa) on hard, non-porous, inanimate surfaces & to control odors produced by these microorganisms. Made from botanically pure plant extracts with pleasant aromatherapeutic vapors. No synthetic fragrances, dyes, ammonia or chlorine.

SUITABLE FOR use in residential, commercial or medical applications, including health care & food preparation facilities, 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, construction materials such as water damaged sheet metal, walls, floors, boat surfaces & cavities & *any other surface where bacteria or unpleasant odors are a concern.*

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

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; allow to air-dry, **no rinsing or wiping is required**, except on direct oral, skin or food contact surfaces which require a potable water rinse after treatment (e.g. baby toys, prostheses liners & food contact surfaces).

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



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EPA Reg. No. 74771-1
EPA Est. No. 075840-CAN-001
Patented Internationally
Sensible Life Products (div of LBD Ltd)
34-7 Innovation Dr. ON, CA L9H 7H9
800-909-2813 www.ControlGerms.com

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT 13 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 74771-1

[NEW!]

Benefect[®]

Broad Spectrum Disinfectant

[Kills 99.99% of Bacteria]

[Controls Odors]

[Botanical]

[Lemon & Clove [Spice] Scent]

[Refill]

Net Contents ____ fl. oz.

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

Caution

Keep Out of the Reach of Children