

706-65

06/26/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 26 2003

Mr. Ronald Cepa
Claire Manufacturing Company
500 Vista Avenue
Addison, IL 60101

Subject: Claire Disinfectant Bathroom Cleaner
Amendment Date: March 31, 2003
EPA Receipt Date: April 2, 2003

Dear Mr. Cepa,

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

- Update label per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Since this product is effective against *Candida albicans*, appropriate mold and mildew directions must be added to the label stating "*This product effectively controls the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Apply by holding can upright 6" to 8" from surface to be treated. Spray as to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.*"
2. Since this product is effective against *Trichophyton mentagrophytes*, add the following "Fungicidal" directions by stating "*This product demonstrates effective fungicidal activity against pathogenic fungi, Trichophyton mentagrophytes, in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, or clean hard, nonporous surfaces commonly contacted by barefeet. Follow disinfection directions.*"

General Comments

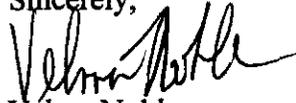
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NEW LABEL

JUN 26 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 706-65



DISINFECTANT BATHROOM CLEANER



Disinfects
HIV-1 (AIDS Virus), Influenza A2/JapanVirus and
Herpes Simplex Virus Types 1 and 2
on Hard Inanimate Nonporous Environmental Surfaces

For Use in Homes and Other Residential Dwellings,
Hospitals, Nursing Homes, Clinics, Medical Facilities, Businesses,
Hotels, Motels, Restaurants, Schools, Institutions and Commercial Establishments

ANTIBACTERIAL
Kills Common Kitchen Germs
Bactericidal *Virucidal Fungicidal

Cleans and Deodorizes
Spray and Wipe Shining Clean

ACTIVE INGREDIENTS:

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride..... 0.115%
n-alkyl (50% C12, 30% C14, 17% C16, 3% C18) dimethyl ethylbenzyl ammonium chloride..... 0.115%

OTHER INGREDIENTS.....
99.770%

Total 100.000%

EPA Reg. No. 706-65

EPA Est. 706-IL-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements

NET WT. ___ OZ. / ___ GRAMS

Needs no rinsing

KILLS: *Candida albicans*, *Escherichia coli*, *Klebsiella pneumoniae*, *Penicillium pinophilum*, *Penicillium variable*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Trichophyton mentagrophytes*, Vancomycin-resistant *Enterococcus faecalis*, *Adenovirus Type 2, *Herpes Simplex Virus Types 1 and 2, *Influenza A2/Japan Virus and Vaccinia (Poxvirus) on hard, inanimate, non-porous environmental surfaces.

DISINFECTS: Acts as a disinfectant on hard, non-porous environmental surfaces as toilet seats, fixtures, glazed tile, wash bowls, shower stalls, walls, finished woodwork and countertops. The easy way to clean, disinfect and deodorize. Spray and wipe clean. Cleans and disinfects without scouring or scratching. Use in nursery and sickroom, for garbage and diaper pails, for any washable hard, non-porous environmental surface that needs disinfecting as you clean.

DIRECTIONS FOR USE

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

TO CLEAN AND DEODORIZE: Remove all gross filth or heavy soil from surfaces to be treated prior to using this product. **SHAKE WELL BEFORE EACH USE.** Point valve opening toward area to be cleaned, press down firmly and spray evenly. Wipe clean with a dry cloth, turning frequently.

TO DISINFECT: After surface is cleaned, hold can upright 6" to 8" from surface to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping.

When used as a disinfectant on food contact surfaces such as counter tops, tables, and appliances, wash surfaces thoroughly with a potable water rinse. Do not use on utensils, dishes, or glasses.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV) (associated with AIDS):

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

Personal Protection: When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks or eye coverings.

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

Contact Time: Spray surface to be treated 3-4 seconds, from a distance of 6-8 inches, until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping.

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

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/high-level disinfection.

Storage: Store in a cool, dry place (preferably locked) inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition.

Disposal: Replace cap, wrap container in several layers of newspaper and dispose in trash collection. Do not incinerate or puncture.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth, if possible.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
<p>Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-228-5635 for emergency medical treatment information.</p>	

{Note: The grid format for the First Aid statements will be used if market label space permits; otherwise, a paragraph format will be used.}

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near fire, sparks or heated surfaces. Do not store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F (49°C) may cause bursting. Incineration of container may cause explosion.

A Product of:
Claire Manufacturing Company
 500 Vista Avenue
 Addison, IL 60101

{ } = indicates language that does not appear on market labeling

