

498-179

3-17-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

March 17, 2003

Ms. Aludia B. Hernandez
Technical & Regulatory Compliance Manager
Chase Products Co.
P.O. Box 70
Maywood, IL 60153

Subject: Champion SprayOn Spray Disinfectant Formula 3
EPA Registration Number 498-179
Application Dated October 3, 2002

Dear Ms. Hernandez:

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

- efficacy data to support new label claims

General Comments:

The submitted confirmatory efficacy data (MRID # 457776-01) Product Test Method 15th edition is supportive of the product test batches #1 (Mx#7-9761) and batch #1 (Mx#7-9761) surface disinfectant for hard nonporous inanimate surfaces against Enterococcus facialis Vancomycin Resistant (ATCC 51299)(VRE), with a pressurized solution (Ready-to-Use) for previously, cleaned, hard non-porous inanimate surfaces which are thoroughly spray with a pressurized solution 6 inches from the surface and allowed to remain wet for an exposure time of at least 10 minutes in a single application.

CONCURRENCES

| SYMBOL | | | | | | | | |
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| SURNAME | | | | | | | | |
| DATE | | | | | | | | |

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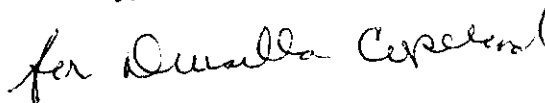
Labeling Comments:

1. On the middle of back panel, after the microorganism *Salmonella choleraesuis*, revise the statement "on hard, nonporous, surfaces in 20 seconds" to read "on precleaned hard, nonporous, surfaces for 20 seconds".
2. On the back panel, under the fungicidal directions, revise the statement it is also effective against fungi such as *Trichophyton interdigitale* (caused of ringworm or athlete's foot) in appropriate areas such as shower room floors, locker room benches or bathe mats" to read, "it kills tricphyton interdigitilae (athlete's foot fungi) on hard, nonporous inanimate surfaces in appropriate areas such as shower room floors, locker room benches or bath mats".
3. Delete the wording "causes of ringworm". As per Pesticide Assessment Guidelines (Subdivision H), only claims for controlling cross-contamination or the causative agent in/or on hard inanimate surfaces are permitted.

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,



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

Enclosure

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FRONT PANEL

CHAMPION SPRAYON

SPRAY DISINFECTANT FORMULA 3

*Kills 99.9%
of germs (sanitizing)
in 20 seconds**

- KILLS MOST GERMS
- ELIMINATES ODORS
- PREVENTS MOLD AND MILDEW

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD AND BODY FLUIDS.

KILLS-STAPHYLOCOCCUS AUREUS, SALMONELLA CHOLERAESUIS, PSEUDOMONAS AERUGINOSA, STREPTOCOCCUS PYOGENES AND VANCOMYCIN RESISTANT ENTEROCOCCUS FAECALIS (VRE).

NET WT. XX OZ. (X LB. XX OZ.) XXX g

OPTIONAL:
Contains no CFCs or other ozone depleting substances
Federal regulations prohibit CFC propellants in aerosols

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 17 2003

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See precautionary statements on back of can.

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

498-179

BACK PANEL

**FORMULATED FOR HOSPITAL • SCHOOL • HOTEL • MOTEL
• OFFICE • RESTAURANT • LOCKER AND REST ROOM
• FACTORY • INSTITUTION • HOME • BEAUTY SHOP • BARBER SHOP**

SPRAY DISINFECTANT • SHAKE BEFORE USING

DIRECTIONS FOR USE

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

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

**Sanitizes: Kills 99.9% Staphylococcus aureus (staph), Klebsiella pneumoniae (K. pneumoniae), Escherichia coli, Campylobacter jejuni and Salmonella choleraesuis on hard, nonporous surfaces in 20 seconds.*

Kills HIV-1 (AIDS VIRUS) on precleaned environmental surfaces/objects previously soiled with blood and body fluids.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS on precleaned environmental surfaces/objects 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 HIV.

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.

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.

CONTACT TIME: Leave surface wet for 10 minutes.

After surface is cleaned, hold can upright and spray 6 to 8 inches from surface to be treated until surface becomes wet. Allow spray to dry without wiping, or allow spray to contact treated surface for a minimum of 10 minutes prior to wiping.

FOR DISINFECTION OF INANIMATE SURFACES

This disinfectant spray is a germicidal that kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Streptococcus pyogenes and Vancomycin Resistant Enterococcus faecalis (VRE). Use to disinfect urinals, toilet seats, washbowls, shower stalls, telephones, empty hampers, diaper pails, athletic equipment, light switches, garbage cans and lockers.

DIRECTIONS: Clean object to be sprayed using usual cleaning methods. Hold dispenser upright and spray 6 inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off.

It is also effective against fungi such as Trichophyton interdigitale (causes of ringworm or athlete's foot), in appropriate areas such as shower room floors, locker room benches or bath mats.

FOR SANITIZING INANIMATE, NON-FOOD CONTACT SURFACES

Use to sanitize inanimate, hard, nonporous, non-food contact surfaces.

DIRECTIONS: Clean object to be sprayed using usual cleaning methods. Hold dispenser upright and spray 6 inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 20 seconds before wiping off.

FOR CONTROL OF MOLD & MILDEW

Prevent mold and mildew on hard surfaces such as ceramic, metal and glass, in basement closets, attic storage areas, summer cottages.

DIRECTIONS: Clean object by usual cleaning methods. Hold dispenser upright and spray 6 inches from surface until surface is wet. Repeat application when new growth appears.

FOR SPACE DEODORIZER & AIR FRESHENER

Use to deodorize meeting room, classroom, kitchen, bathroom, sickroom, living room and churches.

DIRECTIONS: Hold can upright and point valve opening away from face. Spray upward for 3 seconds into corners as well as center of room, filling room with mist.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

CAUTION

May cause eye irritation. Avoid contact with the eyes and skin. Avoid breathing of spray mist. Avoid contamination of foodstuff.

FIRST AID

IF IN EYES: 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. 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.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. DO NOT PUNCTURE. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw container into fire or incinerator. Do not spray on varnished, painted or plastic surfaces.

STORAGE & DISPOSAL

STORAGE: Store in a cool, dry area away from heat or open flame.

DISPOSAL: Do not reuse empty container. This container may be recycled in one of the limited number of aerosol recycling centers in the country. Before recycling, empty the can by using the product according to the label. DO NOT PUNCTURE! If recycling is not available, wrap the container and discard in the trash.

THE USER OF THIS PRODUCT ASSUMES ALL RISKS OF USE, STORAGE AND HANDLING NOT IN ACCORDANCE WITH ITS DIRECTIONS AND CAUTIONS.

ACTIVE INGREDIENTS:

- n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
- dimethylbenzyl ammonium chloride..... 0.1%
- n-Alkyl (68% C12, 32% C14)
- dimethyl ethylbenzyl ammonium chloride..... 0.1%
- Ethanol.....30.8%

OTHER INGREDIENTS: 69.0%

Total 100.0%

CONTAINS SODIUM NITRITE

EPA Reg. No. 498-179-XXXXX

EPA Est. No. 498-IL-1

KEEP OUT OF REACH OF CHILDREN

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[OPTIONAL: Questions about this product? Call (708) 865-1000.
MEDICAL INFORMATION ONLY:
Chem-Tel, Inc. (800) 255-3924]

[OPTIONAL RECYCLE SYMBOL]

[OPTIONAL MADE IN USA GRAPHIC]

[OPTIONAL UPC SYMBOL]

Chase Products Co.
Putting the best at your fingertips.®
P.O. Box 70 - Maywood, IL 60153
www.chaseproducts.com

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BOTTOM OF LABEL
