

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 22, 2003

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

Subject:

Spraypak Disinfectant/Lubricant

EPA Registration No. 498-194

Application dated February 11, 2003

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

Additional label claim

Efficacy Review

The efficacy data (MRID # 458628-01) demonstrated effectiveness of this product as a disinfectant against Vancomycin Resistant *Enterococcus faecalis*, ATCC #51299 when product is sprayed directly on hard, non-porous surfaces at a distance of 6-8 inches, and the surfaces remain wet for an exposure time of 10 minutes.

Label Comments

1. The signal word "Warning" and the "Keep Out of Reach Of Children" statement must be placed under the ingredient statement. Note that the ingredient statement is normally required to be listed on the front panel of the label.

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- 2. Add the subheading "Physical or Chemical Hazard" above the statement EXTREMELY FLAMMABLE. Contents under pressure do not use or store your heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
- 3. In the directions for disinfection of inanimate surfaces, delete the word "POWERFUL" from the directions. The word Powerful is an implied heighten efficacy claim.
- 4. Expand the subheading to read:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by the use, storage or disposal of this product

PESTICIDE STORAGE: PESTICIDE DISPOSAL: CONTAINER DISPOSAL:

General Comment

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely

Adam Heyward

Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosure

SPRAYPAK

SPRAY DISINFECTANT/LUBRICANT

DISINFECTS • CLEANS • COOLS • LUBRICATES • PREVENTS RUST

Virucidal* Tuberculocidal Fungicidal Staphylocidal Pseudomonacidal

[Optional: Chase/Other Care Tip: Oil blade after every use for increased effectiveness.]

KILLS STAPHYLOCOCCUS AUREUS, SALMONELLA CHOLERAESUIS, PSEUDOMONAS AERUGINOSA, STREPTOCOCCUS PYOGENES, MYCOBACTERIUM BOVIS (BCG), TRICHOPHYTON MENTAGROPHYTES, INFLUENZA A/(HON1) ATCC VR-95, INFLUENZA B/(H₂N₂)(ARUP), HERPES SIMPLEX I, HERPES SIMPLEX II AND VANCOMYCIN RESISTANT ENTEROCOCCUS FAECALIS (VRE) ON INANIMATE SURFACES.

[OPTIONAL NO-CFCs GRAPHIC]

NET WT. XX OZ. (XXX g)

KEEP OUT OF REACH OF CHILDREN WARNING

See precautionary statements on back of can.

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUL 2 2 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 498-194

BACK PANEL

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

Meets AOAC germicidal spray products test standards for hospital disinfectants.

(LOGO) SPRAY DISINFECTANT/LUBRICANT

For use by hair stylists, barbers, animal groomers and veterinarians.

DISINFECTS AND LUBRICATES HAIR CLIPPERS: Acts as a virucide, fungicide, bactericide and tuberculocide. Leaves a light lubricating film on clipper blades that reduces friction, smooths the clipping action and prolongs the effective life of the blade.

COOLS HAIR CLIPPERS: Turn the clipper off occasionally during use to spray the blade and teeth. The lubricating aerosol sprays away hair, dandruff and dust particles, and cools the metal.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS KEEP OUT OF REACH OF CHILDREN

WARNING

Causes eye irritation. Do not get in eyes. Avoid contact with skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ATTENTION: This product contains o-phenylphenol, a chemical known to the State of California to cause cancer in accordance to Proposition 65 (State of California Safe Drinking Water and Toxic Enforcement Act of 1986).

PHYSICAL HAZARDS

EXTREMELY FLAMMABLE. Contents under pressure. Do not use or store near heat or open flame. DO NOT PUNCTURE OR INCINERATE CONTAINER. Exposure to temperatures above 130°F may cause bursting.

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.

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 powerful germicidal that kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Streptococcus pyogenes, Mycobacterium bovis (BCG) and Vancomycin Resistant Enterococcus faecalis (VRE).

It also kills viruses and fungi on hard, nonporous inanimate surfaces. *Viruses: Influenza A/(HON1) ATCC VR-95, Influenza B/(H₂N₂)(ARUP), Herpes Simplex Type 1 and Herpes Simplex Type 2. Fungi: Trichophyton mentagrophytes (athlete's foot).

Use to disinfect inanimate environmental surfaces, urinals, toilet seats, washbowls, shower stalls, telephones, empty hampers, diaper pails, athletic equipment, light switches, garbage cans, lockers, under sinks, kitchens, sickrooms, pet areas and other places where odor-causing germs are a problem.

TO CLEAN: Clean object to be sprayed using usual cleaning methods.

DIRECTIONS TO DISINFECT: Hold dispenser upright and spray 6 to 8 inches from precleaned surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off. Repeat application as necessary.

DIRECTIONS FOR DISINFECTION OF HAIR CLIPPERS: After each use, clean clipper blades to remove hair and other organic soil. With clipper turned off, hold dispenser upright 6 to 8 inches from blades. Spray teeth of clipper blades until wet. Keep surface wet for 10 minutes. Allow to air dry. Between full applications, spray clipper to cool blades and blow away stray hairs. Use regularly to keep blades lubricated.

FOR CONTROL OF MOLD & MILDEW: Controls mold and mildew on hard surfaces such as ceramic, metal and glass in basement closets, attic storage areas, summer cottages.

TO CLEAN: Clean object to be sprayed by usual cleaning methods.

DIRECTIONS TO CONTROL MOLD & MILDEW: Hold dispenser upright and spray 6 to 8 inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off. Repeat application when new growth appears.

FOR SPACE DEODORIZER & AIR FRESHENER: Use to deodorize meeting room, classroom, kitchen, bathroom, sickroom, living room and churches.

Eliminates unpleasant odors in the air, including cooking and bathroom odors, without heavy perfume. Actually eliminates odors by neutralizing them.

DIRECTIONS TO DEODORIZE: 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.

DO NOT USE ON POLISHED WOOD FURNITURE OR RAYON FABRICS.

STORAGE: Store in a cool, dry area away from heat or open flame. Do not contaminate water, food or feed by the use, storage or disposal of this product.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! **If empty:** Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

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

ACTIVE INGREDIENTS:

O-Phenylphenol	*************	0.1%
Ethanol		
OTHER INGREDIENTS:	*************	36.7%
	Total	100.0%

EPA Reg. No. 498-194

EPA Est. No. 498-IL-1

[OPTIONAL CHEM-TEL NO.]

[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

BOTTOM OF LABEL	