

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 18 1997

Chase Products Co.
The Quality First Company
P. O. Box 70
Maywood, IL 60153

Attention: Ms. Aludia B. Hernandez
Technical & Regulatory
Compliance Manager

Subject: SprayPak Spray Disinfectant Formula 2
EPA Registration Number 498-134
Label amendment to include efficacy claim against TB
bacteria dated June 23, 1997

The supporting efficacy data for a minor formulation change by increasing ethanol content from 55% to 63.2% for the effectiveness against Mycobacterium bovis (BCG) have completed review. The following comments are a result of this review.

The submitted efficacy data by the Modified AOAC TB test appear acceptable to support effectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) when sprayed as an undiluted pressurized spray on pre-cleaned hard, non-porous surfaces for a contact time of 10 minutes at room temperature (20-25 C).

Proposed Labeling

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy is enclosed for your records.

- a. The claim "Virucidal" must be keyed by a symbol to the paragraph listing the tested viruses.
- b. Under the heading "Directions to Disinfect" revise the statement "Hold dispenser upright and spray 6 to 8 inches from surface..." to read "Hold dispenser upright and spray 6 to 8 inches from pre-cleaned surface..."

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

-2-

- c. Change "Mycobacterium tuberculosis" to read "Mycobacterium bovis (BCG)".
- d. Specify the strain of Influenza B virus.

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,

Portia M. Jenkins
Acting Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:

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FRONT PANEL
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SPRAYPAK
SPRAY DISINFECTANT
FORMULA 2

Virucidal Tuberculocidal
Fungicidal Staphylocidal
Pseudomonacidal

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,
MYCOBACTERIUM TUBERCULOSIS, TRICOPHYTON MENTAGROPHYTES,
INFLUENZA A/PUERTO RICO, INFLUENZA B/CLINICAL ISOLATE,
HERPES SIMPLEX I AND HERPES SIMPLEX II ON INANIMATE SURFACES.

[GRAPHIC DESIGN SIMILAR TO LYSOL]

KILLS GERMS
ELIMINATES ODOR
CONTROLS MOLD AND MILDEW

NET WT. ___ OZ. (___ g)

KEEP OUT OF REACH OF CHILDREN

WARNING
See precautionary statements on back of can.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 18 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 498-134

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BACK PANEL
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FORMULATED FOR HOME • HOSPITAL • SCHOOL • HOTEL • MOTEL • OFFICE
• RESTAURANT • LOCKER AND REST ROOM • FACTORY • INSTITUTION

SPRAYPAK SPRAY DISINFECTANT
FORMULA 2

Meets AOAC germicidal spray products test standards for hospital
disinfectants.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

NOV 18 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 498-134

WARNING

Do not get in eyes. Avoid contact with skin. Avoid contamination of
foodstuff.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

IF SWALLOWED: Drink large quantities of water. Do not induce
vomiting. Avoid alcohol. Contact physician or Poison Control Center
in your area.

IF IN EYES: Flush eyes with water for at least 15 minutes. If
irritation occurs, contact a physician.

IF ON SKIN: Rinse with cold water. Contact physician if irritation
persists.

PHYSICAL HAZARDS

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* and *Mycobacterium tuberculosis*.

It also kills fungi such as *Trichophyton mentagrophytes* (athlete's foot) and viruses such as Influenza A/Puerto Rico, Influenza B/Clinical Isolate, Herpes Simplex I and Herpes Simplex II on inanimate surfaces.

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 surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off. Repeat application as necessary.

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

RECEIVED
EXPERIMENTALS
in EPA Letter Dated:

NOV 18 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 498-134

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 reuse empty container. Replace cap and discard container in trash. Do not incinerate or puncture.

ACTIVE INGREDIENT:

O-Phenylphenol	0.1%
Ethanol.....	63.2%

INERT INGREDIENTS:	36.7%
Total	100.0%

EPA Reg. No. 498-134

EPA Est. No. 498-IL-1

CHASE PRODUCTS CO.
 The Quality First Company®
 P.O. Box 70 • Maywood, IL 60153

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BOTTOM OF LABEL

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ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
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 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 498-134