

1026

FEB 15 1995

Chase Products Company  
 P.O. Box 70  
 Maywood, IL 60253

Attn: Alludia B. Hernandez,  
 Government Affairs Administrator

Subject: Spraypak Disinfectant Formula #2  
 EPA Registration No. 498-134  
 Your Labeling Amendment of March 14, 1994

This letter responds to your amendment request proposing bactericidal product label claims submitted with supporting efficacy data. The proposed amendment and data have been reviewed and the following comments apply.

1. The submitted AOAC Germicidal data is acceptable and support the subject product's effectiveness as a bactericide against Streptococcus pyogenes when used as an undiluted pressurized spray on precleaned, hard, non-porous surfaces with a contact time of ten minutes at room temperature.

2. The revised product labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Two copies of the finished printed labeling which contains these comments must be submitted to the Agency before releasing the product for shipment.

a. On the back panel of the label (page 2 of the draft), revise the statement "meets rigid AOAC efficacy standards for Hospital type aerosol disinfectants" to read: "Meets AOAC Germicidal Spray Products Test Standards for Hospital Disinfectants"

CONCURRENCES

SYMBOL	7505C						
SURNAME	Loayza						
DATE	FEB 15 1995						

- b. Revise the text and format of the Precautionary Statements on the back panel of the label to read as follows:

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

"Do not get in eyes. Avoid contact with skin. Avoid contamination of food stuff."

- c. Below the Precautionary Statements indicated above, insert a Statement of Practical Treatment as follows:

**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."

- d. Add the following statement to the Storage instructions on page 4 of the draft label: "Do not contaminate water, food or feed by the use, storage or disposal of this product."

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



Ruth G. Douglas  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (7505C)

-976

**BEST AVAILABLE COPY**

FRONT PANEL

**SPRAYPAK**

**SPRAY DISINFECTANT, FORMULA 2**

**KILLS GERMS  
ELIMINATES ODOR  
CONTROLS MOLD AND MILDEW**

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

ACTIVE INGREDIENT:	
O-Phenylphenol.....	0.1%
INERT INGREDIENTS:.....	99.9%
	Total: <u>100.0%</u>

EPA Reg. No. 498-134

EPA Est. No. 498-IL-1

**KILLS STAPHYLOCOCCUS AUREUS, SALMONELLA CHOLERAESUIS,  
PSEUDOMONAS AERUGINOSA AND STREPTOCOCCUS PYOGENES.**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

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**FEB 15 1995**

~~Under the Federal Insecticide,  
Fungicide and Rodenticide Act  
this product is a pesticide  
EPA Reg. No.~~

498-134

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

**SEE PRECAUTIONARY STATEMENTS ON BACK OF CAN**

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

BACK PANEL

**SPRAYPAK SPRAY DISINFECTANT, FORMULA 2**

Meets rigid AOAC efficacy standards for Hospital type aerosol disinfectants.

FORMULATED FOR HOME . HOSPITAL . SCHOOL . HOTEL . MOTEL . OFFICE . RESTAURANT . LOCKER AND REST ROOM . FACTORY . INSTITUTIONS .

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS  
W A R N I N G**

Do not get in eyes. Avoid contact with skin. If sprayed into eyes wash with water; if irritation persists, consult your physician. Avoid contamination of food stuff. Keep out of reach of children.

**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.

Kills HIV-1 (AIDS VIRUS) on pre-cleaned 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 pre-cleaned 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.

**BEST AVAILABLE**

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**CONTACT TIME:** Leave surface wet for 10 minutes.

After surface is cleaned, hold can upright and spray six to eight 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 ten minutes prior to wiping.

**FOR DISINFECTION OF INANIMATE SURFACES:** This disinfectant spray is a powerful germicidal that kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Streptococcus pyogenes.

It also kills fungi such as Tricophyton Mentagrophytes (athlete's foot) and viruses such as Influenza A (HONI) ATOC VR-95, Influenza B (H2N2) (ARUP), Herpes Simplex I and Herpes Simplex II on inanimate surfaces.

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

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

**DIRECTIONS TO DISINFECT:** Hold dispenser upright and spray six to eight inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off. Repeat applications as necessary.

**FOR CONTROL OF MOLD & MILDEW:** Controls mold and mildew on hard surfaces such as ceramic, metal, 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 six to eight 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, class room, kitchen, bathroom, sick room, 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 upwards for three seconds into corner as well as center of room filling with mist.

**DO NOT USE ON POLISHED WOOD FURNITURE OR RAYON FABRICS.**

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

DISPOSAL: Do not re-use empty container. Replace cap and discard container in trash. Do not incinerate or puncture.

ABH/mm(3/9/94)(5\498-134)

ACCEPTED  
with COMMENTS  
in EPA Letter 1084

FEB 15 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
and the Federal Insecticide,  
Fungicide, and Rodenticide Act  
under EPA Reg. No.  
498-134

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