UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

254-11

101:

P.2/6

AUG 3 | 1995

King Research, Inc. 114 - 12th Street Brooklyn, NY 11215

Attention: James Bergman Plant Manager

Subject: BARBICIDE EPA Registration No. 954-11 Your Amendment Dated April 25, 1995 EPA Received Date April 28, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update the product labeling to include the word "Hospital" on the front panel, has been reviewed by the Agency and found to be acceptable provided that you:

1. Make the following minor revisions to the BARBICIDE label before you release the product for shipment bearing the amended labeling.

a. For the final product labeling please ensure that you use the appropriate type size for the front panel precautionary statements, especially the signal word. Based on the label submitted, the type size requirements for the signal word "DANGER" would be a minimum of 18 points.

b. Place an asterisk, as indicated, at the word "VIRUCIDE*" on the front panel.

c. Revise the back panel use directions statements under "...CLEANING AND DECONTAMINATION AGAINST HIV...." to read:

"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

	CONCURRENCES	
SYMBOL 75057		
SURNAME DAVIA CO		
DATE 7/21/95		
EPA Form 1320-1A (1/90)	Printed on Recycled Paper	OFFICIAL FILE COPY

FM 90 215-65

AUG 17 '95 03: 18PM REGULATORY AFFAIRS

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-1) (associated with AIDS)."

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the product labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Doreen Aviado of my staff at (703) 305-6554.

ì

Sincerely,

Marion J. Johnson, Jr. Product Manager (31) Antimicrobial Program Branch Registration Division (7505C)

,

)) y

BARBICIDE

-The-Tested- HOSPITAL GERMICIDE PSEUDOMONOCIDE FUNGICIDE AND VIRUCIDE

Anti-Rust Formula

ACTIVE INGREDIENT: Alkyl (50%C₁₄, 40%C₁₂, 10%C₁₆) dimethyl benzyl ammonium chloride 5.12% INERT INGREDIENTS 94.88% (Contains sodium nitrite)

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT If swallowed, promptly drink a large quantity of water. Avoid alcohol. Call a physician immediately. If on skin, immediately flush with plenty of water for at least 10 minutes and call a physician. On clothing, remove and wash contaminated clothing before reuse. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

> SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

> > A PRODUCT OF

MFG. BY KING RESEARCH, INC. Brooklyn, NY 11215

EPA Registration No. 954-11AA EPA Establishment No. 954-NY-1 Net Contents 16 Fl. Oz. 473 ml Printed in USA

)

ACCEPTED with COMMENTS in EPA Jacux Dand

•

- 17H1;

AUG 3 1 1995

Under the Federal Insenticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 954-11

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND

DOMESTIC ANIMALS DANGER: KEEP OUT OF REACH OF CHILDREN. CORROSIVE, CAUSES EYE AND SKIN DAMAGE. DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. HARMFUL OR FATAL IF SWALLOWED. AVOID CONTAMINATION OF FOOD, WEAR EYE PROTECTION AND RUBBER GLOVES WHEN HANDLING. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

STORAGE AND DISPOSAL

- Do not contaminate water or food by storage or disposal.
- Do not store on side.
- Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate is a violation of Federal Law. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL Do not reuse empty container. Wrap container and put in trash.

DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labelling. BARBICIDE is recommended for use in beauty shops, barber shops and hairstyling establishments. Mix 1 ounce BARBICIDE in 32 ounces water. This makes 1600 ppm active product. Hospital Disinfectant: Mix 2 ounces BARBJCIDE in 32 ounces water. This makes 3200 ppm active product. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled. Dilute only as needed. INSTRUMENTS AND TOOLS: Thoroughly clean brushes, combs, rollers, manicure and other salon tools prior to complete immersion for 10 minutes (or as required by local authorities). Rinse to remove BARBICIDE after immersion.

PERFORMANCE: When tested with full immersion for 10 minutes in a solution created as above, BARBICIDE has been found to be effective as a disinfectant, germicide, bactericide, as a fungicide (against Trichophyton mentagrophytes), and as a virucide* (against Herpes Simplex Type 1 and Type 2) and Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS virus).

ACCEPTED with COMMENTS in EPA Letter Dated:

1124

AUG 3 | 1995

Under the reduced Insec**ticide**, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No 254-11 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 joiling of inanimate surfaces/objects with blood or body fluids in which the surfaces/objects likely to e 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 poverings.

CLEANING PROCEDURE

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

DISPOSAL OF INFECTIOUS MATERIALS

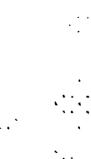
Blood and other body fluids should be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

CONTACT TIME Leave surface wet for 10 minutes.

ACCEPTED with COMMENSE in EPA Letter Date:

AUG 3 1 1995

Under the reserved Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide represented under EPA Reg. No. 57.574-11



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 in which the surfaces/objects likely to e 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.

ACCEPTED with COMMENTES in EPA Letter Dated:

AUG 3 1 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide represented under EPA Reg. No. 7574-11