

954-11

3-24-2003

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 24 2003

Ms. Christina Swick
Agent for King Research Inc.
Lewis & Harrison
122 C Street, NW Ste. 740
Washington, DC 20001

Subject: Barbacide
EPA Registration No. 954-11
Amendment Date: September 30, 2002
EPA Receipt Date: October 1, 2002

Dear Ms. Swick,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of Hepatitis B Virus (HBV) claim and use site, tanning facilities
- Update sources of actives and inert ingredients

Conditions

Revise the label as follows:

1. In the Agency letter dated October 18, 1999, comment 7 under Label comments was incorrect. The current precautionary language for a product categorized as Toxicity I for primary eye irritation and skin irritation is "Causes *irreversible eye damage* and skin burns." Since the product is Tox. I for primary skin irritation, the 7th statement in the precautionary text must be revised to include "*protective clothing.*"
2. Since this product is sold in containers less than one gallon, the appropriate "Storage and Disposal" instructions are as follows:

Storage and Disposal: Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap container and put in trash.

3. Since this product is supporting a fungicidal claim, the label must have appropriate directions by stating. "*This product kills Trichophyton mentagrophytes (the agent that causes Athletes foot fungus) when used as a disinfectant on bathroom floors, shower stalls, and bath tubs.*"

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

- 4. The HIV Directions must be placed as page 3. It must coincide with the "Directions for Use" text.

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Efficacy of Disinfectant Using Duck Hepatitis B Virus	Submitted study, MRID 457699-01	Acceptable
Confirmatory Virucidal Efficacy of Disinfectant Using Duck Hepatitis Virus	Submitted study, MRID 457699-02	Acceptable

General Comments

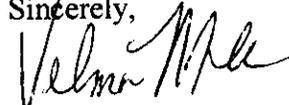
The Confidential Statement of Formula dated September 30, 2002 is acceptable. It is in compliance with PR Notice 91-2 and in agreement with the label.

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,


Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510C)

3/5

BARBICIDE®

Hospital

GERMICIDE PSEUDOMONACIDE 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 nitrate)

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID

Call poison control center or doctor immediately for treatment advice. **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. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **IF SWALLOWED:** Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

A PRODUCT OF KING RESEARCH®

Brooklyn, NY 11215

EPA Reg. No. 954-11-AA
EPA Est. No. 954-NY-1

Net Contents 16 Fl. Oz. 473 ML

Printed in USA

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 24 2003

Under the Federal Insecticide,
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 DAMAGE AND SKIN BURNS. DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. HARMFUL 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.

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

MAR 24 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

95411

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE

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 mixture or 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 labeling. To make a HOSPITAL DISINFECTANT mix 2 ounces of BARBICIDE in 32 ounces of water. BARBICIDE is recommended for use in hospitals, health care facilities, tanning facilities and in beauty salons, barbershops and hairstyling establishments. SURFACES: On inanimate, hard non-porous surfaces such as floors, sink tops, tables, acrylic tanning beds, telephones, toilet seats and door handles. Apply solution prepared as above to pre-cleaned surfaces with a cloth, mop, sponge or coarse mist pump or trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air-dry. Prepare a fresh solution after each use. BEAUTY/BARBER INSTRUMENTS AND TOOLS: Thoroughly clean brushes, combs, clipper blades, shears, razors, and other inanimate hard-surfaced non-porous tools and implements prior to complete immersion for 10 minutes (or as required by local authorities) in a solution prepared as above. Rinse to remove BARBICIDE after immersion and dry before use. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled. PERFORMANCE: When tested with full immersion for 10 minutes in a solution prepared as above, BARBICIDE has been found to be effective against Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus, Trichophyton mentagrophytes, Herpes simplex Type 1 and Type 2, Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus) and Hepatitis B Virus.

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

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OR HBV ON 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 human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

ACCEPTED with COMMENTS in EPA Letter Dated:

MAR 24 2005

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

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.