



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 23, 2003

Susan Watson
Regulatory Mgr. - Labels/Registrations
Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

Subject: **Misty Disinfectant & Deodorant RTU**
EPA Registration No. 10807-178
Application Date: September 15, 2003
Receipt Date: September 28, 2003

Dear Ms. Watson:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Proposed Amendment:

- Update label in accordance with PR Notice 2001-1
- Update to Storage and Disposal Statements
- Change of Primary Brand Name

General Comments:

1. Revise the Precautionary Statements to read:

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

WARNING: CAUSES EYE IRRITATION. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin, or clothing. Avoid breathing spray mist. Use adequate ventilation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating drinking, or using tobacco.

2. Move the following text from the Precautionary Statements to the Directions for Use Statement for Disinfection and Mildew Control:

"Before using, food and packaging materials must be removed or covered. Treated food contact surfaces must be covered. Treated food contact surfaces must be scrubbed with detergent and rinsed with potable water prior to reuse."

3. Since this product will be used in hospitals, the following paragraph per PR Notice 94-4 must be added to the label in the "Directions for Use" section of the label:

"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 decontaminate critical or semi-critical devices prior to sterilization of high-level disinfection."

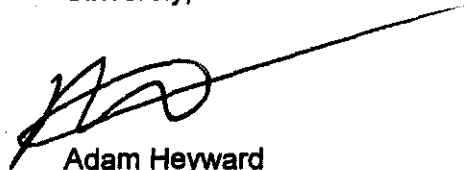
Other Comments:

The Primary Brand Name had been changed from "Hospital III Disinfectant and Deodorant" to **"Misty Disinfectant & Deodorant RTU."**

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

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

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

ENCLOSURE:



MISTY

Disinfectant & Deodorant RTU

- Inhibits Mold & Mildew Growth for 7 Days on Hard Surfaces and 28 Days on Fabric!
- Tuberculocidal • Staphylocidal • Bactericidal • Fungicidal • Pseudomonocidal • *Virucidal
- Kills Herpes simplex virus type 2 and HIV-1 (AIDS virus) on environmental hard surfaces

ACTIVE INGREDIENTS:

o-Phenylphenol	0.177%
p-tert-Amylphenol	0.045%
Ethyl alcohol	67.000%
INERT INGREDIENTS:	32.778%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN.

WARNING:

See side panel for additional precautionary statements.

R-221

NET CONTENTS 1 GALLON (3.8 LITERS)

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 23 2008

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Under the Federal Insecticide,
Fungicide, and Herbicide Act as
amended, for the pesticide
registered under EPA Reg. No. 10807-178

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

WARNING: CONTAINS SODIUM NITRITE-CAUSES EYE IRRITATION. Do not get in eyes, flush at once with water for 15 minutes. Call a physician. Avoid skin contact. Avoid breathing of spray mist. Use adequate ventilation. Avoid contact with food. Before using, food and packaging materials must be removed or covered. Treated food contact surfaces must be covered. Treated food contact surfaces must be scrubbed with detergent and rinsed with potable water prior to reuse.

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

PHYSICAL AND CHEMICAL HAZARDS: FLAMMABLE. Keep away from heat or open flame.

***SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS. KILLS HIV 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 on 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). Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. Disinfection will occur in 10 minutes at 25°C. Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection. Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR DISINFECTION: Thoroughly clean surface to be disinfected. Remove heavy soil and gross filth. Hold dispenser upright about 6 to 9 inches from surface to be disinfected and spray until surface is wet. Effective in 10 minutes at 20°C. **FOR DEODORIZING:** Hold dispenser upright. Spray into air towards the center of the room. **FOR MILDEW CONTROL:** Clean surface. Spray surface until wet. Repeat application every week to

maintain control. **IMPORTANT:** Do not use on polished wood, furniture, or rayon fabrics. Acts instantly and remains effective for long periods on unpleasant odors from fecal matter, urine, burns, smoke, mildew and mold, decay, garlic, onions, food putrefaction, stale air, perspiration, tobacco, sick rooms, musty closets, fish.

STORAGE & DISPOSAL: STORAGE: Do not expose product to heat, spark or open flame. Store container in a cool dry location. Do not expose product to temperature extremes. Store product in original shipping container in a locked storage area. Keep container closed when not in use. Do not contaminate water, food or feed by storage or disposal. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. In the event of a spill or leak, contain product with a dry absorbent and dispose of in accordance with state or local regulations. Wear protective clothing during clean up procedures. **CONTAINER DISPOSAL: IF EMPTY:** Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

USES: This powerful hospital disinfectant and deodorant acts quickly on germ laden surfaces such as refuse cans, toilet seats, telephones, wash basins, urinals, laundry chutes, door knobs, metal beds and springs, wheel chairs, linen carts, hampers, dressing carts, clean-up carts, light switches, office machinery and other equipment, after the surface has been properly cleaned. Will reduce bacteria on environmental surfaces. Non-selective odor suppressant for space odor conditioning and deodorizing surgical dressings. Deodorant attacks malodor at the source. Does not cause anemia. Suppresses and eliminates odors by chemically neutralizing odor-producing materials. Effective on odors from any source in hospitals, nursing homes, ambulances, from post-colostomy, postileostomy dressing and bags, and malignant diseases. Also effective on odors in the home, kitchens, bathrooms, industrial plant processes, food processing and packaging plants and food stores. This product will control the following organisms: *Aspergillus niger*, *Tubercle bacillus*, *Mycobacterium smegmatis*, *Penicillium glaucum*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Salmonella schotmuelleri* (paratyphoid B), *Salmonella typhosa*, *Shigella parady-senteria*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Trichophyton interdigitale*. Completely inhibits growth of mildew (mold or fungi) on cloth. ***Virucidal.** Kills Herpes simplex virus type 2 and HIV-1 (AIDS virus) on environmental hard surfaces.

MADE IN U.S.A. BY:
amrep
990 Industrial Park Drive
Marietta, Georgia 30062

07/03p
EPA REG. NO. 10807-178
EPA EST. NO. 10807-TX-1

R-221

NOTE: Areas highlighted in blue are per PR Notice 2001-1 and 2001-6. Nliquids\B0221-LABL(07-03p).doc as of 07/30/03

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 23 2003

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended and its predecessor,
registered under EPA Reg. No. 10807-178

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