



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 3 2009

Sam Turetsky
Regulatory Manager – Product Compliance
Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

Subject: **Misty II Disinfectant & Deodorant**
EPA Registration No. 10807-177
Application Date: June 9, 2009
Receipt Date: June 11, 2009

Dear Mr. Turetsky:

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

Proposed Amendment:

- Update several raw material suppliers
- Add new label claims

General Comments:

The total weight must be entered into cell location number 17. The basic confidential statement of formula dated, May 27, 2009 supersede all previously accepted ones. Submit a revised basic confidential statement of formula with the total weight shown in cell 17.

Labeling Comments:

1. The proposed label claims are acceptable regarding the use of the product, Misty II Disinfectant and Deodorant, as a bactericide against *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575), *Staphylococcus aureus* Methicillin Resistant (ATCC 33592), and *Staphylococcus aureus* Community Associated Methicillin Resistant (Genotype USA 400) at a contact time of 10 minutes in the absence of organic soil.
2. Clarify the hampers with the descriptor "non-porous".
3. The use of the term "other equipment" is too vague. Add additional use sites consistent with the term.
4. Add the statement "from treated surface" to the cross contamination claim.
5. Remove the term malignant diseases, post-colostomy, and postileostomy from the list of odor causing environments.

6. The proposed label must be revised to include use directions for deodorization.
7. On the proposed label, change *Salmonella choleraesuis* to *Salmonella enterica*, and change "*Trichophyton interdigitale*" to "*Trichophyton mentagrophytes*" for revised nomenclature. Additionally, change "Tubercle bacillus" to the actual organisms that was tested (e.g. *Mycobacterium bovis*)
8. ATCC designation numbers are required in one of the following locations:
 - on the data matrix;
 - on the master label (as optional text) with the listing of the organisms claimed; or
 - As the final page of the master label (as optional text).

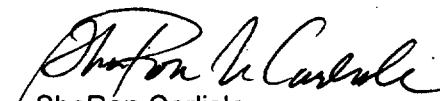
Other Comments:

Future labeling amendments may be accomplished by submitting a copy of the electronic label. Refer to the following website for guidance on electronic submissions, including label: <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>. If you have questions concerning electronic labeling, a list of contacts is available at the above website.

Submit three (3) copies of the label bearing the revisions referred to above for Agency review.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: carlisle.shaRon@epa.gov or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: DER D366475
EPA Stamped label

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 3 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,

10807-177

NOTE: To match EPA stamped "accepted" label w/ comments dated 08/05/03. Areas highlighted in blue at proposed additions of VRE, MRSA, CA-MRSA claims.

USES: This Hospital Disinfectant and Deodorant acts within 10 minutes to disinfect 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, Cleanup Carts, Light Switches, Office Machinery, and other equipment after the surface has been properly cleaned. Will reduce the hazard of cross contamination by bacteria from environmental surfaces.

Molecular aerosol deodorant attacks malodor at the source. Does not cause anosmia. Suppresses and eliminates odors by chemically neutralizing odor producing materials. Effective on odors from any source when used as a deodorant in hospitals, nursing homes, ambulances, from post colostomy, postileostomy dressing and bags, and malignant diseases. Also effective on odors in kitchens, bathrooms, industrial plant processes, food processing and packaging plants and food stores.

This product will control the following pathogenic organisms when used as a surface disinfectant: (Tubercle bacillus, Mycobacterium smegmatis, Pseudomonas aeruginosa, Salmonella choleraesuis, Salmonella schottmuelleri (paratyphoid B), Salmonella typhosa, Shigella paradysenteriae, Staphylococcus aureus, Streptococcus pyogenes, and Trichophyton interdigitale, Methicillin Resistant Staphylococcus aureus (MRSA), (ATCC 33592); Vancomycin resistant Enterococcus faecalis (VRE), (ATCC 51575); Community Associated Methicillin Resistant Staphylococcus aureus (CA-MRSA), (NARSA NRS123) (Genotype USA400). *Virucidal. Kills Herpes simplex virus type 1 and type 2 and HIV-1 (AIDS virus) on environmental hard surfaces. Inhibits growth of mildew (mold fungi) such as Aspergillus niger and Penicillium variable on hard surfaces for 7 days and for 28 days on fabric.

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.

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

DIRECTIONS: SHAKE WELL BEFORE USING **FOR DISINFECTING:** Clean surface thoroughly with an effective detergent followed by a potable water rinse in order to remove heavy soil or gross filth. Allow to air dry. Hold dispenser upright about 6 to 8 inches from surface to be disinfected and spray 3 seconds or until surface is thoroughly wet. Allow to remain for at least 10 minutes at 20°C (68°F) for effective results **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.

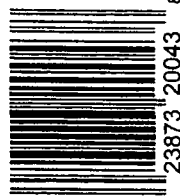
STORAGE & DISPOSAL: **STORAGE:** Store in a cool area away from heat or open flame. **DISPOSAL:** Do Not Puncture or Incinerate! IF EMPTY, Place in trash or offer for recycling if available. IF PARTLY FILLED: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS: **CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID STATEMENTS: 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. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

PHYSICAL OR CHEMICAL HAZARDS: THIS PRODUCT CONTAINS AN EXTREMELY FLAMMABLE PROPELLANT. Do not use or store near fire, sparks or heated surfaces. Turn off pilot lights in gas appliances and unplug or turn off electrical equipment in the use area. After airing out phase is completed, relight pilot lights and reconnect electrical current. Do not smoke in the use area. Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Incineration of container may cause explosion.

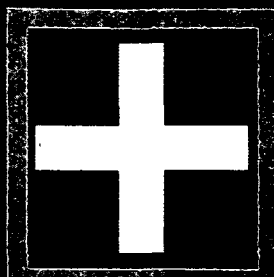
***SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS, KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood 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.**



EPA REG. NO. 10807-177 EPA EST. NO. 10807-GA-1

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

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MISTY II

Disinfectant & Deodorant

- Inhibits Mold and Mildew Growth for 7 Days on Hard Surfaces and for 28 Days on Fabric!
- Tuberculocidal • Staphylocidal • Bactericidal
- Fungicidal • Pseudomonicidal • Virucidal
- Kills Herpes simplex virus type 1 and type 2 and HIV-1 (AIDS virus) on environmental hard surfaces
- Excellent for Veterinarian and Professional Grooming Tools and Equipment (Disinfects, Cleans, Cools)
- Effective Against Antibiotic Resistant Strains VRE, MRSA, CA-MRSA

ACTIVE INGREDIENTS:

ortho-phenylphenol	0.177%
para-tertiary-amyphenol	0.045%
ethyl alcohol	61.348%
OTHER INGREDIENTS:	36.430%
TOTAL:	100.000%

FORMULATION CONTAINS SODIUM NITRITE AND 3% ALCOHOL (METHYL ALCOHOL OR ISOPROPYL ALCOHOL)

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KEEP OUT OF REACH OF CHILDREN.

CAUTION:

See back panel for additional precautionary statements.
NET WT. 1 LB. 0.5 OZ. (16.5 OZ.) (468 grams)

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