

10807-177

9/17/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

SEP 17 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Sam Turetsky
Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

Subject: Misty II Disinfectant & Deodorant
EPA Registration Number: 10807-177
Application Date: April 20, 2010
Receipt Date: April 27, 2010

Dear Mr. Turetsky:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA) section 3(c)(7)(A) is acceptable with conditions.

Proposed Amendment

Add microorganisms Influenza A virus, Influenza B virus, and Swine influenza A (H1N1) virus.

Conditions

Revise the label as follows:

1.) Since this product is used in institutional setting on hard, nonporous surfaces, you must either add the following statement, "This product is not for use on medical devices and equipment," or MOU language must be added to the "Directions for Use":

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) contact 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

2.) Revise the HIV-1 Directions by incorporating subheadings such that the section reads:

Personal Protection: Clean up *must* always be done wearing protective gloves, gowns, masks,

SYMBOL	and eye protection.						
SURNAME							
DATE							

Cleaning Procedure: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

Contact Time: Disinfection occurs in 10 minutes.

Disposal of Infectious Material: Blood, body fluids, cleaning materials, and clothing *must* be autoclaved and disposed of according to local regulations for infectious waste disposal.

Data Summary

Data Requirement	Means of Support	Status
Virucidal Efficacy against Influenza A Virus	Submitted study, MRID 48075501	Acceptable, RTU in 10 min (no soil)
Virucidal Efficacy against Influenza B Virus	Submitted study, MRID 480755-02	Acceptable, RTU in 10 min (no soil)

General Comments

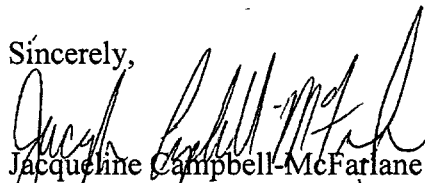
A stamped accepted label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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 constitutes acceptance of these conditions.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfaarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline Campbell-McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label

	CONCURRENCES					
	Efficacy Data Evaluation					
SYMBOL						
SURNAME						
DATE						

NOTE: To match EPA stamped "accepted" label w/ comments dated 12/07/2009. Areas highlighted in blue are additions to text reflecting proposed additions of Influenza A and B (along with H1N1) 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, Non-Porous Hampers, Dressing Carts, Cleanup Carts, Light Switches, Office Machinery, and other hard, nonporous surfaces after the surface has been properly cleaned. Will reduce the hazard of cross contamination from treated surface 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, and ambulances. 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: Mycobacterium bovis (BCG), Mycobacterium smegmatis (ATCC 700044), Pseudomonas aeruginosa (ATCC 15442), Salmonella enterica (ATCC 10708), Salmonella schottmuelleri (paratyphoid B) Salmonella typhosa, Shigella paradysenteriae, Staphylococcus aureus (ATCC 6538), Streptococcus pyogenes, Trichophyton mentagrophytes (ATCC 9533), 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 Influenza A virus (ATCC VR-544) (Strain Hong Kong), and Influenza B Virus (ATCC VR-823) (Strain B/Hong Kong/5/72), Herpes simplex virus type 1 (Strain S-148) and type 2 (ATCC VR-734) and HIV-1 (AIDS virus) (strain III rf) on environmental hard surfaces. Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Inhibits growth of mildew (mold fungi) such as Aspergillus niger (ATCC 6275) and Penicillium variable (NRRL 3765) 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 AND DEODORIZING:** 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.

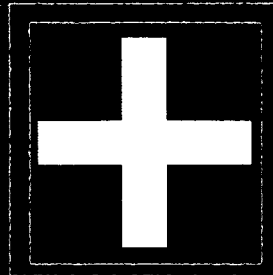
***SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS. KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood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

05/10p
EPA REG. NO. 10807-177 EPA EST. NO. 10807-GA-1
(Equivalent to 20.74 Fluid Ounces)

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



221-20



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**
- **Pseudomonocidal • * Virucidal**
- **Kills Herpes simplex virus type 1 and type 2 and HIV-1 (AIDS virus) on environmental hard surfaces**
- *** Effective Against Antibiotic Resistant Strains VRE, MRSA, CA-MRSA**
- **Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)**
- **Excellent for Veterinarian and Professional Grooming Tools and Equipment (Disinfects, Cleans, Cools)**

ACTIVE INGREDIENTS:
ortho-phenylphenol 0.177%
para-tertiary-amylphenol 0.045%
ethyl alcohol 61.348%
OTHER INGREDIENTS: 38.430%
TOTAL: 100.000%
FORMULATION CONTAINS SODIUM NITRITE AND 3% ALCOHOL (METHYL ALCOHOL OR ISOPROPYL ALCOHOL)

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)

ACCEPTED
with COMMENT
EPA Letter Dat.
SEP 17 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10807-177

221-20

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