



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 2, 2016

Susan Watson
Regulatory Manager, Labels and Registrations
Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

Subject: Label and CSF Notification per PRN 98-10 – Add EST number and revise 2 CSFs
Product Name: Misty II Disinfectant & Deodorant
EPA Registration Number: 10807-177
Application Date: February 25, 2016
Decision Number: 515151

Dear Ms. Watson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

The CSFs submitted with your application have been stamped “Notification” and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/25/2016
- Alternate CSF 1 dated 02/25/2016

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact Tom Luminello at (703) 308-8075 or by email at luminello.tom@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Tom Luminello". The signature is written in a cursive style with a large, looped "L" and "O".

for
Jacquie Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

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-phenylphenol0.177%

para-tertiary-amylphenol0.045%

ethyl alcohol61.348%

OTHER INGREDIENTS:38.430%

TOTAL: 100.000%

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

NOTIFICATION

10807-177

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/02/2016

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)

{Back Panel}

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.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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.

[For Reviewer: Storage & Disposal statements may be boxed.]

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.

[For Reviewer: Boxed & "Bulleted" format will be used if label space permits; otherwise a paragraph format will be used.]

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. **PERSONAL PROTECTION:** Clean up must always be done wearing protective gloves, gowns, masks, and eye protection. **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 MATERIALS:** Blood, body fluids, cleaning materials, and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

EPA Reg. No. 10807-177

EPA Est. No. 58996-MO-1 (A)

EPA Est. No. 10807-GA-1 (M)

EPA Est. No. 11623-GA-1 (O)

EPA Est. No. 11623-GA-2 (L)

EPA Est. No. 11623-GA-3 (P)

Distributed by

Amrep, Inc.

990 Industrial Park Drive

Marietta, GA 30062

770.422.2071 • 800.241.7766