

10807-21

11/12/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

NOV 12 2010

Subject: Misty Disinfectant Foam Cleaner
EPA Registration No. 10807-21
Amendment Date: April 30, 2010
EPA Receipt Date: June 11, 2010

Dear Mr. Turetsky,

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

Proposed Amendment

- Submit Alternate Formulation
- Submit Efficacy Data for Review

Conditions

Revise the label as follows:

- 1) Revise the list of organisms on the left panel such that this list is preceded by an asterisk "*". Place an asterisk next to the first organism in the list on the right panel. This will clarify to the user the complete names of the organisms against which this product is effective.
- 2) Change Herpes simplex virus type 2 (ATCC VR-734 (**Strain F (G)**)) to read Herpes simplex virus type 2 (ATCC VR-734 (**Strain G**)).
- 3) Add the following Mildewstat directions immediately following the directions to clean and deodorize: *"To use as a mildewstat: Follow directions above. Allow to contact surfaces for 10 minutes. Reapply every 7 days as needed."*

CONCURRENCES							
SYMBOL	7510P						
SURNAME	<i>[Signature]</i>						
DATE	11/12/10						

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4) Change the statement: "AGAINST HIV OF SURFACES/OBJECTS" to read "AGAINST HIV ON SURFACES/OBJECTS"

5) Add the following statements to the Storage and Disposal section to bring this text into agreement with PR Notices 94-2, 2007-1 and 2007-4. Immediately following the statement "Do not puncture or incinerate." add: "Non refillable container. Do not reuse or refill this container."

6) Add the following language to the Precautionary Statements: "... Wash thoroughly...after handling and before eating, drinking, chewing gum, using tobacco or using the toilet." In addition, revise the statement: "Avoid contact with skin, eyes, or clothing" by deleting the repetitive language as follows: "Avoid contact with skin".

Data Summary

The alternate CSF dated 5/19/10 is acceptable. The associated data reviews are attached.

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy 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) and section 4 (a) 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 any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,

Tracy Lantz

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

Enclosure: Stamped Label, DER DP379993, DP379997

7510P:T. Lantz:11/12/2010:10807-21 PRIA acceptable WC

CONCURRENCES

Table with 8 columns and 3 rows labeled SYMBOL, SURNAME, and DATE.

NOTE: To match EPA stamped "accepted" label dated 02/24/10. Areas highlighted in blue are additions to text reflecting proposed additions of Influenza A and B (along with H1N1), Avian, Herpes, mildew claims.

This is a concentrated general purpose cleaner which cleans, disinfects, and deodorizes. It kills Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442), HIV-1 (AIDS virus)*, Vancomycin Resistant Enterococcus faecalis (VRE), (ATCC 51575), Vancomycin Intermediate Staphylococcus aureus (VISA), (HIP 5836), Vancomycin Resistant Staphylococcus aureus (VRSA), (NARSA VRSA1), Methicillin Resistant Staphylococcus aureus (MRSA), (ATCC 33592), Community Associated Methicillin Resistant Staphylococcus aureus (CA-MRSA), (NARSA NRS123) (Genotype USA400), Influenza A (H1N1) virus (ATCC VR-1469) (Strain A/PR/8/34), Influenza B virus (ATCC VR-823) (Strain B/Hong Kong/5/72), Avian Influenza A (H5N1) virus (Strain VNHSN1-PR8/CDC-RG) (CDC #2006719965), Herpes Simplex virus type 1 (ATCC VR-733) (Strain F(1)), Herpes Simplex virus type 2 (ATCC VR-734) (Strain F(2)), and prevents mildew on hard non-porous surfaces when used as directed. 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). This is a foaming cleaner that must be used on glazed tile, glazed porcelain, glazed ceramics, metal, stainless steel, bathtubs, hampers, tables, chairs, and walls. For use in hospitals, schools, hotels, motels, offices, restaurants, locker and rest rooms. Surfaces must be cleaned and disinfected on a regular basis. All food contact surfaces must be rinsed with potable water before reuse.

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

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **TO CLEAN AND DEODORIZE:** Shake can before using. Hold can six to eight inches from surface to be cleaned. Spray area until covered with a white foam. Allow foam to penetrate and wipe off with a clean cloth, mop or sponge. No scrubbing is necessary. For heavily soiled areas, remove gross soil before using. This product will not leave grit or soap scum.

TO DISINFECT PRE-CLEANED, HARD NON-POROUS SURFACES (such as those listed above): Follow directions as above and allow foam to penetrate and remain wet for 10 minutes. Then wipe with a clean cloth, mop or sponge. Rinse all food contact surfaces with potable water before reuse.

***KILLS HIV-1 ON PRECLEANED 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) Contact Time: Leave surfaces wet for 10 minutes at 25°C.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings. **CLEANING PROCEDURES:** 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 must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal. **CONTACT TIME:** Leave surfaces wet for 10 minutes at 25°C.

STORAGE & DISPOSAL: Do not contaminate water, food, or feed by storage and disposal. **PESTICIDE STORAGE:** Store in a cool area away from heat and open flame. Store in original containers in a locked storage area inaccessible to children. **CONTAINER 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. **PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these waste cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS: **WARNING:** Causes substantial but temporary eye injury and skin irritation. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

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. **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. **IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Have product container or label with you when calling a poison 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 appliance 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 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.

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

06/10p
EPA REG. NO. 10807-21
EPA EST. NO. 10807-GA-1
(Equivalent to 18.73 Fluid Ounces)



MISTY®

Disinfectant Foam Cleaner

- **Kills Staph, Salmonella, Pseudomonas and HIV-1 (AIDS virus)* on hard surfaces when used as directed**
- **Contains No Abrasives to Damage Porcelain Surfaces**
- ***Effective Against Antibiotic Resistant Strains VRE, VISA, VRSA, MRSA, & CA-MRSA**
- **Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)**
- **Prevents Mildew on Hard Non-Porous Surfaces**

ACTIVE INGREDIENTS:
n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%)
dimethyl benzyl ammonium chlorides 0.10%
n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl
ammonium chlorides 0.10%
OTHER INGREDIENTS: 99.80%
TOTAL: 100.00%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See back panel for additional precautionary statements.
NET WT. 19 OZ. (1 LB. 3 OZ.)(539 grams)

A00250
ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 12 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10807-21

not