



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

NOV 18 2003

Ms. Susan Watson
Regulatory Manager
Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Misty Enviro-40 Detergent/Disinfectant
EPA Registration No. 10807-98
Application Date: 8/14/03
Receipt Date: 8/26/03

Dear Ms. Watson:

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

- Response to PR Notice 2001-1

LABEL COMMENTS

1. You must submit separate "Cleaning and Deodorizing" directions. They must be clearly separated from each other.
2. Update the "Storage and Disposal" statements for container size one gallon and up. For the proper language, see the Label Manual or PR Notice 2001-6.
3. Expand the "Food Processing Plants" to include the following language: floors, walls and storage areas, add 3 ounces of this product to 5 gallons (0.60 ounces per gallon) of water (or equivalent use dilution) (450 ppm active quat). For heavily soiled areas, a pre-cleaning step is required. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. For sprayer application, use a coarse spray. Allow to remain wet for 10 minutes, then remove excess liquid. Before using this product, food products and packaging materials must be removed from area or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.
4. Add the following directions for "Food Service Establishments": countertops, appliances, tables. Before using this product, food products and packaging materials must be removed from area or carefully protected. Add 3 ounces of this product to 5 gallons (0.60 ounces per gallon) of water (or equivalent use dilution) (450 ppm active quat). For

heavily soiled areas, a pre-cleaning step is required. Apply solution with a mop, cloth, sponge or hand pump sprayer so as to wet all surfaces thoroughly. For sprayer application, use a coarse spray. Allow to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water.

- 5. Add the following statement to the label: This product should not be used on glass, eating utensils, inner surfaces or appliances.

LABEL COMMENTS

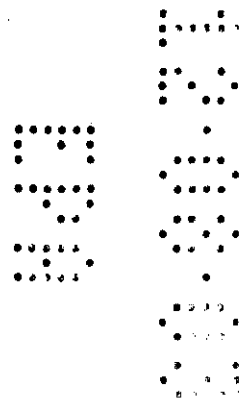
A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)





MISTY®

Enviro-40

Detergent/Disinfectant

- **Cleans, Disinfects, Deodorizes & Sanitizes**
- **Dual Quat Based • Virucide* • Fungicide**
- (against Pathogenic fungi) • Concentrated • Unfragranced**

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	2.25%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	2.25%
INERT INGREDIENTS:	95.50%
TOTAL:	100.00%

B00252

KEEP OUT OF REACH OF CHILDREN.

DANGER:

FIRST AID STATEMENT: 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 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 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 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. Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous injection of a shortacting barbiturate drug. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

See added cautions on side panel.

NET CONTENTS 1 GALLON (3.8 LITERS)

B0252-LABL(07-03p) 10807-006.pmd

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8/13/2003, 4:10 PM

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

NOV 18 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10807-98

1 OF 2

1/10/04

ENVIRO-40

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER: KEEP OUT OF REACH OF CHILDREN. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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

This detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants, food service establishments and other institutions where housekeeping is of prime importance.

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.

DISINFECTION: To disinfect hard inanimate surfaces (such as walls, floors, table tops), add 2 ounces of product per gallon of water. Apply solution with mop, cloth or sponge or mechanical sprayer so as to wet thoroughly. Allow to remain wet for 10 minutes. To disinfect toilet bowls, flush toilet, add 2 ounces of product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush. Prepare a fresh solution for each use. Pre-cleaning all surfaces is required in Federally inspected meat and poultry plants.

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops), add 2 ounces of product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.

SANITIZATION: To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare 200 ppm active quaternary solution by adding 2 ounces of product to 3 gallons of water. To sanitize immobile items (such as tanks, chopping blocks, counter tops), flood area with 200 ppm solution or apply with a cloth or sponge, making sure to wet all surfaces completely for at least 60 seconds. For food contact surfaces wash with potable water. Prepare a fresh solution for each use. To sanitize mobile items (such as drinking glasses, eating utensils), immerse in 200 ppm solution for at least 60 seconds making sure to immerse completely. Wash food contact surfaces with potable water. Prepare a fresh solution daily or more frequent as soil is apparent.

This product is a phosphate free concentrated detergent/disinfectant which provides effective cleaning, deodorizing, disinfection, and sanitation. This detergent/disinfectant has been specifically designed for places where housekeeping is of prime importance in controlling the hazard of cross contamination. The product when diluted at the rate of 2 ounces per gallon of water is an effective disinfectant against the organism *Pseudomonas aeruginosa* and meets all requirements for hospital use. When used as directed this product is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, the product is designed to provide both general cleaning and disinfecting. In addition, the product deodorizes those areas which are generally hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and any other area which is prone to odors caused by microorganisms.

DISINFECTION: At 2 ounces per gallon dilution, the product exhibits effective disinfectant activity against the following: *Pseudomonas aeruginosa* PDR-10, *Brevibacterium ammoniagenes*, *Escherichia coli*, *Streptococcus faecalis*, *Klebsiella pneumoniae*, *Shigella Dysenteriae*, *Salmonella schottmuelleri*, *Enterobacter aerogenes*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Streptococcus salivarius*. At this level the product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

VIRUCIDAL ACTIVITY: The product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against HIV (AIDS virus)*, influenza A2/Asian (representative of the common flu virus) Herpes Simplex Type 1 (causative agent of fever blisters and mononucleosis), Adenovirus type 5 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group).

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

MOLD & MILDEWSTAT: This product prevents and controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces.

SANITIZATION: When used for sanitization of previously cleaned food equipment or food contact items, limit active quaternaries to 200 ppm. Potable water rinse is required. This product is an effective sanitizer when diluted in water up to 250 ppm hardness (Ca CO3).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: *KILLS HIV-1 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 23°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.

STORAGE & DISPOSAL: DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE AND

DISPOSAL. STORAGE: 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 and 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 and local regulations. Wear protective clothing during clean-up. **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.

07/03p

EPA REG. NO. 10807-08

EPA EST. NO. 10807-TX-1

HMS RATING: Health-1; Flammability-0; Reactivity-0; Personal Protection-B.

MADE IN U.S.A. BY:

Amrep

990 Industrial Park Drive

Marietta, Georgia 30062

NOTE: Areas highlighted in blue are per PR Notice 2001-1 and 2001-6. (liquids/B0252-LABL(07-03p).doc as of 07/28/03