

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 18 2003

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

Subject: Misty Enviro-125
EPA Registration Number 10807-113
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

- 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.
- You must submit separate "Cleaning and Deodorizing" directions. They must be clearly separated from each other.
- Update the Storage and Disposal statements for container that is greater than one gallon. Please read the label manual in Chapter 13 for guidance or read PR Notice 2001-6.
- You will need to be more specific about "other institutions". Define it.
- Add a statement on the label stating: Do not use on glass, eating utensils, inner surfaces or appliances.

CONCURRENCES

SYMBOL	75100						
SURNAME	B. Jones						
DATE	11-18-03						

GENERAL COMMENTS

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

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

Sincerely,



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

MISTY

Enviro-125

Detergent/Disinfectant

- Cleans, Disinfects, Deodorizes & Sanitizes • Dual Quat Based
- Virucide* • Concentrated • Unfragranced

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	6.25%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	6.25%
INERT INGREDIENTS:	87.50%
TOTAL:	100.00%

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, respiratory depression and convulsion may be needed. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. See additional precautionary statements on back panel.

BO0257

NET CONTENTS 1 GALLON (3.8 LITERS)

Restricted to sale, to use and storage by persons only.

00257-LABL(07-03p) 10807-113.pmd

0/13/2003, 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. 10807-113

1 OF 2

3/4

ENVIRO-125

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:
 DANGER: Keep out of reach of children. Corrosive. Causes severe eye and skin damage. Do not get into eyes, on skin or clothing. Harmful if swallowed. Wear goggles and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. 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.

DIRECTIONS FOR USE AND GENERAL INFORMATION:
 ENVIRO-125 is a phosphate free concentrated detergent/disinfectant which provides effective cleaning, disinfecting, deodorizing, and sanitization. The detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance in controlling the hazards of cross-contamination.

ENVIRO-125, when diluted at a rate of 1/2 ounce per gallon of water, is an effective disinfectant against the organism *Pseudomonas aeruginosa* and meets all requirements for hospital use. When used as directed, ENVIRO-125 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, ENVIRO-125 deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and any other areas which are prone to odors caused by microorganisms. Efficacy tests have demonstrated that ENVIRO-125 is an effective bactericide, fungicide, and virucide* in the presence of organic soil (5% blood serum).

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: At 1/2 ounce per gallon dilution, ENVIRO-125 exhibits effective disinfectant activity against the following:

- Pseudomonas aeruginosa* PRD-10
- Brevibacterium ammonitegens*
- Escherichia coli*
- Klebsiella pneumoniae*
- Shigella dysenteriae*
- Salmonella schottmulleri*
- Staphylococcus aureus*
- Streptococcus salivarius*

At this level the product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

DISINFECTANT: To disinfect hard, inanimate surfaces (such as walls, floors, table tops), add 1/2 ounce of ENVIRO-125 detergent/disinfectant per gallon of water. Apply solution with mop, cloth or sponge or mechanical sprayer so as to wet thoroughly. Allow to remain for 10 minutes and then let air dry. To disinfect toilet bowls, flush toilet, add 1/2 ounce of ENVIRO-125 detergent/disinfectant directly to the bowl water. Scrub the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush. For heavily soiled areas, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

SAINTIZATION: To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare 300 ppm active quaternary ENVIRO-125 solution by adding 1/2 ounce ENVIRO-125 to 5 gallons of water. To sanitize inanimate bases (such as beds, sleeping bleats, counter tops) flood the area with 200 ppm ENVIRO-125 solution or apply with a cloth or sponge, making sure to wet all surfaces completely for at least 60 seconds. Let air dry. Prepare a fresh solution of each use.

SAINTIZATION: When used for sanitization of previously cleaned food equipment of food contact items, first active quaternary to 200 ppm. At this level no potable water rinse is required. ENVIRO-125 is an effective sanitizer when diluted in water up to 800 ppm based on CaCO3. To sanitize eatable items (such as drinking glasses, eating utensils), immerse in a 200 ppm ENVIRO-125 solution for at least 60 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

VIROICIDAL ACTIVITY: This product when used on environmental inanimate hard surfaces at 1/2 ounce per gallon of hard water exhibits effective virucidal activity against influenza A2-Acan (representative of the common flu virus), Herpes simplex type 1 (representative of fever blisters and mononucleosis), Adeno virus type 2.

MOLD AND MILDEWICIDAL: ENVIRO-125 prevents and controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces.

MILDEWICIDAL: To control mold and mildew on pre-cleaned, hard, non-porous surfaces (such as floors, walls, table tops), add 1/2 ounce of ENVIRO-125 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 rubber growth reappears.

STORAGE & DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. **STORAGE:** Do not store below 40°F. Store in original container. **PESTICIDE DISPOSAL:** Pesticides, mixtures, or residues that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies. **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.

EPA REG. NO. 10007-113 EPA EST. NO. 10007-TX-1
 HHS RATINGS: Health-1; Flammability-0; Reactivity-0; Personal Protection-B.

MADE IN U.S.A. BY:
antrep
 960 Industrial Park Drive
 Marietta, Georgia 30062

NOTE: Areas highlighted in blue are per PRI Notice 2001-1 and 2001-6.
 (liquids)B0257-LAB(07-03p) doc as of 07/28/03