

33176-24

12-5-2007

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 05, 2007

Susan Watson
MBL Industries, Inc., Subsidiary of
Amrep, Inc.
990 Industrial Park drive
Marietta, GA 30062

Subject: Product Name: Airysol Brand Surface Disinfectant Spray
Decision Number: D-3382477
EPA Registration Number: 33176-24
Application Date: 28-Sep-2006
Receipt Date: 18-Oct-2006

Dear Mrs. Watson:

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

Proposed amendment:

- Add claim label against Human immunodeficiency virus Type 1.

Conclusion/Recommendations

The submitted efficacy data (MRID #472056-01) supports the use of the product, "Airysol Brand Surface Disinfectant Spray" as a disinfectant with virucidal activity against Human immunodeficiency virus Type 1 (HIV-1) on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes.

Label comments:

Make the following label revisions:

1. The ATCC designation numbers must be listed with the organisms on the Master Label.
2. The designation organism name *Salmonella choleraesuis* has been changed to "*Salmonella enterica*." This change must be reflected on the current and any future label for the product, Airysol Brand Surface Disinfectant Spray.

General comments:

For detailed information and considerations, refer to the enclosed EPA/AD Product Science Branch efficacy review dated November 29, 2007.

Submit three (3) copies of the revised label bearing the revisions as stated above. A stamped copy of the accepted labeling is enclosed.

If you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epamail.epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: [stamped labeling & efficacy review]

NOTE: To match EPA stamped "accepted" label and comments letter dated 12/21/06; Areas highlighted in blue are additions to text reflecting proposed additions of HIV-1 claims.

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. Avoid contamination of food and food utensils. In case of food contact, surfaces must be thoroughly scrubbed with detergent and rinsed with potable water prior to reuse.

FIRST AID: 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. You may also contact 1-800-xxx-xxxx for emergency medical treatment information. *NOTE [Toll free phone number language may be modified to fit company's policy] [National Poison Control is 1-800-222-1222]* **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.

PHYSICAL OR CHEMICAL HAZARD: Flammable! Contents under pressure. Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

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

This product is designed for use in Homes, Nursing Homes, Hospitals, Institutions, Offices, Schools, Motels and Hotels. When used as directed this product will disinfect pre-cleaned inanimate nonporous hard surfaces (such as walls, desk tops, sink tops, telephones, door knobs, diaper pails, toilet seats, bed pans, linen carts, hampers, wheel chairs, light switches, garbage pails) and other pre-cleaned inanimate hard nonporous surfaces. This product demonstrates effective disinfection on pre-cleaned hard non-porous inanimate surfaces against (*bacteria*) *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*. This product also kills viruses on pre-cleaned hard non-porous inanimate surfaces. ***Viruses:** HIV-1 (AIDS Virus), Influenza A/Hong Kong virus, Influenza B virus, Herpes Simplex virus Type 1, Herpes Simplex virus Type 2 and Canine Distemper virus. This product is fungicidal against **Pathogenic fungi**, *Trichophyton mentagrophytes* (Athletes Foot Fungus), when used as directed on pre-cleaned hard non-porous inanimate surfaces found in the bathroom, shower stall, and locker room, or other pre-cleaned hard nonporous surfaces commonly contacted by the bare feet. In addition, this product disinfects and deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins and cans, restrooms, shower stalls) and other areas prone to odors caused by microorganisms. **SURFACE DISINFECTION AND DEODORIZATION:** (1) Shake well before using. (2) First pre-clean surface to be treated using this product or usual cleaning methods. (3) Hold can six inches from surface and spray until completely wet, allowing the surface to remain wet for 10 minutes. (4) Allow to air dry. Food contact surfaces must be thoroughly scrubbed with detergent and rinsed with potable water prior to use. **MOLD AND MILDEWSTAT:** To control mold and mildew on pre-cleaned hard non-porous inanimate surfaces (such as floors, walls, table tops), spray the surfaces to be treated. Make sure to wet completely and allow the surface to remain wet for 10 minutes. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

***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).

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, or 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 should 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.

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 devices prior to sterilization or high-level disinfection. (or)

This product is not for use on medical device surfaces.

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

(Equivalent to 26.5 Fluid Ounces)



MANUFACTURED BY:
MBL INDUSTRIES, INC.
a solely owned subsidiary of Amrep, Inc.
990 Industrial Park Drive
Marietta, GA 30062

08/07p



Surface Disinfectant Spray

- Germicidal • Fungicidal • Staphylocidal • Pseudomonacidal • Virucidal* • Deodorizes and Refreshes
- Prevents Mold and Mildew on Hard Non-Porous Surfaces

(NOTE To meet CA Barbers requirements, use:

- Disinfects • Germicidal • Fungicidal • Virucidal* • Cools, Lubricates, Cleans, Prevents Rust on Clippers)

ACTIVE INGREDIENTS:

n-Alkyl (60% C-14, 30% C-16, 5% C-12, 5% C-18)	
dimethyl benzyl ammonium chlorides	0.1%
n-Alkyl (68% C-12, 32% C-14)	
dimethyl ethylbenzyl ammonium chlorides	0.1%
Ethyl alcohol	53.0%
INERT INGREDIENTS:	46.8%
(Contains sodium nitrite)	
TOTAL:	100.0%

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC - 5 2007

EPA REG. NO. 33176-24 EPA EST. NO. 10807-GA-1

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See side panels for additional precautionary statements.

NET WT. 1 LB. 3 oz. (19 OZ.)(539 GRAMS)

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

33176-24

h/c

[Alternate Directions for Grooming Clippers]

This product has been designed for use by hair stylists, barbers, beauticians, veterinarians, and animal groomers for use in pre-cleaning, disinfecting and maintaining clippers. It acts as a virucide*, bactericide and fungicide while also cooling, lubricating and providing protection against rust. Regular use will help to maintain clean blades that operate with reduced friction and with smoother clipping action. Will help to prolong equipment life. This product is designed for use in pet salons, animal hospitals, barber and beauty shops. When used as directed it will disinfect metal clipper blades. This product demonstrates effective disinfection on pre-cleaned hard non-porous inanimate surfaces against (*bacteria*) Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and (*fungi*) Trichophyton mentagrophytes (Athletes Foot Fungus). ***Viruses:** Influenza A virus/Hong Kong, Influenza B virus/Hong Kong, Herpes Simplex virus Type 1, Herpes Simplex virus Type 2 and Canine Distemper virus.

CLEANING PROCEDURE: Prior to disinfection, (1) Shake well before using. (2) With the clipper turned off, spray the clipper blades, wetting the entire blade surface including between teeth of blades until hair or other organic soil is removed.

TO DISINFECT GROOMING CLIPPERS PRIOR TO EACH USE: (1) Shake well before using. (2) With the clipper turned off, first pre-clean clipper blades with this product as directed above or by usual cleaning methods to remove hair and other organic soil. (3) Hold can 6 inches from blades. Spray entire blade surface including between teeth of blades until wet. Keep surface wet for 10 minutes. (4) Allow to air dry. Between disinfectant applications, spray clippers with this product to spray away hair, dandruff and dust particles while cooling and lubricating the blades.

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Surface Disinfectant Spray

- Germicidal • Fungicidal • Staphylocidal •
Pseudomonacidal • Virucidal*
• Deodorizes and Refreshes
• Prevents Mold and Mildew on Hard Non-Porous
Surfaces

(NOTE To meet CA Barbers requirements, use:

"• Disinfects • Germicidal • Fungicidal • Virucidal* •
Cools, Lubricates, Cleans, Prevents Rust on Clippers")

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n-Alkyl (68% C-12, 32% C-14)
dimethyl ethylbenzyl ammonium chlorides 0.1%
Ethyl alcohol 53.0%
INERT INGREDIENTS: 46.8%
(Contains sodium nitrite)
TOTAL: 100.0%

EPA REG. NO. 33176-24 EPA EST. NO. 10807-GA-1

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