

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Stacy Harris
Gulf States International Inc.
c/o Adams Technology Systems
5145 Forest Run Trace
Alpharetta, GA 30022

JUN 21 2002

Subject: Medipure
EPA Registration No. 70261-1
Amendment Date: May 11, 2002
EPA Receipt Date: May 14, 2002

Dear Ms. Harris,

The following amendment submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, Rodenticide Act, as amend, is acceptable with the conditions listed below.

- Addition of Hepatitis B Virus

Conditions

Revise the label as follows:

1. On page 2, you need to qualify the surface, porcelain, as hard non-porous by stating "glazed" porcelain.
2. Under the Disinfection, Deodorizing, & Cleaning directions, you will need to add the following statements, "For food contact surfaces, such as kitchen counters, appliances, and tables, rinse with potable water after disinfection. Do not use on silverware, glasses, and dishes."
3. Add the statement, Do not use on dishes, glasses, or silverware, " must be added to the "Food Service Establishment" directions.
4. Under Fungicidal Activity, revise the end of the statement to read ".....when used as directed on clean hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other areas that are commonly contacted by bare feet."

General Comments

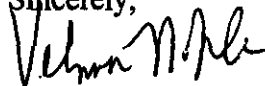
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) 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 regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

3 7 5

MEDI-PURE

CLEANER
MILDEWSTAT (on hard
inanimate surfaces)
*VIRUCIDE

DEODORIZER
DISINFECTANT
TUBERCULOCIDAL
FUNGICIDE (against
pathogenic fungi)

ACTIVE INGREDIENTS:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.105%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.105%
OTHER INGREDIENTS:	<u>99.790%</u>
Total:	100.000%

KEEP OUT OF REACH OF CHILDREN WARNING

See side panels for additional precautionary statements.

EPA REG. NO. 70261-1
EPA EST. NO. 1839-IL-01

GULF STATES INTERNATIONAL, INC.
PO Box 628 • Union Springs, AL 36089

NET CONTENTS: _____

U.S. Patent No. 5,444,094

ACCEPTED
with COMMENTS
in EPA Letter Dated:

(Middle Panel)

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amended, for the pesticide,
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485

DIRECTIONS FOR USE

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

Medipure is designed specifically as a general non-acid cleaner and disinfectant for use in homes, hospitals, nursing homes, schools, hotels, and restaurants; authorized by USDA for use in federally inspected meat and poultry processing plants. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets. For plastic and painted surfaces, spot test on an inconspicuous area before use. May be used in the kitchen on counters, sinks, appliances, and stovetops. A rinse with potable water is required for surfaces in direct contact with food. In addition, this product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.

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.

DISINFECTION, DEODORIZING AND CLEANING - Remove gross filth or heavy soil prior to application of the product. Hold container six to eight inches from surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum.

One-step cleaning and disinfection of toilet bowls and urinals: Remove water from bowl by forcing water over trap with a swab mop applicator. Press swab mop against side of the bowl to remove excess water from applicator. Apply 1 to 2 ounces of this product evenly, allowing sufficient time for product to cover entire surface of bowl for maximum cleaning. Swab bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand 10 minutes and flush.

To disinfect food processing premises: floors, walls and storage areas, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product.

Food products and packaging materials must be removed or carefully protected prior to using this product.

To disinfect food service establishment food contact surfaces: countertops, appliances, tables, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product.

TUBERCULOCIDAL ACTIVITY - This product exhibits disinfectant efficacy against Mycobacterium tuberculosis (BCG) in 10 minutes at 20 degrees Centigrade when used as directed on previously cleaned hard nonporous inanimate surfaces.

BACTERICIDAL ACTIVITY - When used as directed, this product exhibits effective disinfectant activity against the organisms: Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli 0157:H7, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin intermediate resistant Staphylococcus aureus (VRSA), Vancomycin resistant Enterococcus faecalis (VRE) and meets the requirements for hospital use.

***VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate, non-porous surfaces, exhibits effective virucidal activity against HIV-1 (associated with AIDS), Canine Parvovirus, and Poliovirus Type 1 and Hepatitis Virus (HBV)..

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of 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-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use 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 product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Gulf States International, Inc.
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575

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL ACTIVITY - This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

KEEP OUT OF REACH OF CHILDREN. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
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 with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.
If swallowed: Call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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 treatment advice.

(OPTIONAL) You may contact xxx/xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. 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.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.
PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL - *Plastic Containers:* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
For containers 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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