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10324-80

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PS 172

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 02 1998

Mason Chemical Company
721 W. Algonquin Road
Arlington Heights, IL 60005

Subject: Maquat 5.5-M
EPA Registration No. 10324-80
Amendment Dated September 19, 1997

Attn: Marc M. Mason
General Manager

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Please submit one (1) copy of the finished printed label before this product is released for shipment. Also, refer to the enclosed "risk Assessment and Science Support Label Amendment" for comments.

If you have any questions concerning the comments in this letter, you may contact Zenobia Jones at (703) 308-6198.

Sincerely,



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

CONCURRENCES

SYMBOL	7510W						
SURNAME	Stone						
DATE	12-30-98						

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. This Product has been formulated to aid in the reduction of cross-contamination in these areas.

This product is a "one-step" disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed. This product is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, this product will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

PRECAUTIONARY STATEMENTS

DANGER

Hazards to Humans and Domestic Animals

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling. Harmful or fatal if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

DIRECTIONS FOR USE

GENERAL CLASSIFICATION

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

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.

This product is a proven "one-step" disinfectant-cleaner-mildewstat-sanitizer-fungicide-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply this product to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, glazed porcelain and bed frames with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. Spray should remain coarse. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or more often if the solution becomes diluted or soiled.

DISINFECTION - To disinfect hard, non-porous surfaces, in hospitals add 2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At 1 1/4 oz. per gallon of water this product will disinfect hard non-porous surfaces in schools, industry and non-medical institutions. At 2 oz. per gallon use-level, the activity of this product has been evaluated by the AOAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

<i>Pseudomonas aeruginosa</i>	<i>Enterococcus faecalis</i>
<i>Escherichia coli</i>	<i>Salmonella typhi</i>
<i>Salmonella choleraesuis</i>	<i>Klebsiella pneumoniae</i>
<i>Staphylococcus aureus</i>	<i>Shigella dysenteriae</i>
<i>Streptococcus pyogenes</i>	<i>Serratia marcescens</i>
<i>Enterobacter aerogenes</i>	<i>Brevibacterium ammoniagenes</i>
<i>Shigella flexneri</i>	<i>Shigella sonnei</i>
<i>Proteus vulgaris</i>	<i>Staphylococcus aureus</i> (Methicillin resistant)
<i>Enterococcus faecalis</i>	<i>Listeria monocytogenes</i>
<i>Proteus mirabilis</i>	<i>Campylobacter jejuni</i>
<i>Staphylococcus epidermidis</i> (antibiotic resistant)	<i>Enterobacter cloacae</i>
<i>Pseudomonas aeruginosa</i> (Antibiotic resistant)	<i>Escherichia coli</i> (Antibiotic resistant)
<i>Corynebacterium ammoniagenes</i>	<i>Klebsiella pneumoniae</i> (Antibiotic resistant)
<i>Enterococcus faecium</i> (Vancomycin resistant)	

MAQUAT 5.5-M

Disinfectant-Cleaner-Fungicide-Mildewstat Virucide* - Sanitizer-Deodorizer For Hospitals, Veterinary Use, Institutional and Industrial Use
Effective in hard water up to 400 ppm hardness (calculated as CaCO₃) in the presence of 5% serum contamination

Active Ingredients:

Octyl Decyl Dimethyl Ammonium Chloride	1.650%
Diocetyl Dimethyl Ammonium Chloride	0.825%
Didecyl Dimethyl Ammonium Chloride	0.825%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	2.200%
Inert Ingredients:	94.500%
TOTAL	100.000%

**KEEP OUT OF REACH OF
CHILDREN
DANGER**

STATEMENT OF PRACTICAL TREATMENT. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink egg whites, gelatin solution; or if these are not available, drink large quantities of water. Call a physician immediately.

NOTE TO PHYSICIAN. Probable mucosal damage may contraindicate the use of gastric lavage.

MASON CHEMICAL COMPANY "THE QUATERNARY SPECIALISTS"

721 W. Algonquin Road
Arlington Heights, IL 60005
847-290-1621
Toll Free:
1-800-362-1855

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAR 2 1998

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

10324-80

E.P.A. Reg. No. 10324-80
E.P.A. Est. No. 10324-IL-1

NET CONT. TS

For Schools, Industry and Non-Medical Institutional Uses:

At 1 1/4 oz. per gallon of water, this product delivers excellent cleaning and germicidal effectiveness. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Escherichia coli* and *Serratia marcescens*. The same AOAC tests used to confirm performance for hospitals were used.

Non-Acid Toilet Bowl Disinfectant/Cleaner Application

1. Add 1.5 oz. to the bowl (0.75 gal.) and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

2. Empty toilet bowl or urinal and apply a 2 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical spray. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

Fungicidal Control

This product is an effective fungicide against *Candida Albicans*, *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, etc. at 2 oz./gallon.

Mold and Mildew Control - At 1 1/4 oz. per gallon, this product will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

***Virucidal Performance** - At 1 1/4 oz. per gallon use level, this product was evaluated and found to be effective in the presence of 5% blood serum against the following viruses: Avian Influenza/Turkey/Wisconsin, Newcastle disease, Pseudorabies virus, Canine distemper, Infectious Bovine Rhinotracheitis, Influenza A/Brazil virus, Herpes Simplex Type I and Type II and Vaccinia on inanimate environmental surfaces.

At 1.25 oz./gallon in the presence of 5% blood serum and 400 ppm of hardness for a 2 minute contact time, this product was found to be effective against HIV-1 (AIDS Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES SOILED WITH BLOOD/BODY FLUIDS

Effective against HIV in 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 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).

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 Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the 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 2 minutes. This contact time will not control other common type of viruses and bacteria.

Sanitizing-Non-Food Contact Surfaces (such as floors, walls, tables, etc.)- At 1 oz. per 2 3/4 gallon use-level, this product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 80 seconds.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Store only in original container. Do not reuse empty container. Keep this product under locked storage sufficient to make it inaccessible to children of persons unfamiliar with its proper use.

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.

CONTAINER DISPOSAL - (Larger than 1 gal.) - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. In addition, plastic containers may be disposed of by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. (1 gal and smaller). Do not reuse container. Wrap container and put in trash.