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10324-80

8/26/97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

AUG 26 1997

Attention: Marc M. Mason

Subject: Maquat 5.5M
EPA Registration No.10324-80
Your Submission Dated February 28, 1997
EPA Receive Date of March 5, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to add an additional virucidal claim against HIV-1 (AIDS virus) to the product label, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. Under the Directions for Use section of the product label, change "...porcelain..." to read "...glazed porcelain...".

2. Also under the Directions for Use, change "Prepare fresh solution daily or when use solution becomes visibly dirty" to read "Prepare fresh solution daily or more often if the solution becomes diluted or soiled."

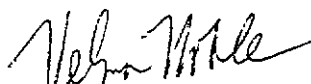
3. Change "Streptococcus faecalis" to read "Enterococcus faecalis".

4. Specify the type of Herpes Simplex virus tested.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,



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

Enclosure		CONCURRENCES					
SYMBOL	7510W:J.Fairfax:8/26/97:10324-80						
SURNAME	J.Fairfax						
DATE	8/26/97						

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Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. MAQUAT 5.5-M has been formulated to aid in the reduction of cross-contamination in these areas.

MAQUAT 5.5-M 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. MAQUAT 5.5-M is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, MAQUAT 5.5-M 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 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.

MAQUAT 5.5-M is a proven "one-step" disinfectant-cleaner-sanitizer-fungicide - mildewstat - virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply MAQUAT 5.5-M to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks tile, porcelain and bedframes with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visible dirty.

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, MAQUAT 5.5-M will disinfect hard non-porous surfaces in school, industry and non-medical institutions.

2 oz. per gallon use-level. The activity of MAQUAT 5.5-M has been evaluated in presence of 5% serum and 400 ppm hard water 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:

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis
Escherichia coli
Streptococcus pyogenes
Klebsiella pneumoniae

Enterobacter aerogenes
Streptococcus faecalis
Shigella dysenteriae
Brevibacterium ammoniagenes
Salmonella typhi
Serratia marcescens

MAQUAT 5.5-M

Disinfectant-Cleaner-Sanitizer-Fungicide Mildewstat-Virucide*-Deodorizer for Hospitals, 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.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 10324-80
EPA Establishment No. 10324-IL-1



MASON CHEMICAL COMPANY "THE QUATERNARY SPECIALISTS"

721 W. Algonquin Rd.
Arlington Heights, IL 60005
(708) 290-1621
Toll Free:
1-800-362-1855

For Schools, Industry and Non-Medical Institutional Uses: At 1 1/4 oz. per gallon of water, MAQUAT 5.5-M delivers excellent cleaning and germicidal effectiveness. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Escherichia coli* and *Serratia marcescens*. The same AOAC tests used to confirm performance for hospitals were used.

Fungicidal Control

MAQUAT 5.5-M is an effective fungicide against 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./gallon MAQUAT 5.5-M 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, MAQUAT 5.5-M was evaluated and found to be effective in the presence of 5% serum and 400 ppm hard water, against the following viruses: Influenza A/Brazil, Herpes Simplex and Vaccinia, on inanimate environmental surfaces.

At 1.25 ozs. Per 1 gallon in the presence of 5% blood serum and 400 ppm of hardness 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 SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS*.

Effective against HIV 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 of inanimate surfaces/objects with blood or body fluids, and in which 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 all 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. MAQUAT 5.5-M is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 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 lock and key. Store in a secure location inaccessible to children or 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 recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by 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 burn, stay out of smoke. (1 gal. and smaller). Do not reuse empty container. Wrap container and place in trash.