

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 17 1995

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

Attention: Mark M. Mason
General Manager

Subject: Maguat 615-HD
EPA Registration No. 10324-72
MOU Compliance Amendment dated November 28, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, will be acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. Under the Statement of Practical Treatment, remove egg whites and gelatin solution, revise statement to read "If swallowed, drink promptly a large quantity of water."
2. Revise disclaimer statement to conform with the wording in PR-Notice 94-4 to read "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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".

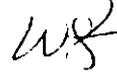
A stamped copy of your labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS
& DOMESTIC ANIMALS**

DANGER

**KEEP OUT OF REACH OF CHILDREN
CORROSIVE**

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

DIRECTIONS FOR USE

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 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.

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 to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain, and bed frames 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 visibly dirty.

Disinfection - to disinfect hard, non-porous surfaces, add 0.5 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. (The activity has been evaluated in the 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
- Salmonella schottmuelleri
- Streptococcus faecalis
- Shigella dysenteriae
- Brevibacterium ammoniagenes
- Salmonella typhi
- Serratia marcescens

BEST AVAILABLE COPY

MAQUAT 615-HD

**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	6.510%
Dioctyl dimethyl ammonium chloride	3.255%
Didecyl dimethyl ammonium chloride	3.255%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	8.680%

Inert Ingredients:	78.300%
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 promptly a large quantity of egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

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

**SEE LEFT PANEL
FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

**E.P.A. Reg. No. 10324-72
E.P.A. Est. No. 10324-IL-1
NET CONTENTS**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

Under the Federal Insecticide,
Mason Chemical Company and Rodenticide Act as
amended for the pesticide
*The Quaternary Specialists under EPA Reg. No.
721 W. ALGONQUIN ROAD
ARLINGTON HEIGHTS, IL 60005
1-800-362-1855

Fungicidal Performance - This product is an effective fungicide against mold and mildew on non-food contact surfaces (the athletic surfaces in areas such as shower and bath areas, etc.)

Mold and Mildew Control - Will effectively inhibit the growth of mold and mildew on surfaces (as indicated in guidelines to dry off surface and repeat).
Virucidal Performance - A study was evaluated in the presence of hard water and found to be effective against viruses: influenza A/Brazil, influenza on hard non-porous surfaces.
Sanitizing-Non-Food Contact Surfaces - (walls, tables, etc.) At 0.5% dilution is an effective sanitizer against Klebsiella pneumoniae on environmental surfaces. Treatment time: 60 seconds.

STORAGE

Do not contaminate water. Open dumping is prohibited. Do not reuse empty container. Do not reuse under locked storage sufficient to protect children or persons unfamiliar with the product.
PESTICIDE DISPOSAL - This product is highly flammable and hazardous. Improper disposal by incineration or incineration is a violation of Federal law. Wastes cannot be disposed of in the open. For instructions, contact your State Health Department, Control Agency, or the Hazardous Waste Management Division of the nearest EPA Regional Office.
CONTAINER DISPOSAL - (or equivalent). Then offer for recycling, puncture and dispose of in accordance with procedures approved by the appropriate authority. In addition, plastic containers should be incinerated, or if allowed by local authorities, burned. If burned, stay out of the area. Do not reuse empty container for other purposes.

Cross-contamination is of concern in hospitals, but in general has been formulated to prevent cross-contamination in these areas.

A one-step disinfectant cleaner with a broad spectrum of bactericidal activity prevent the growth of mold and mildew when used as directed.

This product is an effective disinfectant for use on non-food contact surfaces. When used as directed, this product is effective in toilet areas, behind garbage cans and garbage bags where bacterial growth can occur.