

Marc M. Mason
General Manager
Mason Chemical Company
721 W. Algonquin Road
Arlington Heights, IL 60005

SEP 16 2002

Subject: Amendment per FIFRA
Maquat 3.8-M
EPA Registration No. 10324-79
Application Dated: June 17, 2002
EPA Received Date: June 19, 2002

6"

Dear Mr. Mason:

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

Proposed Amendment

- Update First Aid Statements
- Update Storage and Disposal Statements
- Update Precautionary Statements

Label Comments

1. Revise the Precautionary Statements to read as follows:
"Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse."
2. Revise the Storage and Disposal section by changing the Container Disposal statement to read as follows:
"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."
3. Revise the Disinfection directions to include the statements "Wipe excess or allow to air dry. For heavily soiled areas, a preliminary cleaning is required prior to disinfection. Prepare a fresh solution at least daily or when use solution becomes visibly dirty."

CONCURRENCES

SYMBOL	7510C						
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DATE	9/13/02						

- 4. Revise the statement under the section "For Schools, Non-Medical..." that reads "It is effective against...Escherichia coli. The same AOAC tests used above to confirm suitable performance for hospitals were used." to read "It is effective against...Escherichia coli based on AOAC use dilution testing."
- 5. Revise the Sanitizing directions to include the statements "Wipe excess or allow to air dry. For heavily soiled areas, a preliminary cleaning is required prior to sanitization. Prepare a fresh solution at least daily or when use solution becomes visibly dirty."
- 6. Since this product has claims as a cleaner and deodorizer, you must have cleaning and deodorizing directions for this product label to read as follows:
"To Clean and Deodorize: Add 2 oz. per gallon of water. Swab with cloth, mop or mechanical spray device so as to thoroughly wet surfaces. Wipe excess or allow to air dry. Prepare a fresh solution at least daily or when use solution becomes visibly dirty."
- 7. Revise the HIV-1 instructions by moving the heading **"SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACE/OBJECTS SOILED WITH BLOOD/BODY FLUIDS"** to be placed before the **"PERSONAL PROTECTION"** section.
- 8. Revise the HIV-1 instructions by capitalizing and bold facing the statement **"EFFECTIVE AGAINST HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS..."**

General Comments

A stamped copy of the label is enclosed for your records. Please submit a copy of the final printed label before distributing or selling the product bearing the revised language. Should you have any questions regarding this letter, please contact me at 703-308-6233.

Sincerely,



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

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

DANGER KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

(If container is 5 gallons or larger the following statement must appear on the label)

ENVIRONMENTAL HAZARD

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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Do not mix with oxidizers, anionic soaps and detergents

(If the container is greater than one gallon use the following storage and disposal statements)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

PESTICIDE STORAGE: 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 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 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.

(If container is one gallon or less use the following storage and disposal statements)

STORAGE AND DISPOSAL

Store in original container and place in locked storage area. Keep from freezing. Do not contaminate water, food, or feed by storage or disposal. Small spills may be mopped up or flushed away with water or absorbed on some absorbent material. Wrap container and put in trash. Securely wrap original container in several layers of newspaper and discard in trash.

MAQUAT 3.8-M

Disinfectant, Cleaner, Sanitizer, Fungicide, Mildewstat, Virucide*-Deodorizer, with Organic Soil Tolerance For Hospitals, Institutional and Industrial Use

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride	1.14%
Diocetyl Dimethyl Ammonium Chloride	0.57%
Didecyl Dimethyl Ammonium Chloride	0.57%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	1.52%

INERT INGREDIENTS:	96.20%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

See left panel for additional precautionary statements

First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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:
SEP 16 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No
10324-79

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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 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" - cleaner-disinfectant - mildewstat - sanitizer - fungicide - virucide in the presence of moderate amounts of organic soil.

Apply this product to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks 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, treated surfaces must remain wet for 10 minutes.

For Hospitals and Nursing Homes, add 2 oz. per gallon of water. The activity of this product has been evaluated in the presence of 5% serum 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>Streptococcus faecalis</i>
<i>Escherichia coli</i>	<i>Salmonella choleraesuis</i>
<i>Klebsiella pneumoniae</i>	<i>Staphylococcus aureus</i>
<i>Shigella dysenteriae</i>	<i>Salmonella schottmuelleri</i>
<i>Brevibacterium ammoniagenes</i>	<i>Serratia marcescens</i>
<i>Enterobacter aerogenes</i>	

For Schools, Non-Medical Institutional and Industrial Uses: At 1 oz. per gallon of water. This product delivers excellent cleaning and germicidal effectiveness. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Escherichia coli*. The same AOAC tests used above to confirm suitable performance for hospitals were used.

FUNGICIDAL PERFORMANCE

This product at 1 oz. per gallon 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.

Mold and Mildew Control - At 1 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 oz. per gallon use level, this product was evaluated in the presence of 5% serum and found to be effective against the following viruses: Influenza A/Brazil Herpes Simplex and Vaccinia on hard non-porous surfaces.

At 2 ozs. per 1 gallon in the presence of 5% blood serum for a two 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/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Effective against HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/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 I (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 two minutes. This contact time will not control other common types of viruses and bacteria.

Sanitizing-Non-Food Contact Surfaces (such as floors, walls, tables, etc.) - At 1/2 oz. per gallon use-level. This product is an effective sanitizer agent against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

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