

10324-85

8/3/2000

Page 186

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

AUG 3 - 2000

ATTENTION: Marc M. Mason

SUBJECT: Maquat 86-M
EPA Registration Number 10324-85
Your Amendment Dated: January 17, 2000
EPA Received Date: February 9, 2000

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. On page one, the left panel revise the statement "This disinfectant has been formulated to aid in the reduction of cross-contamination in these areas." to read "This disinfectant has been formulated to aid in the reduction of cross-contamination *on treated surfaces* in these areas."

B. Add an asterisk (*) after the words "viricidal," "viricide," and "virus" as they appear on the left panel in the second and seventh sections on the first page: "viricidal*".

C. Delete the phrase "Prepare a fresh solution daily or more often if the solution becomes diluted or soiled." This product is used undiluted therefore this phrase is inappropriate.

D. Revise the directions for "Disinfection" as follows: immediately following the heading

"Disinfection" on the left panel place the statement: "For heavily soiled areas, a preliminary cleaning is required." This statement would then be followed by "To disinfect hard, non-porous							
SYMBOL							
SURNAME	7510C						
DATE	9/28/00						

surfaces, treated surfaces..." The statement "For heavily soiled areas, a preliminary cleaning is required." may be deleted from its earlier location.

E. Revise your fungicidal directions as follows: " This product is an effective fungicide against *Candida albicans*. *This product will also effectively control the growth of Trichophyton mentagrophytes on hard nonporous surfaces in* locker rooms, dressing rooms, shower and bath areas, and exercise facilities. Treated surfaces must remain wet for 10 minutes. *Apply as directed previously.* "

This revision is as per Subdivision H: Labeling Guidelines for Pesticide Use Directions for Antimicrobial Products, section 101-3, p.25.

F. Revise the directions for "Disinfecting and Cleaning Toilet Bowls and Urinals" by adding the following statement to item 1. and deleting it from item 6. "Preliminary cleaning is required for heavily soiled surfaces."

G. Make the following revisions to the section of the label which describes the use of this product against HIV-1.

1. Revise the following statement such that it is not in bold type and all upper case letters: "This product was found to be effective against the HIV-1 (AIDS Virus) in the presence of 5% blood serum and 400 ppm of hard water."

2. Move the statement "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS." such that it immediately precedes the subheading "Personal Protection".

3. Revise the statement which begins "Effective against HIV in pre-cleaned..." and ends "...with blood/body fluids" exactly as follows: "KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS" then continue with "in health care settings..." in lower case letters.

H. Revise the directions to "Sanitizing Non-Food Contact Surfaces" by changing the contact time to **60 seconds** to agree with the last stamped label for this product.

I. Make the following revisions to the "Directions for Household Use".

1. Move the subheading "Kitchen/Household Use" such that it immediately follows the heading "Directions for Household Use". Also delete the section "1. Spray soiled area. 2. Wipe soiled area clean." Following the statement "Do not use on paint or acrylic plastics." add the phrase "Wipe soiled area clean."

2. The following comments are taken from the efficacy review for this product: "High chairs and the interiors of microwave oven, refrigerators and freezers are considered food contact surfaces. The data does not support the use of this product on such food contact surfaces, and

SYMBOL	the claim for these uses is not allowed. This product may only be used on the exteriors of these						
SURNAME							
DATE							

appliances. Because of the possible residue on high chairs the product **cannot** be used on high chairs." Thus, the following changes must be made to the household instructions: delete "high chairs," and revise to state "refrigerator or freezer *exteriors*," and "microwave *exteriors*".

3. Revise the statement "Rinse after use on surfaces that come in contact with food." to read "Rinse *with potable water* after use on surfaces that come in contact with food." Also add the same statement to the directions for use on the left panel of page one.

4. Your label may not list the abbreviated names of organisms without including the complete name of the organism in conjunction with the abbreviation. Revise this section to state "This product kills germs, viruses*, fungi, and mildew including *Escherichia coli* 0157:H7 (*E. Coli* 0157:H7), *Escherichia coli* (antibiotic resistant) (*E. Coli*), *Salmonella choleraesuis* (*Salmonella*), *Pseudomonas aeruginosa* (*Pseudomonas*), *Staphylococcus aureus*..."

5. Delete the instructions for HIV from this section. This language is only required to appear on the master label once. You may use it as needed on any subsets of the label which are printed. Delete beginning with "This product was found to be effective..." through "...other common types of bacteria and viruses listed on this label."

J. Make the following corrections to the "Storage and Disposal" statements.

1. The statement "Do not contaminate water, food or feed by storage and disposal." must follow the "STORAGE AND DISPOSAL" heading and is not to be included in the "Storage Instructions". Directly under this statement, change the subheading to read "PESTICIDE STORAGE".

2. Revise the "Pesticide Disposal" statement to read: "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Since your Application for pesticide indicates that this product is only marketed in plastic containers revise the "CONTAINER DISPOSAL" statement as follows: "Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

4. Revise the household "STORAGE AND DISPOSAL" to state "Wrap in newspaper and discard in trash or recycle." deleting the information about rinsing.

K. Since you list the site "Veterinary Use," your label must include the following directions for this site: "For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, and catteries. Remove all animals and feed from premise, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with undiluted product and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse."

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

L. Add the following statement to the directions for "Kitchen/Household Use":
"This product is not to be used on dishware, glasses or eating utensils."

M. The Agency requests further information on the identity of the Influenza virus/Brazil and Vaccinia virus utilized in the submitted confirmatory data. To support claims for public health, the organisms tested must be identified by the specific source from which they were obtained (ATCC ?) along with other supporting identifying data. Please submit this information so it may be included in you file.

N. The submitted Confidential Statement of Formula for the Alternate Formulation dated 1/17/00 is acceptable and will be made part of the record for this file.

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, this registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of this product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510C: T. Lantz: 7/28/00: 10324-85e				CONCURRENCES			
SYMBOL							
SURNAME							
DATE							

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

This formulation is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and will inhibit 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

Hazard to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

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

Apply this product undiluted 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. If mechanical spray is used, spray should be 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, treated surfaces must remain wet for 10 minutes. Then wipe excess with sponge, mop or cloth or allow to air dry. The activity of this formulation 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	Salmonella typhi
Escherichia coli	Klebsiella pneumoniae
Salmonella choleraesuis	Shigella dysenteriae
Staphylococcus aureus	Serratia marcescens
Streptococcus pyogenes	Brevibacterium ammoniagenes
Enterobacter aerogenes	Shigella sonnei
Shigella flexneri	Staphylococcus aureus (Methicillin resistant)
Proteus vulgaris	Listeria monocytogenes
Enterococcus faecalis	Campylobacter jejuni
Proteus mirabilis	Enterobacter cloacae
Staphylococcus epidermidis (antibiotic resistant)	Escherichia coli (Antibiotic resistant)
Pseudomonas aeruginosa (Antibiotic resistant)	Klebsiella pneumoniae (Antibiotic resistant)
Corynebacterium ammoniagenes	Escherichia coli 0157:H7
Enterococcus faecium (Vancomycin resistant)	

MAQUAT 86-M

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

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride	0.026%
Diocetyl Dimethyl Ammonium Chloride	0.013%
Didecyl Dimethyl Ammonium Chloride	0.013%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	0.034%

INERT INGREDIENTS:

TOTAL	99.914%
	100.000%

KEEP OUT OF REACH OF
CHILDREN
CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if symptoms persist.

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists.

See left panel for additional
precautionary statements

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:
Aug 03 1988

E.P.A. Reg. No. 10324-85

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

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,

registered under EPA Reg. No. 10324-85

NET CONTENTS

BATCH NO

FUNGICIDAL CONTROL

This product is an effective fungicide against *Candida albicans*, *Trichophyton mentagrophytes* (the athlete's foot fungus) when used in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities. Treated surfaces must remain wet for 10 minutes.

Mold and Mildew Control - 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.

Disinfection and Cleaning Toilet Bowls and Urinals:

1. With a swab mop applicator, remove water from bowl by forcing out trap.
2. Press swab mop against side of bowl to remove excess water from applicator.
3. Apply 1-2 oz. of Maquat 86-M evenly onto surface to be cleaned and disinfected.
4. Swab entire surface area especially under the rim where outlets are located.
5. Allow Maquat 86-M to remain wet on surfaces at least 10 minutes.
6. Flush toilet and rinse applicator thoroughly. Preliminary cleaning is required for heavily soiled surfaces.

***Virucidal Performance** - This product was evaluated and found to be effective in the presence of 5% serum and 400 ppm hard water, against following viruses:

Avian Influenza/Turkey/Wisconsin, Newcastle Disease, Pseudorabies virus, Canine distemper, Infectious Bovine Rhinotracheitis, Herpes Simplex Type I & II, Influenza A/Brazil and Vaccinia on inanimate hard non-porous environmental surfaces. Treated surfaces must remain wet for 10 minutes.

THIS PRODUCT WAS FOUND TO BE EFFECTIVE AGAINST THE HIV-1 (AIDS VIRUS) IN THE PRESENCE OF 5% BLOOD SERUM AND 400 PPM OF HARDNESS SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOODY/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 types of bacteria and viruses listed on this label.

SANITIZING NON-FOOD CONTACT SURFACES (Such as floors, walls, tables) - This product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumonia* on hard non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes.

DIRECTIONS FOR HOUSEHOLD USE

Apply this product undiluted with a cloth, sponge, mop or directly on surface with a mechanical spray. If a mechanical spray is used spray must be coarse. Hold container 6 inches to 8 inches from surface and spray until thoroughly wet. Do not use on paint or acrylic plastics.

KITCHEN/HOUSEHOLD CLEANING

1. Spray on soiled area.
2. Wipe soiled area clean.

DISINFECT/DEODORIZE

To disinfect hard, nonporous surfaces such as floors, walls, counters, sinks, tubs, toilets, tile, appliances, refrigerator or freezer interiors, microwave interiors, high chairs, stove tops and hoods, tables, garbage pails, faucets apply as is with cloth, sponge, mop or mechanical spray. If a mechanical spray is used, spray must be coarse. Hold container 6 inches to 8 inches from surface and spray until thoroughly wet. Treated surface must remain wet for 10 minutes before wiping. For heavily soiled areas a pre-cleaning step is required. The pre-clean step should be done according to the instructions under Kitchen/Household Cleaning. Rinse after use on surfaces that come in contact with food.

This product kills germs, virus, fungi and mildew such as: *E. coli* 0157:H7, *E. coli*, *Salmonella*, *Pseudomonas*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Campylobacter jejuni*, Herpes Simplex I and II, Influenza A Brazil, *Trichophyton mentagrophytes* (athletes foot fungus) and HIV.

THIS PRODUCT WAS FOUND TO BE EFFECTIVE AGAINST THE HIV-1 (AIDS) VIRUS IN THE PRESENCE OF 3% BLOOD SERUM AND 400 PPM OF HARDNESS. SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOODY/BODY FLUIDS.

ective 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 types of bacteria and viruses listed on this label.

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

ENVIRONMENTAL HAZARD

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 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.

STORAGE AND DISPOSAL

STORAGE INSTRUCTIONS: 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 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 in areas inaccessible to small children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash (or recycle).

(Storage and Disposal for households)

STORAGE AND DISPOSAL

Store in areas inaccessible to small children. Rinse empty container thoroughly and discard in trash or recycle.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 03 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10324-85