

10324-80

08/01/2000

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

AUG 1 - 2000

Subject: Maquat 5.5 M
EPA Registration No. 10324-80
Amendment Date: 1/17/00
EPA Receive Date: 2/04/00

Attention: Mr. Marc Mason

The amendment, referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) is acceptable provided that you address the following comments before you release this product for shipment.

Product Chemistry

The Confidential Statements of Formulas for alternate formulas #1 and #2 dated 1/17/00 are acceptable. The formulations are in compliance with PR Notice 91-2 and in agreement with the label.

Efficacy

The Agency re-reviewed the submitted efficacy studies in MRID Nos. 442690-01, -03, -04, -10, and 443015-02 since these studies were placed on file at the time of submission and not reviewed. The studies support this product's efficaciousness against *Pseudomonas aeruginosa* ATCC #15422, *Corynebacterium (Brevibacterium) ammoniagenes* ATCC #6871, Herpes simplex virus Type 1 ATCC #VR-260.

In regard to the acceptance of Influenza virus/Brazil and Vaccinia virus, the Agency needs additional information on the identity of the two viruses. The submitted data did not confirm the organism's source (American Type Culture Collection ID numbers, ATCC) or use the biochemical method to confirm identification. (For guidance, you should refer to MRID No. 442690-1 in which the organisms identities are confirmed by the ATCC number and Vitek analysis.) The Agency will conditionally allow you to list these viruses on the label, you must submit the additional information.

7570C
Campbell
8/01/00

Label Recommendations

1. On page one, left panel, the second sentence should state "This product has been formulated to aid in the reduction of cross contamination *on treated surfaces* in these areas."
2. On page one, the left panel in the 1st and 6th paragraph, add an asterisk (*) after the words, "virucidal", "virucide", and "virus."
3. Under the precautionary statements, revise the protective eyewear sentence to include *protective clothing and rubber gloves* since this product is Toxicity Category I for primary skin irritation.
4. The statements, "For heavily soiled areas, a preliminary cleaning is required," and "Prepare a fresh solution daily or more often if solution becomes diluted or soiled" should be placed in all the directions after the contact time instructions.

For example: To disinfect hard, non-porous surface, add 2 oz. per gallon of water. Treated surfaces should remain wet for 10 minutes, then allow to air dry or wipe (?). For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or more often if solution becomes diluted or soiled.

5. Revise the heading "Disinfection" to state "*Hospital Disinfection*" and delete the 1 1/4 use dilution rate from this section since you already have specific directions for this rate under schools, industry, and non-medical institutional uses on the right panel.
6. According to DIS/TSS 15, cleaning and deodorizing instructions must appear separately from the disinfection directions. Therefore, you will need to add cleaning/deodorizing instructions that reflect the following:

Mix 1 1/4 oz. per gallon of water to deodorize/clean surfaces.
7. For all the use directions, you will need to state whether the surfaces may air dry or should be wiped off after the contact time.
8. Revise your fungicidal directions to state "*This product is effective fungicide against Canida albicans. This product also will effectively control the growth of Trichophyton mentagrophytes on hard, non-porous 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 under hospital disinfection.*"
9. Under the toilet bowl directions, you will need to add the pre-cleaning statement.
10. Revise the statement which begins "Effective against HIV in pre-cleaned... and ends" ...with blood/body fluids" exactly as follows: "KILLS HIV ON PRE-CLEANED

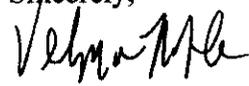
ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS” then continue with “in health care settings” in lower case.

11. Under “Non-food Contact Surface” directions, the contact time should be changed to 60 seconds to agree with the last stamped label for this product.
12. Since you list the site, “Veterinary Use”, your label must include the following directions for this site: *“For cleaning and disinfecting the following hard non-porous 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 2 oz. per gallon of water 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.”*
13. Under Poultry and Swine Sanitation, delete the “cleaning and disinfection” paragraph because the correct directions for this site are cited on page two.
14. Under the shoe bath instructions, add the statement *“Scrape waterproof work boots and place in use solution of 2 oz. per gallon of water for 60 seconds prior to entering area.”*
15. Revise the heading, “Sanitizing incubators and hatchers using fogging devices” to read “Sanitizing incubators, hatchers, and *hatchery rooms* using fogging devices.” Then, delete the directions for sanitizing hatchery rooms. The directions for these sites were the same except the hatchery room instructions were incomplete.
16. You will need to delete the directions for “whirlpool units” and “ultrasonic bathing units.” The Agency does not have a guideline for disinfecting whirlpool unit and ultrasonic bathing units water. In order to add this use site on the product label, you will need to submit efficacy data according to the National Sanitation Foundation Standard 50 Annex H. (For guidance: you should go the Internet site: www.nsf.org)
17. The statement, *“Do not contaminate water, food, or feed by storage and disposal,”* must be placed immediately following the Storage and Disposal heading.

A stamped label is enclosed for your records. Submit two (2) final printed labels before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

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Sincerely,



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

Enclosure: Efficacy Data Evaluation

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 irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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, tables, floors, toilets, garbage pails, critical medical devices and dental and medical equipment surfaces including bed frames, bedrails, wheel chairs, dental chairs, medical beds, whirlpool bath tubs, whirlpool units, ultrasonic bathing units and other hard nonporous surfaces (such as chairs, countertops, sinks, tile, glazed porcelain, metal, stainless steel, ceramic, fiberglass, stone and plastic). Apply with a cloth, sponge 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:

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 5.5-M
 Disinfectant-Cleaner-Fungicide-Mildewstat
 Virucide* - Sanitizer-Deodorizer For Hospitals,
 Farms, Veterinary Use, Institutional and Industrial
 Use, Whirlpools 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%
Dioctyl 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

If on skin: Wash with plenty of soap and water. Get medical attention.
If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
If swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol.

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

E.P.A. Reg. No. 10324-D-0
 E.P.A. Est. No. 10324-IL-1

AUG 01 2000

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 10324-80

NET CONTENTS

BATCH NO

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. Treated surfaces must remain wet for 10 minutes. 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 of water. Treated surfaces must remain wet for 10 minutes.

Mold and Mildew Control - At 1 1/4 oz. per gallon of water, 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 of water use level, treated surfaces must remain wet for ten minutes. 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 hard nonporous surfaces.

At 1.25 oz./gallon of water 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: Surface wet for 2 minutes. This contact time will not control other common type of viruses and bacteria listed on this label.

Sanitizing-Non-Food Contact Surfaces (such as floors, walls, tables, etc.): At 1 oz. per 2 3/4 gallons of water use-level, this product is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae on non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes.

FOR POULTRY AND SWINE SANITIZATION:

SITE PREPARATION

The first step in any on-going sanitization program should be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, disinfection can be accomplished in one easy step.

CLEANING AND DISINFECTION

For all general cleaning and disinfection, use 2 ounces of this product per gallon of water. Apply this product using a cloth, mop, sponge or pressure sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution after each use.

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APPLICATIONS AND USE DILUTION

POULTRY AND SWINE PREMISE

Remove all animals and feeds from premises, trucks, coops, and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 2 ounces of this product per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

HATCHERIES: Use 2 ounces of this product per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

VEHICLES: Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and this product. Use 2 ounces per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes.

SHOE BATHS: Shoe baths containing one inch of freshly made disinfectant solution should be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or when solution appears dirty.

DRESSING PLANT USE: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the recommended use solution 2 ounces of this product per gallon of water. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water.

SANITIZING HATCHERY ROOMS USING FOGGING DEVICES

Remove all animals and food from premises, vehicles and enclosures. Remove all litter and manure from floors, walls, and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix 2 gallons of Maquat 5.5-M to 2.25 gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, fog for one minute for each 4000 cubic feet of space in the room.

SANITIZING INCUBATORS AND HATCHERS USING FOGGING DEVICES

Mix 19 ounces of this product to 122 ounces water. Fog 3-8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatcher treatments at least 24 hours prior to pulling the hatch. Do not allow people to contact or breath this fog and do not enter until the fog has settled (30-60 minutes after fogging is completed). It is acceptable to fog setters and hatchers with 3.0 ounces of Maquat 5.5-M on an hourly or every other hour basis. If this is done, fog for 30-90 seconds once per hour or once every two hours. When fogging is completed, ventilate building and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building must be entered, then the individuals entering the building must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING FOR ROOM AND MACHING SURFACES.

DISINFECTION OF WHIRLPOOL UNITS: After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve.

Add 2 ounces of this product for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift and any/all related equipment with a clean swab, brush or sponge.

After the unit has been thoroughly cleaned, drain the solution from the unit and rinse any/all cleaned surfaces with fresh water.

Repeat for heavily soiled units.

Treated surfaces must remain wet for 10 minutes.

(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.

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

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).

This product meets AOAC efficacy tests standard for hospital disinfectants.

This product meets EPA Sanitizer Test Standards for hard non-porous, non food contact surface sanitizer.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 9, 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10324-80