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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Elizabeth Tannehill Regulatory Manager Mason Chemical Company 721 W. Algonquin Road Arlington Heights, IL 60005

MAY 10 2004

SUBJECT:

Maquat 256-1010N

EPA Registration Number: 10324-134 Application Dated: November 7, 2003 Receipt Date: November 12, 2003

#### Dear Ms. Elizabeth Tannehill:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

- add public health pests
- submission of acute toxicity studies

## **Efficacy Data**

## **Acceptable Studies**

Data Requirement	Means of Support	Status	
Human Coronavirus	Submitted study, MRID 46121002	Acceptable @ 1:256 in 250 ppm hard water and 5% soil for 10 minutes	
Canine Coronavirus	Submitted study, MRID 46121001	Acceptable @ 1:256 in 250 ppm hard water and 5% soil for 10 minutes	

No claims may be made for these organisms as the causative agent of Severe Acute Respiratory Syndrome (SARS).

CONCURRENCES								
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## **Toxicity Data**

## Acceptable Studies

Data Requirement	Means of Support	Status
Acute Oral Toxicity	Submitted study, MRID 46121006	Acceptable, Tox III
Acute Dermal Toxicity	Submitted study, MRID 46121003	Acceptable, Tox III
Primary Eye Irritation	Submitted study, MRID 46121004	Acceptable, Tox I
Primary Skin Irritation	Submitted study, MRID 46121005	Acceptable, Tox I

### **Conditions**

Revise the label as follows:

- A. Make the following revisions to page two:
- 1. Upon reexamining your label it has become apparent that the following sections in the right column of this page belong within the directions for use section of the label. Move the sections which begin as following into the directions for use section:

"This product is a Hospital Disinfectant at ..."

"This product is Bactericidal according to the AOAC ... "

The listing beginning: "Bacteria"

The listing beginning: "Viruses"

The listing beginning: "Fungi and Mold" The section beginning: "Hepatitis Virus"

- 2. Revise the section beginning "Bacteria" by correcting the 5 instances where you have referred to "Antibiotic Resistance" to read "Antibiotic Resistant"
  - B. Make the following revisions to page three:
- 1. As requested in the Registration Notice for this product, add the following heading to the beginning of the left column on this page: "Disinfection/Virucidal/Fungicidal".
- 2. Revise the first section at the top of the left column by correcting to read "...remain wet for 10 minutes"
- 3. Revise the second section at the top of the left column by correcting to read "For heavy-duty use add 2 ounces per gallon (16 milliliters per liter)..."

- 4. Revise the second to last section at the bottom of the left column by correcting to read "From Concentrate: Add ½ ounce (4 milliliters per liter) to the toilet..."
- 5. Revise the section headed: "Applications and Use Dilution Poultry (and Swine) Premise" directions by correcting to read: "...racks and other feeding *and* watering appliances."
  - C. Make the following revision to page four:

Since you have not provided data to support food contact sanitization, delete the references to the treatment of utensils in dressing plants.

#### **General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Caugust LINgok

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label

7510C:T.Lantz:5/10/04:10324-134a

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

DANGER, KEEP OUT OF REACH OF CHILDREN, Corrosive, Causes irreversible eve damage and skin burns. Harmful is absorbed through skin or swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles, safety glasses or face shield and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing before reuse.

(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.

### 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 in areas inaccessible to small children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap translation in the posticide, and so that the posticide is the posticide. and discard in trash (or recycle). recistered under EPA Reg

# **MAQUAT® 256-1010N**

Disinfectant - Cleaner - Mildewstat - Fungicide - Virucide\* - Deodorizer for Hospitals, Nursing Home, Institutional and Industrial Use.

Effective in hard water up to 250 ppm hardness (Calculated as CaCO<sub>3</sub>) in the presence of 5% serum contamination.

#### **ACTIVE INGREDIENTS:**

Didecyl Dimethyl Ammonium Chloride	15.36%
INERT INGREDIENTS:	
TOTAL	

## **KEEP OUT OF REACH OF CHILDREN DANGER**

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

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

10324-134

**NET CONTENTS** 

BATCH NO

Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions and industry. This formulation has been formulated to aid in the reduction of cross-contamination on treated surfaces.

This product is a one-step neutral disinfectant that is effective against a broad spectrum of bacteria, is virucidal\* (including HIV-1), fungicidal and inhibits the growth of mold and mildew and their odors when used as directed.

When used as directed, this product will deodorize surfaces in rest room and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

This product is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on hard non-porous surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities.

This formulation is recommended for use in hospitals, medical and dental offices. nursing homes, public rest rooms, institutions, schools, colleges, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels. For use in households,

This product contains no phosphorous.

This product is a no rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

This product can be used with a mop and bucket, trigger sprayers, sponge or by soaking.

This product provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat.

This product improves labor results by effectively controlling odors.

This product cleans, shines, deodorizes and disinfects hard non-porous surfaces. Inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and smelling fresh.

This product is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

This product is for use in kitchens, bathrooms and other household areas.

This product is a neutral pH multi surface cleaner, deodorizer and disinfectant. Use on windows, mirrors, and other non-food contact glass surfaces.

Use this product on the multi-touch surfaces responsible for cross-contamination.

Use this product on finished floors, high speed burnished floors, conductive flooring, washable walls, tables, chairs, bathroom bowls, sinks, basins, shower stalls, tubs, glazed tiles, toilet, countertops, stove tops, exteriors surfaces of appliances and refrigerators, cabinets, garbage cans, tables, outdoor furniture, chairs, desks, telephones, door knobs and handles, and glass surfaces including windows and mirrors.

This product is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area

Tray Dumping Area Chick Holding Area Chick Processing Area Chick Loading Area

Egg Holding Area Setter Room

Hatchery Room

**Poultry Buildings** 

This product is recommended for Swine Premise Sanitation:

Farrowing Barns and Areas Dressing Plants Waterers and Feeders

Hauling Equipment

Loading Equipment Nurserv

Blocks Creep Area Chutes

This product is a Hospital Disinfectant at ½ ounce per gallon (4 milliliters per liter), (1:256 dilution), modified in the presence of 250 ppm hard water with a 10 minute contact time.

This product is Bactericidal according to the AOAC Use Dilution Test method, Virucidal\* according to the virucidal qualification on hard inanimate surfaces. Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum against:

#### Bacteria

Enterobacter aerogenes ATCC#15038 Enterococcus faecalis Antibiotic Resistance ATCC#51575 Enterococcus faecalis Vancomycin Resistance (VRE) ATCC#51299 Enterococcus faecium Antibiotic Resistance ATCC#51559 Escherichia coli O157:H7 ATCC#35150 Klebsiella pneumoniae ATCC#4352 Klebsiella pneumoniae Antibiotic Resistance ATCC#700603

Listeria monocytogenes ATCC#19117 Pseudomonas aeruginosa ATCC#15442 Salmonella choleraesuis ATCC#10708

Salmonella schottmuelleri ATCC#8759 Salmonella typhi ATCC#6539

Serratia marcescens ATCC#14756 Shigella dysenteriae ATCC#13313 Staphylococcus aureus ATCC#6538

Staphylococcus aureus-MRSA ATCC#33592 Staphylococcus aureus-GISA HIP 5836

Staphylococcus epidermidis ATCC#35983

Staphylococcus epidermidis Antibiotic Resistance ATCC#51625 Streptococcus pyogenes "Flesh Eating Strain" Bird M#-Clinical Isolate

Pimpicide, and Bodinstride Act es amended for the pastickie. registered under KPA Reg. No.

10324-134

Viruses

Bovine Viral Diarrhea NADL Strain Canine Coronavirus Hepatitis B Virus (HBV) Hepatitis C Virus (HCV) Herpes simplex virus Type 1 ATCC#VR-733 Herpes simplex virus Type 2 ATCC#VR-734

HIV Type 1 HTLV-IIIa Human Coronavirus Influenza A Beijing virus H<sub>1</sub>N<sub>1</sub> Strain Influenza A Hong Kong virus ATCC#VR-544 Influenza B virus ATCC#VR-823 Vaccinia virus ATCC#VR-119

Fungi and Mold

Aspergillus niger ATCC#16404 (no soil used in testing) Candida albicans ATCC#10231

Trichophyton mentagrophytes ATCC#9533

In

#### **Hepatitis Virus**

At ½ ounce of this product per gallon of water (or equivalent use dilution) in the presence of 400 ppm hard water (CaCO<sub>3</sub>) and 5% serum this product was proven to be effective against Hepatitis B and Hepatitis C Virus with a contact time of 10 minutes.

## **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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

(Or use the following sentence if not used on medical devices or medical equipment.) Not for use on medical devices or medical equipment surfaces.

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For water hardness up to 250 ppm add ½ ounce per gallon (4 milliliters per liter) of water (1:256) to disinfect hard non-porous surfaces OR mix a 2 ounce packet with 4 gallons of water. Treated surfaces must remain wet fro 10 minutes.

For heavy-duty use add 2 ounces per gallon (64 milliliters per liter) of water (1:64), to disinfectant hard non-porous surfaces.

Apply at ½ ounce per gallon of water to hard inanimate, non-porous surfaces thoroughly wetting surfaces as recommended and required, with a cloth, mop, sponge or sprayer.

For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6-8 inches frag. Rub with brush, sponge or cloth. Do not breathe spray.

Treated surfaces must remain wet for 10 minutes. Prepare a fresh solution at least daily or when use solution becomes diluted or soiled.

Rinse all surfaces which come in contact with food such as counter **Expectation directions**. tables and stovetops with potable water before reuse. This product **Expectation for Food Storage Areas**: For use on non-food contact surfaces such as disinfect or clean eating utensils, glassware and dishes.

Mold and Mildew Control Directions: To control the growth of mold and mildew and their odors on hard, non-porous surfaces, apply at ½ ounce per gallon of water to thoroughly wet all treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappears.

\*KILLS HIV, HBV AND HCV ON PRECLEANED 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 on 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), Hepatitis B and Hepatitis C Virus.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOOD/BODY FLUIDS.

**PERSONAL PROTECTION:** Clean up should always be done wearing protective latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV, HBV and/or HCV must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Leave surface wet for 10 minutes with ½ ounce per gallon (4 milliliters per liter) use solution.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

#### NON-ACID TOILET BOWL DISINFECTANT/CLEANER DIRECTIONS

Preclean to remove heavy soil.

From Concentrate: Add ½ ounce (15 milliliters) to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim. Allow to stand for 10 minutes and flush.

From Use Solution: Empty toilet bowl or urinal and apply ½ ounce per gallon (4 milliliters per liter) use solution to exposed surfaces, including under the rim with a cloth,

mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush. For sprayer application, use a coarse spray device.

For Heavy Duty Cleaning: Empty toilet bowl or urinal and apply 2 ounces per gallon (16 milliliters per liter) use solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush. For sprayer application, use a coarse spray device.

r sprayer. Glass Cleaning/Deodorizing Directions: Add ¼ to 1 ounce per gallon (2-8 milliliters Decision of water to clean and deodorize windows, mirrors, and glass surfaces. Use a COMP Exterse spray device. Spray 6-8 inches from surface. Rub with sponge or cloth. Do not Direction Directions.

Directions for Food Processing Plants: Before using this product, food products and packaging materials must be removed from the room or carefully protected. For use on correction contact surfaces such as floors, walls, tables, garbage cans and disposal tables. Follow disinfection directions.

the position of water to disinfections for Food Storage Areas: For use on non-food contact surfaces such as section of water to disinfection directions.

#### **POULTRY (and SWINE) PREMISE SANITATION**

**Site Preparation:** The first step in any on-going sanitation program is 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.

## APPLICATIONS AND USE DILUTION POULTRY (and SWINE) PREMISE

Remove all animals and feeds from premises, trucks, cars, coops and crates. Remove all litter, droppings and manure from floors, wails and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding end watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use ½ ounce 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 all treated feed racks, troughs, automatic feeders, fountains and waterers and other equipment that may contact food or water 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 ½ ounce of this product per gallon of water to treat the following hard non-porous surfaces: 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. Rinse with potable water before reuse. Then allow to air dry.

**VEHICLES:** lean all vehicles including mats, crates, cabs, and wheels with high pressure water and this product. For sprayer applications, se a coarse spray device. Use ½ ounce per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

SHOE BATHS: Shoe baths containing one inch of freshly made solution (½ ounce per gallon of water) should be placed at all entrances to buildings and hatcheries and at all

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the entrances to the production and packaging rooms. Change the solution in the bath daily or sooner if 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, ½ ounce 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.

ACCEPTED
with COMMENTS
in EDA Letter Dend:

第四 10 2004

Under the Paderal Insucticide, Pungloble, and Rodersticide Act as amended, for the pasticide, recistered under EPA Rec. No.

10324-134

## 2 OUNCE PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL

MIX EACH PACKET WITH 4 GALLONS OF WATER FOR DISINFECTION

## **MAQUAT® 256-1010N**

E.P.A. Reg. No. 10324-134 E.P.A. Est. No. 10324-IL-1

NET CONTENTS: 2 FLUID OZ.

#### 

#### **KEEP OUT OF REACH OF CHILDREN**

#### DANGER

SEE OUTER CONTAINER FOR PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

DISPOSAL: Do not reuse container. Wrap and put in trash collection.

# MASON CHEMICAL COMPANY "THE QUATERNARY SPECIALISTS"

721 W. Algonquin Road Arlington Heights, IL 60005

847-290-1621

Toll Free: 1-800-362-1855

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