

10324-66

2/27/2002

Page 1 of 4

FEB 27 2002

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

Subject: Revised Label
DEFEND
EPA Registration Number 10324-66
Application Dated January 23, 2002

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 the following comments:

Proposed amendment:

updating precautionary, first aid and disposal statement.

1. For consistency, the statement "Have the product container or label with you when calling a poison control center or doctor, or going for treatment". In case of emergency call toll free: 1-800-362-1855" should be placed below the first aid statement instructions. See PR Notice 2001-1 for detailed information.
2. Delete the "Keep Out Of Reach Of Children" statement from the precautionary statements.

CONCURRENCES							
SYMBOL	175100						
SURNAME	[Signature]						
DATE	2-25-02						

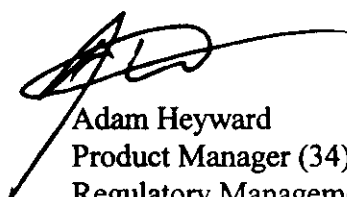
3. Delete the organism "Klebsiella pneumoniae" from the label since no efficacy data exist on file to support the claim.

General comment:

A stamped copy of the accepted with comments labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or LaVerne Dobbins at (703) 308-6378.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure:

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

DANGER, Keep Out of Reach of Children. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get into 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

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
Do not use or store near heat or open flame.

(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 and discard in trash (or recycle).

DEFEND

PINE OIL QUATERNARY DISINFECTANT

Cleaner, Disinfectant, Fungicide, Mildewstat, Deodorizer, Sanitizer with Organic Soil Tolerance For Medical and Non-Medical use Areas*, Plus Disinfectant Hard Water (400 ppm calculated as CaCO₃) Tolerance for Non-Medical Use Areas** Hospital, Institutional and School Use.

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride.....	0.570%
Didecyl Dimethyl Ammonium Chloride.....	0.285%
Diocetyl Dimethyl Ammonium Chloride.....	0.285%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	0.760%
Pine Oil.....	2.500%

INERT INGREDIENTS:	95.600%
TOTAL	100.000%

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.

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. Reg. No. 10324-66
E.P.A. Est. No. 10324-IL-1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 27 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide, NET CONTENTS
registered under EPA Reg. No. 10324-66

BATCH NO

Cross contamination is of major housekeeping concern in schools, medical institutions, and industry. This product has been formulated to aid in the reduction of cross contamination.

This product is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is 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.

This product is a proven "one-step" disinfectant - cleaner mildewstat - sanitizer - fungicide - presence of organic soil.

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.

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.

Apply to walls, floors and other hard (inanimate) 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. Surfaces must remain wet for 10 minutes. Let air dry.

DISINFECTION - Non-Medical Use Areas* - (Schools, institutions, and industries). At 2.5 ounces 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:

- | | |
|--------------------------------------|---------------------------------|
| <i>Brevibacterium ammoniagenes</i> ✓ | <i>Serratia marcescens</i> ✓ |
| <i>Enterobacter aerogenes</i> ✓ | <i>Shigella dysenteriae</i> ✓ |
| <i>Escherichia coli</i> ✓ | <i>Staphylococcus aureus</i> ✓ |
| <i>Klebsiella pneumoniae</i> ? | <i>Streptococcus faecalis</i> ✓ |
| <i>Salmonella choleraesuis</i> ✓ | <i>Streptococcus pyogenes</i> ✓ |
| <i>Salmonella typhi</i> ✓ | |

Non-Medical Use Areas (Hard Water)** At 5 ounces per gallon use level the activity of this product has been evaluated in the presence of both 5% blood serum and 400 ppm hard water against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Escherichia coli*.

Medical Use Areas* - Hospitals and Nursing Homes. At 5 ounces per gallon use level. At this dilution this product is effective against *Pseudomonas aeruginosa*.

FUNGICIDAL CONTROL At 2.5 ounces per gallon use level. This product when used on surfaces such as locker rooms, dressing rooms, shower and bath areas, exercise facilities. Fungicidal activity has been demonstrated in the presence of both 5% blood serum and 400 ppm hard water against *Trichophyton mentagrophytes* (the athlete's foot fungus).

Mold and Mildew Control - At 2.5 ounces 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). Treated surfaces must remain wet for 60 seconds. Allow to dry on surface and repeat when mildew growth returns.

Sanitizing-Non-Food Contact Surfaces (such as floors, walls, tables, etc.) At 1 ounce per gallon use-level, prepared in water up to 600 ppm hardness. This product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

Acceptable for use in federally inspected meat and poultry establishments. The use of all cleaning compounds in federally inspected meat and poultry establishments must be followed by a potable water rinse. Do not use undiluted. Avoid contact with eyes and mucous membranes.

424