

PM 3/ 10324-57 4-16-97 1073

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 16 1997

Mason Chemical Company
721 West Algonquin Road
Arlington Heights, IL 60005

Attention: Marc M. Mason

Subject: Maquat 42
EPA Registration Number 10324-57
Your Submission Dated September 30, 1996
EPA Received Date October 5, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add HIV claims to the product labeling, is acceptable.

This product is substantially similar to the referenced product, Activ VIII 64, EPA Reg. No. 10324-59. Therefore, the submitted referenced data are acceptable to support the effectiveness of this product as a virucide against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of moderate amount of organic soil (5% blood serum) when used at a 1:43 dilution (3 ounce/gallon) in 459 ppm hard water (as CaCO₃) for a contact time of 2 minutes at room temperature (20-25 degrees Celsius).

Revise the "Note to Physician" section to read as follows: "Measures against circulatory shock, respiratory depression, and convulsions may be needed".

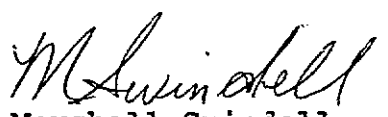
A stamped copy of the labeling is enclosed for your records.

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely yours,



Marshall Swindell
Acting Product Manager(31)
Antimicrobial Program Branch
Registration Division(7505W)

PRECAUTIONARY STATEMENTS

DANGER

HAZARD TO HUMAN AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN

Causes eye and skin irritation. Do not get in eyes, skin or on clothing. Harmful if swallowed.

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 detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants, food service establishments and other institutions where housekeeping is of prime importance.

DISINFECTION - To disinfect hard inanimate surfaces (such as walls, floors, table tops) apply solution with mop, cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry.

DILUTION RATES - General Disinfection - add 2 ounces per gallon of water. Hospital Disinfection - add 3 ounces per gallon of water. To disinfect toilet bowls, flush toilet, add 2 ounces of detergent/disinfectant directly to the bowl water, swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush. For heavily soiled areas, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops) clean surfaces then add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.

At 3 ozs. per 1 gallon in the presence of 5% blood serum and 400 ppm of hardness for a 2 minute contact time Maquat 42 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 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 type of viruses and bacteria.

MAQUAT 42

detergent/disinfectant

Cleaner Detergent Deodorizer

Disinfectant Fungicide (against Pathogenic fungi) Virucide*

Mildewstat (on hard inanimate surfaces)

ACTIVE INGREDIENTS:

n-Alkyl (80%C14, 30%C16, 5%C12, 5%C18) dimethyl benzyl ammonium chloride 1.60% n-Alkyl (68%C12, 32%C14) dimethyl ethylbenzyl ammonium chloride 1.60%

INERT INGREDIENTS: 96.80% TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

See left panel for additional precautionary statements.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink promptly a large quantity of water. Call a physician.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

MASON CHEMICAL COMPANY

"THE QUATERNARY SPECIALISTS"

721 W. ALGONQUIN ROAD ARLINGTON HEIGHTS, IL 60005 708-290-1621 Toll Free: 1-800-382-1855



E.P.A. Reg. No. 10324-57 E.P.A. Est. No. 10324-IL-1

Accepted with COMMENTS APR 16 1987

10324-57

This product is a phosphate free cleaner disinfectant designed for general household use, schools, food processing plants, light industries and hospital applications where housekeeping is of prime importance in controlling the hazard of cross contamination. When used as directed, it is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones and bed frames. For larger areas such as patient care facilities and restrooms, the product is designed to provide both general cleaning and disinfecting.

In addition, this product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, and any other areas which are prone to odors caused by microorganisms.

DISINFECTION - At 2 ounces per gallon dilution, this product exhibits effective disinfectant activity against the following: Escherichia coli, Klebsiella pneumoniae, Salmonella schotmuelseri, Shigella dysenteriae, Salmonella choleraesuis, Brevibacterium ammoniagenes, Streptococcus faecalis, Staphylococcus aureus, Enterobacter aerogenes.

At 3 ounces per gallon dilution, this product is an effective hospital disinfectant and demonstrates disinfectant activity against Pseudomonas aeruginosa in addition to the above microorganisms.

Virucidal* Activity: The product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal* activity against influenza A2 - Asian (representative of the common flu virus), Herpes simplex Type 1 (causative agent of fever blisters and mononucleosis), and Vaccinia virus (representative of the pox virus group).

Efficacy tests have demonstrated that this product is an effective bactericide, fungicide, and virucide* in the presence of organic soil (5% blood serum).

MOLD AND MILDEWSTAT - This product prevents and controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces at 2 ounces per gallon dilution.

STORAGE AND DISPOSAL

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 the user 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 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. (1 gal. and smaller). Do not reuse empty container. Wrap container and put in trash.

Best COPY Available

2013