

12204-10

11-19-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 19 2003

Mr. Jerome Schulz
Mid-America Research Corp.
P.O. Box 927
Columbia NE 68602-0927

Subject: **Marc 315 Marcicide**
EPA Registration Number 12204-10
Letter Dated August 21, 2003
EPA Received Date August 21, 2003

Dear Mr. Schulz:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment:

- revise labeling per EPA letter dated 7/31/03

Conditions revise label as follows:

1. The Agency has asked registrant to begin submitting "Master" labels which contain all the claims, use sites, directions, storage/disposal statements, and environmental hazard statements on one label. You submitted product levels for 1 quart containers and another w/o specific net contents. We decided the label w/o the net contents is the "master" label. You must revise your label to bring it into compliance with the above criteria for a "master label by adding a separate Storage and Disposal for containers less than 1 gallon. It must read:

(Containers less than 1 gallon)

Storage and Disposal

Store in a dry place no lower in temperature than 50°F or higher then 120°F. Do not reuse empty. Wrap container and put in trash.

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							


- 2. According to PR Notice 94-4 the MOU statement must appear under the "This product is not to be used as a terminal sterliant/high level disinfectant, on..... under the "Directions For Use".
- 3. In an effort to conserve space, place "Environmental Hazards" after the Precautionary Statements.

General Comments:

The product's primary brand name "Marcicide" is accepted.

A stamped copy of the labeling accepted 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 or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,

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

Enclosure Stamped Label

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DISINFECTION AND DEODORIZING: To disinfect and deodorize hard non-porous surfaces such as glazed bathroom tiles, fixtures, floors, chairs, shower stalls, walls, sinks and bathtubs, proceed as indicated below:

1. Apply product to surface to be treated until it is covered with the solution.
 2. Allow the product to penetrate and remain wet for 10 minutes.
 3. Wipe off with a clean cloth, mop or sponge or let air dry.
- The product will not leave grit or soap scum. For heavily soiled areas, a pre-cleaning step is required. The broad spectrum activity of MARCICIDE has been evaluated in the presence of 5% serum and found to be effective against the following by the AOAC Use-Dilution test:

<i>Pseudomonas aeruginosa</i> PRD-10	<i>Enterobacter aerogenes</i>
<i>Staphylococcus aureus</i>	<i>Salmonella choleraesuis</i>
<i>Salmonella choleraesuis</i>	<i>Streptococcus faecalis</i>
<i>Escherichia coli</i>	<i>Shigella dysenteriae</i>
<i>Klebsiella pneumoniae</i>	<i>Brevibacterium ammoniagenes</i>
	<i>Streptococcus salivarius</i>

AOAC FUNGICIDAL TEST:

MARCICIDE is effective against Trichophyton mentagrophytes (the athlete's foot fungus) when used as directed above on surfaces in areas such as locker rooms, shower and bath areas, exercise areas, dressing rooms, etc.

Virucidal* Activity: The product when used as directed above on environmental inanimate hard surfaces exhibits effective virucidal* activity against Influenza A2-Asian (representative of the common flu virus), Herpes simplex (causative agent of fever blisters and mononucleosis), Adeno virus type 2 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group).

Mildewstat: To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops), spray product to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

ENVIRONMENTAL HAZARDS

This product 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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



MARCICIDE

DESIGNED FOR HOSPITAL AND INSTITUTIONAL USE

ACTIVE INGREDIENTS:

n-Alkyl (80% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₀) dimethyl benzyl ammonium chlorides	0.035%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.035%
INERT INGREDIENTS	99.930%
	100.000%

EPA Registration No. 12204-10

EPA Establishment No. 12204-NB-1

KEEP OUT OF REACH OF CHILDREN-WARNING

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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 on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. 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 the 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 by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIANS: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured by

M-315

MID-AMERICAN RESEARCH CHEMICAL CORP.

COLUMBUS, NE 68601

Disinfectant • Detergent • Deodorizer
Fungicide (against Pathogenic fungi) • Virucide*
Mildewstat (on hard inanimate surfaces)

FEATURES

MARCICIDE is a ready-to-use non-phosphate disinfectant, deodorizer and mildewstat designed for institutional use, such as hospitals, nursing homes, and schools where housekeeping will be of prime importance in controlling the hazard of cross-contamination from environmental surfaces. Provides the assurance you need in this area, when used as directed. For use on floors, walls, sink tops, garbage pails, telephones, restrooms, bed pans and operating rooms.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING-KEEP OUT OF REACH OF CHILDREN

Causes substantial but temporary eye injury and skin irritation. Do not get in eyes, on skin, or on clothing. Wear protective face shield or goggles. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL
PESTICIDE STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL: Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For containers 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

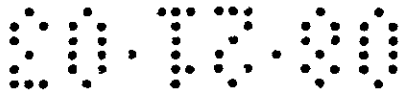
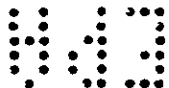
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

HMS Ratings: Health 1, Flammability 0, Reactivity 0- NFPA Ratings: 1,0,0

Net Contents: _____

RU8-03

Bulk label - 2nd Revision



ACCEPTED
With COMMENTS
in EPA Letter Dated:
NOV 19 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 12204-10

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