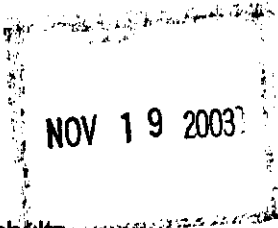


12204-5

11/19/2003

1/3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



Jerome Schütz
Technical Director
Mid-America Research Corp.
P.O. Box 927
Columbia, NE 68602-0927

Subject: Marcicide IV
EPA Registration No. 12204 -5
Amendment dated: August 21, 2003
EPA Received date: August 21, 2003

Dear: Mr. Jerome Schultz,

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

- Response to Agency Letter dated August 1, 2003

Label Comments

1. The Agency has asked registrants to begin submitting "Master" labels which contain all claims, use sites, directions, storage/disposal statements, and environmental hazards statements on one label. You submitted product levels for 1 quart containers and another without specific net contents. We decided the label without the specific net contents is the "Master" label. You must revise your label to be in compliance with the above criteria for a "Master" label by adding a separate Storage and Disposal statement for one gallon container sizes:

Storage and Disposal

*Store in a dry place no lower in temperature than 50° F or higher than 120° F.
Store in areas inaccessible to children to person unfamiliar with its use. Do not reuse empty container. Wrap container and discard in trash..*

2. The change of the products Primary Brand Name to MARCICIDE IV is acceptable.
3. According to the Label Review Manual 3rd Edition the Note to Physician should be located in close proximity to the First Aid Statements, but should be clearly distinguished from it. In other words, it should not be placed within the First Aid Statement, but should appear below the First Aid Statement.

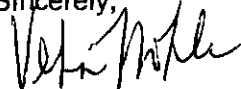
CONCURRENCES							
SYMBOL	7510(G)						
SURNAME	ALBERTS						
DATE							

4. Revise the IF ON SKIN or CLOTHING statement as follows: Take off contaminated clothing. Rinse skin **immediately** with plenty of water for 15-20 minutes. Call poison center or doctor for treatment advice.
5. In an effort to conserve space place the "Environmental Hazards" statement after the Precautionary statements.

General Comments

A stamped copy of the labeling accepted with comments 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 Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (7510c)

Bulk Label

2nd Revision

FEATURES

A disinfectant, fungicide and virucide 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, rest rooms, bed pans and operating rooms. Effective against Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa. Also effective against pathogenic fungi, Trichophyton mentagrophytes.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage and skin burns. Do not get in the eyes, on skin, or on clothing. Wear protective clothing, faceshield or goggles, and rubber gloves. Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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.

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

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.

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.

Net Contents _____



MARCICIDE IV

with CO-ENVIRONMENTAL
in EPA Letter Dated:

NOV 19 2003
• DISINFECTANT • FUNGICIDE

under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 12204-5
• VIRUCIDE*

DESIGNED FOR HOSPITAL AND INSTITUTIONAL USE



FRESH MINT FRAGRANCE



ACTIVE INGREDIENTS:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chlorides	2.25%
INERT INGREDIENTS	95.50%
Total	100.00%

EPA Reg. No. 12204-5
EPA Est. No. 12204-NB-1

KEEP OUT OF REACH OF CHILDREN

DANGER

See left panel for additional precautionary statements.

Manufactured By

M-34

MID-AMERICAN RESEARCH CHEMICAL CORP.
COLUMBUS, NE 68601

DIRECTIONS FOR USE

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

DISINFECTION

Use at 2 ounces per gallon. This product will be effective against Pseudomonas aeruginosa PRD-10 at this level. This has been substantiated by the AOAC Use Dilution Confirmation Test. At this level, the product is fungicidal against pathogenic fungi.

For best results, use with a cloth or mop and apply to walls, floors, and other hard surfaces.

For heavy soil or organic matter, a pre-cleaning step is recommended.

*VIRUCIDAL ACTIVITY

This product, when used on environmental, inanimate, hard surfaces at 2 ounces per gallon of water, is effective against Influenza A₂, Herpes Simplex, Adenovirus type 5, and Vaccinia viruses.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL

STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned stay out of smoke.

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.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. 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.

HMIS Ratings	Health	2	NFPA Ratings	
	Flammability	0		
	Reactivity	0		

RUB-03

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