

Mr. Robert Marvy
William Marvy Company, Inc.
1540 St. Clair Avenue
St. Paul, MN 55105

AUG 15 2002

Subject: Mar-V-Cide
EPA Registration No. 8296-1
Amendment Date: February 5, 2002
EPA Receipt Date: February 19, 2002

Dear Mr. Marvy,

The following amendment is submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of *S. choleraesuis*, *S. aureus*, and *P. aeruginosa* claim.

Conditions

Revise the label as follows:

1. Revise the 1st section of the HIV cleaning/decontamination directions to reflect the following:

KILLS HIV-1 ON PRE-CLEANED HARD NON-POROUS 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 likely to be soiled with blood or body fluids can be associated with the potential transmission of Human Immunodeficiency Virus Type 1 (HIV-1).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2. Based on data on chemically substantially similar products, revise the "Precautionary Statements" to read "CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear eye protection (face shield or goggles), protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."
3. Since this product is sold in 1/2 gallon containers, the Storage and Disposal statements must be revised in accordance with PR Notice 84-1 for 1 gallon or less containers by stating "Store in original container in an area inaccessible to children or individuals unfamiliar with the use of the product. Do not use with soap or synthetic or other disinfectants. Do not reuse empty container. Discard in the trash."
4. Revise the heading, "to make a hospital disinfectant," to state "Preparation of Disinfectant Use Solution"
5. Revise the heading, "surfaces," to read "Disinfection Directions." Also, revise the directions to state "Apply use solution to hard, non-porous surfaces such as floors, walls, cabinets, sinks, counters, tables, chairs, and telephones, thoroughly wetting the surfaces with a cloth, mop, or sponge. Treated surfaces must remain wet for 10 minutes, then allow to air dry. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution after each use."
6. Revise the heading, "instruments and tools," to read "Barber/Beauty Salon Instruments and Tools." Also, revise the directions to state "Immerse pre-cleaned barber/beauty salon instruments and tools (such as combs, brushes, razors, scissors, blades, and manicure instruments) in a use solution of 2 oz per one gallon of water (refer to preparation of use solution) for 10 minutes." For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. A fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments."

7. Since this product is making a fungicide claim, you need specific use directions that state the following "Fungicidal Directions: This product is an effective fungicide against *Trichophyton mentagrophytes*, agent that causes Athlete's foot fungus, in areas such as locker rooms, dressing rooms, shower, and bath areas. Apply use solution to hard, non-porous surfaces such as floors, walls, cabinets, sinks, counters, thoroughly wetting the surfaces with a cloth, mop, or sponge. Treated surfaces must remain wet for 10 minutes, then allow to air dry. For

heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution after each use.”

- 8. The species of *Staphylococcus* is misspelled, it should read “aureus.”

Acceptable Data

The following efficacy data was reviewed and accepted. The data evaluation is attached for your review.

Data Requirement	Means of Support	Status
AOAC Use-Dilution Method against <i>S. aureus</i> and <i>S. choleraesuis</i>	Submitted study, MRID 456174-01	Acceptable
AOAC Use-Dilution Method against <i>P. aeruginosa</i>	Submitted study, MRID 456174-02	Acceptable

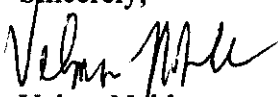
General Comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6415.

Sincerely,

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

Enclosure: Efficacy Data Evaluation

MAR-V-CIDE®

DISINFECTANT, FUNGICIDE, GERMICIDE, VIRUCIDE

For use in hospitals, nursing homes, health care facilities, barber shops, beauty shops and hairstyling salons.

ANTI-RUST FORMULA

ACTIVE INGREDIENT:

n-Al KYL (50% C₁₄, 40% C₁₂, 10% C₁₆)
dimethyl benzyl ammonium chloride 10 %
INERT INGREDIENTS 90 %
TOTAL 100 %

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
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.
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 eyes 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact CHEM-TEL at 1-800-255-3924 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED HARD, NON-POROUS, INANIMATE ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD AND BODY FLUIDS.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS.

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PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use appropriate barrier protection such as 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 this disinfectant.

DISPOSAL OF INFECTIOUS MATERIAL: 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 surface wet for 10 minutes.

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

E.P.A. Reg. No.: 08926-1

E.P.A. Est. No.: 08296-AIN-001

WILLIAM MARVY COMPANY, INC.
1540 ST. CLAIR AVENUE ST. PAUL, MN 55105

1 PINT
(16 FLUID OUNCES) (473 Liters)

ONE-HALF GALLON
(64 FLUID OUNCES) (1 893 Liters)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: KEEP OUT OF REACH OF CHILDREN. CORROSIVE. CAUSES EYE AND SKIN DAMAGE. DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. HARMFUL OR FATAL IF SWALLOWED. AVOID CONTAMINATION OF FOOD. WEAR EYE PROTECTION AND RUBBER GLOVES WHEN HANDLING. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

STORAGE AND DISPOSAL

Do not use with soaps or synthetic or other disinfectants. Do not contaminate water and food. Store in original container or approved container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsables is a violation of Federal Law. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Do not reuse empty container. Wrap container and put in trash.

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. For disinfecting, a precleaning step is required.

TO MAKE A HOSPITAL DISINFECTANT mix one tablespoon of MAR-V-CIDE in one quart of water, or make stock solution by mixing two ounces (1/4 cup) MAR-V-CIDE in one gallon of water.

SURFACES: To disinfect inanimate hard surfaces such as floors, walls, cabinets, sinks, counter tops, tables, chairs and telephones; use two ounces of MAR-V-CIDE per gallon of water for a minimum contact time of 10 minutes. Apply liquid with a mop, sponge, cloth, or bowl mop to thoroughly wet the surfaces. For disinfecting, remove gross filth and heavy soil deposits, then thoroughly wet surface. After application, let air dry. Prepare fresh solution after each use.

INSTRUMENTS AND TOOLS: Thoroughly clean combs, brushes, scissors, clipper blades, razors, manicure implements and other non-porous instruments prior to complete immersion for 10 minutes (or as required by local authorities) in a solution prepared as above. Rinse thoroughly and dry before use.

Fresh solution should be prepared daily or more often if solution becomes diluted or soiled. Dilute only as needed.

PERFORMANCE: When tested with full immersion for 10 minutes in solution created as above, MAR-V-CIDE is effective as a disinfectant, germicide, bactericide, fungicide, and virucide* against:

Salmonella choleraesuis
Staphylococcus aureus
Pseudomonas aeruginosa

Herpes Simplex Type 1 and Type 2*
Trichophyton mentagrophytes
Human Immunodeficiency Virus Type 1
-(HIV-1) (AIDS virus)*

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Aug 15 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 8296-1

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