

DEC 16 1994

MARIL PRODUCTS, INC
620 South 'B' Street, Suite A
Tustin, CA 92680

Attention: James C. Swims
Vice President

Subject: Control III Disinfectant Germicide
EPA Registration No. 55364-3
MOU Compliance Amendment dated September 16, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

- Under the heading "Microbial Activity", in the FDA package insert, remove the following organisms from the table. Efficacy data has not been submitted to EPA to support these claims. *Serratia marsescens*, *Staphylococcus epidermidis*, *Pseudomonas cepacia*, *Streptococcus faecalis*, *Streptococcus pyogenes*, *Streptococcus viridans*, *Proteus vulgaris*, *Proteus mirabilis*, *Shigella dysenteriae*, *Salmonella pullorum*, *Salmonella typhosa*, *Clostridium perfringens*, *Klebsiella pneumoniae*, *Aerobacter aerogenes*, *Haemophilus influenzae*, *Candida albicans*, *Epidermophyton inquina*, *Microsporium audouini*, *Trichophyton interdigitale*.

A stamped copy of the labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2079

If you have any questions concerning this letter, please
contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

USED FOR:

Disinfection of walls, equipment, heat sensitive instruments and tubing in operating rooms, recovery rooms and intensive care rooms.

LAUNDRY:

Use 1/2 ounce CONTROL III per 25 lbs. dry weight of laundry in the final rinse.

HOME USE:

For disinfection of Respiratory Therapy Equipment in the home refer to Technical Bulletin "CONTROL III DISINFECTANT FOR HOME CARE".

*NOTE: CONTROL III DISINFECTANT GERMICIDE has not been tested for effectiveness against Mycobacterium Tuberculosis and must not be relied upon when a Tuberculocidal product is desired.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER:

Keep out of reach of children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food. Remove and wash contaminated clothing.

STORAGE AND DISPOSAL:

- Do not contaminate water, food or feed by spilling or disposal
- Do not reuse empty container

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of pesticide spray or mixture of 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 Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Do not reuse container. Rinse thoroughly before discarding in trash. 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.

Manufactured by Maril Products, Inc.
714) 544-7711

CONTROL III disinfectant GERMICIDE

Rapid Action — Long Life

ACTIVE INGREDIENTS

- n-alkyl (60% C₁₄, 30% C₁₆, 5% C₁₈, 5% C₁₂) dimethyl benzyl ammonium chloride _____ 10%
- n-alkyl (68% C₁₂, 32% C₁₄) dimethyl ethyl benzyl ammonium chloride _____ 10%

INERT INGREDIENTS _____ 80%
100%

ON INANIMATE ENVIRONMENTAL SURFACES EFFECTIVE AGAINST

Pseudomonas aeruginosa • Adenovirus type 5 • Staphylococcus aureus • Vaccinia viruses • Salmonella choleraesuis • Influenza A₂ virus • Escherichia coli • Herpes simplex virus

KEEP OUT OF REACH OF CHILDREN DANGER

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 contaminated clothing before reuse.

If swallowed, drink one or two large glasses of milk, egg whites, gelatin solution, or -- if these are not available -- drink one or two large glasses of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiration depression, and convulsion may be needed.

This product is a concentrate and must be diluted before use.

See left panel for additional precautionary statements.

NET 16 FL. OZ. (1 PT.) EPA Est. #40873 CA-01
EPA Reg. #55364-3

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MARIL PRODUCTS, INC.

620 South B Street, Suite A, Tustin, California 92680 U.S.A.

DIRECTIONS FOR USE:

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

INSERT - DISCLAIMER HERE

- General:
1. Remove heavy soil as required.
 2. Apply CONTROL III DISINFECTANT as directed.
 3. Will not harm surfaces which are safe in water.

OPERATING ROOM GERMICIDE:

Mix 1/2 ounce CONTROL III DISINFECTANT in one gallon of water. Resulting mixture contains 780 ppm active ingredients. Apply to surfaces of fixtures and equipment in operating room. Allow to air dry.

COLD DISINFECTANT:

Clean instruments with CONTROL III Detergent. Disinfect as follows: Mix one ounce CONTROL III Disinfectant in one gallon of water. Immerse instruments for 10 minutes or more. Active concentration is 1560 ppm.

INSTRUMENT STORAGE:

Mix one ounce CONTROL III DISINFECTANT in one gallon of water. Add 6 gms. sodium carbonate per gallon of solution. Solution can be retained for one month.

HIV-1:

See Technical Bulletin "Efficacy Of Control III Products For The Control Of The Human Immunodeficiency Virus Type I (AIDS VIRUS)".

FOOD PROCESSING EQUIPMENT AND DISHES:

Remove all gross food soils with a pre-rinse or by scraping. Then wash all surfaces with a good liquid detergent such as CONTROL III PRE-CLEANER. After washing, rinse all surfaces thoroughly with potable water. To sanitize apply a solution of 1 ounce CONTROL III DISINFECTANT in 8 gallons of water (200 ppm active). Surfaces should remain wet for one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when used solution becomes visibly dirty. For mechanical application, used solution may not be reused for sanitizing applications.

Apply to sink tops, counter tops and other stationary surfaces by cloth or brush. Dishes, silverware, glasses and other similar size food processing equipment can be sanitized by immersion in a 1/2 ounce per 4 gallons of water dilution of CONTROL III DISINFECTANT GERMICIDE. No potable rinse is required.

1.) ADD DISCLAIMER STATEMENT IN BOLD TYPE JUST BELOW "IT IS A with COMMENTS VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER in EPA Letter Dated: INCONSISTANT WITH ITS LABELING.

DEC 10 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No.

55364-3

"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."

2.) REMOVE DIRECTIONS FOR "INSTRUMENT STORAGE" AND "FOOD PROCESSING EQUIPMENT AND DISHES" TO MAKE ROOM FOR DISCLAIMER.

1074

PACKAGE INSERT

CONTROL III DISINFECTANT GERMICIDE
(20% QUATERNARY AMMONIUM CHLORIDE)

A INDICATIONS FOR USE

1. Germicide Level of Activity

Control III Disinfectant Germicide is a low level general use disinfectant when used according to the Directions for Use. A ten minute immersion at 20°C - 25°C will destroy a broad spectrum of vegetative bacteria, fungi and specified viruses - including Pseudomonas aeruginosa, Adenovirus type 5, Staphylococcus aureus, Vaccinia viruses, Salmonella choleraesuis, influenza A2 Virus, Escherichia coli, Herpes simplex virus and HIV-1

Control III Disinfectant Germicide has not been tested for effectiveness against Mycobacterium Tuberculosis and must not be relied upon when a Tuberculocidal product is desired

2. Reuse Period

As a surface disinfectant on walls, floors, beds, mattresses, etc., Control III Disinfectant Germicide is not intended for reuse. A fresh solution should be prepared daily or when solution becomes visibly dirty

On equipment which can be immersed in Control III Disinfectant Germicide, the Control III solution can be reused up to fourteen days provided the required level of germicidal activity exist as described in the Directions For Use. The germicidal activity of the use-solution must be verified daily with Control III test strips.

3. General Information on Selection and Use of Germicides for Medical Device Reprocessing

Choose a germicide with the level of microbial activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or noncritical device. A critical device presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body

A semicritical device makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body

A noncritical device contacts only intact skin during routine use

Second, determine the level of germicidal activity that is needed for the reusable device.

Critical Device - Sterilization required (e.g. products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments)

Semi-Critical Device - Sterilization recommended whenever practical, otherwise High Level Disinfection acceptable (e.g. GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.)

Noncritical Device - Intermediate Level Disinfection recommended when there is a risk of cross-contamination, otherwise Low Level Disinfection acceptable (e.g. bed pans, blood pressure cuffs, linens, etc.)

Medical Equipment Surface - Same as for noncritical device (e.g. crutches, oxygen cylinders, etc.)

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

4 Microbial Activity

Control III is effective against a broad spectrum of bacteria (gram-negative and gram-positive), viruses and fungi. Organisms of special concern which are killed by Control III include:

BACTERIA

- Serratia marsescens
- Staphylococcus aureus
- Staphylococcus epidermidis
- Pseudomonas aeruginosa
- Pseudomonas cepacia
- Escherichia coli
- Streptococcus faecalis
- Streptococcus pyogenes
- Streptococcus viridan
- Proteus vulgaris
- Proteus mirabilis
- Shigella dysenteriae
- Salmonella pullorum
- Salmonella typhosa
- Salmonella choleraesuis
- Clostridium perfringens
- Klebsiella pneumoniae
- Aerobacter aerogenes
- Haemophilus influenzae

VIRUSES

- Herpes simplex
- Adenovirus type 2
- Influenza A2
- Vaccinia
- HIV - 1

FUNGI

- Candida albicans
- Epidermophyton inquina
- Microsporum audouini
- Trichophyton interdigitale

5 Material Compatibility

Control III Disinfectant Germicide is compatible with natural and synthetic rubber, glass, painted surfaces, metal and plastics in normally used applications for wiping or spraying equipment. When used for soaking equipment should be immersed for a maximum of twenty minutes. Extended and repeated soaking may cause tackiness, crazing or discoloration of some plastics and rusting of soft metals.

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6 Cleaning Agent Compatibility

Control III Disinfectant Germicide is compatible with non-ionic, cationic and amphoteric detergents. Since Control III is a cationic chemical, it is not compatible with anionic detergents such as bar soap. Most liquid detergents are acceptable as pre-cleaning agents. The efficacy of Control III is not adversely effected by alkaline or acid solutions. A thorough water rinse is required after cleaning with any detergent to ensure the efficacy of Control III and to avoid any long term detrimental effects on equipment from detergent residues.

B. CONTRAINDICATIONS

1. Control III Disinfectant Germicide is a low level disinfectant. It is not indicated for use where sterilization or high level disinfection is required or practical
2. Control III is not indicated for use against Mycobacterium Tuberculosis
3. Control III is not indicated for use where the possibility of cross-contamination between patients exist.

C. WARNINGS

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 contaminated clothing before use. If swallowed, drink one or two large glasses of milk, egg whites, gelatin solution, or-if these are not available-drink one or two large glasses of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiration depression, and convulsion may be needed.

D. PRECAUTIONS

1. DANGER Keep out of reach of children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food. Remove and wash contaminated clothing.
2. Contaminated reusable equipment must be thoroughly cleaned prior to disinfection since residual contamination can reduce the effectiveness of Control III Disinfectant Germicide.
3. When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks or eye coverings.
4. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.
5. It is a violation of Federal Law to use Control III Disinfectant Germicide in a manner inconsistent with its labeling.

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- 6 Control III Disinfectant Germicide should be used as part of a validated reprocessing procedure for equipment as provided by the manufacturer.
- 7 It is important that the use of Control III Disinfectant Germicide be validated for the disinfection of any equipment not specifically indicated on the label or any equipment where reprocessing directions do not specifically refer to Control III Disinfectant Germicide.

E. DIRECTION FOR USE

- 1. For operating room germicide, mix 1/2 ounce of Control III Disinfectant in one gallon of water. The resulting mixture contains 780 ppm active ingredients. Apply to surfaces of fixtures and equipment in operating room.
- 2. For disinfection of non-critical equipment and devices prepare a solution of Control III Disinfectant Germicide by adding 1/2 ounce Control III to 2 quarts of water in a food grade plastic container or container supplied by Maril Products. If larger volumes are required, add one ounce of Control III for each gallon of water. This solution may be reused for up to 14 days. Check solution daily with test strips to ensure adequate disinfection level of Control III. If the solution becomes visibly dirty or falls below 1,000 ppm dump the used solution and make a fresh solution of CONTROL III. Keep disinfecting solution covered when not in use.
- 3. Blood and other body fluids must be thoroughly cleaned from surfaces before non-critical equipment and devices are disinfected with Control III Disinfectant
- 4. Disassemble equipment according to manufacturer's recommendations. Wash device thoroughly in mild detergent and warm tap water. DO NOT USE SOAP. Rinse parts with tap water.
- 5. Immerse equipment parts in solution of Control III and soak for 10 minutes
- 6. Rinse all equipment parts with hot tap water (allow water to run for 3 minutes before rinsing parts) and allow to air dry.
- 7. After parts are dry cover them with a clean towel until equipment is reassembled.

8 Test Strip Instructions

The CONTROL III TEST STRIP is designed to be an indicator of the germicidal activity level of the CONTROL III DISINFECTANTS. The color of the test strip after it has been dipped into the CONTROL III solution indicates how much germicide is still in the solution.

With a fresh solution of CONTROL III, the test strip will turn DARK GREEN. This means the solution has a high level of germicidal activity. As the solution is used over a period of time, the level of germicidal activity decreases.

As the solution loses potency, the color of the test strip (after being dipped into the CONTROL III solution) will change from dark green to light green to greenish-yellow to yellow. The weaker the solution becomes, the lighter (yellow) the strip will be. The strip will remain yellow in water.

Note: This is a color comparison. It is not reliable for persons who are colorblind.

To test a solution of CONTROL III with a test strip, follow these steps:

1. Tear of one two inch test strip. DO NOT REUSE TEST STRIPS.
2. Dip the strip into the Control III for 2-3 seconds
3. Remove the test strip from the solution, wait 30 seconds then compare with the color chart included.
4. If the color indicates a level of 800 ppm or below/ discard the solution.

F STORAGE:

1. Store in original container before use. Do not store on side. Do not contaminate food or feed by storage or disposal.
2. Unused diluted stock solutions may be stored in covered plastic or stainless steel containers for six months. Do not add used diluted solutions back into unused stock solutions.
3. Diluted solutions can be reused up to 14 days provided it is not contaminated and it indicates the minimum effective activity level as determined with the Control III test strips.

G. TECHNICAL INFORMATION AND ASSISTANCE

Technical information and assistance may be obtained by calling Maril Products Customer Service at 1-800-546-7711 or by writing to

Maril Products, Inc.
 620 South 'B' Street, Suite A
 Tustin, CA 9268

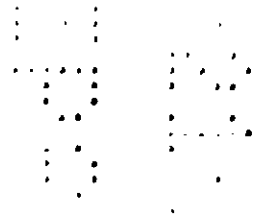
H. USER TRAINING

The decontamination and disinfection of equipment, walls, floors, etc. is critical to safety and health. The user of Control III Disinfectant concentrate should be adequately trained in decontamination and disinfection procedures and the handling of toxic substances such as liquid chemical germicides

I DISPOSAL INFORMATION.

1 Disposal of Used Germicide

Discard used Control III solution to drain. Flush with water.



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2. Pesticide Disposal

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

3. Container Disposal

Do not reuse container. Rinse thoroughly before discarding in trash. 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.

J. HOW SUPPLIED

Control III Disinfectant Germicide and accessories are provided as follows

CONTROL III DISINFECTANT
DISP - 12
Concentrate/Pints/12 per case

CONTROL III DISINFECTANT
DISH - 12
Concentrate/Half-pints/12 per case

CONTROL III DISINFECTANT
DIS - 2 oz. - 24
Concentrate/2 Ounces/24 per case

CONTROL III KIT
HCK - 8
4 kits per case
Each kit contains: 2 quart bucket with lid, 2 oz. Control III, 1 measuring cup and test strips.

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