

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 10-01-87

OUT 10/26/87

Reviewed By Srinivas Gowda ^{WEC} ₁₀₋₂₆₋₈₇ Date 10/26/87

EPA Reg. No. or File Symbol 8383-3

EPA Petition or EUP No. None

Date Division Received 08-17-87

Type Product(s): Hospital Disinfectant

Data Accession No(s) None

Product Mgr. No. 32 (Kempter)

Product Name(s) Permacide Brand Ristex Germicidal Disinfectant

Company Name (s) Sporicidin International

Submission Purpose Amendment to add additional use directions
(Veterinary uses), and additional brand name
labeling (Permacide Brand Ristex Veterinary
Germicidal Disinfectant) with proposed Brand Name
labeling.

Chemical & Formulation Ready-to-use liquid

Active Ingredient (s): 8

Phenol.....	1.41
Sodium Phenate.....	0.24
Sodium Borate.....	0.47

200.00 Introduction

200.1 Use (s)

Proposed labels are attached.

200.2 Background Information

The submission received 08-17-87, is an amendment to add additional use directions (veterinary uses) and additional brand name (Permacide Brand Ristex Veterinary Germicidal Disinfectant). Brand name labeling accompanied the application.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 8383-3

Date Division Received 08-17-87

Data Accession No.(s). None

Product Manager No. PM-32 (Kempter)

Product Name Permacide Brand Ristex Germicidal Disinfectant

Company Name Sporicidin International

PERMACIDE
BRAND
RISTEX GERMICIDAL/DISINFECTANT

.BACTERICIDAL.TUBERCULOCIDAL.FUNGICIDAL.VIRUCIDAL**
.PREVENTS MOLD AND MILDEW
.ELIMINATES ODORS

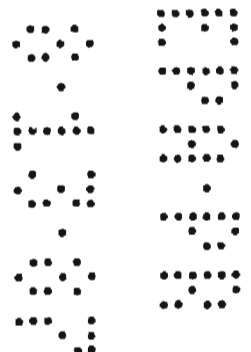
FOR
CONTAMINATION
CONTROL

Active Ingredients...Phenol 1.41% Sodium
Phenate 0.24% Sodium Borate 0.47%
Inert Ingredients.....97.88%

KEEP OUT OF REACH
OF CHILDREN
WARNING

See first aid and additional precautions on back panel.

Net Wt. 22 oz.



SIDE PANEL

AN EXCELLENT DISINFECTANT, FUNGICIDE, VIRUCIDE, AND TUBERCULOCIDE FOR MEDICAL, DENTAL, AND VETERINARY AREAS IN HOSPITALS, CLINICS AND OFFICES as well as nursing homes, ambulances, hotels, schools, boats and health spas.

Action:

1. Reduces the hazards of cross contamination.
2. Prevents mold and mildew.
3. Self-sanitizes surfaces against odor-causing organisms.
4. Kills Athlete's Foot fungi on bathroom, shower and pool surfaces.
5. Non-staining.
6. Effective on non-porous surfaces. It penetrates cracks.
7. Contains no harmful abrasives.
8. Non-flammable.

Permacide Brand (Ristex) Germicidal/Disinfectant is effective when used as directed for disinfection but differs in composition from other Sporidicin brand products.

Directions:

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

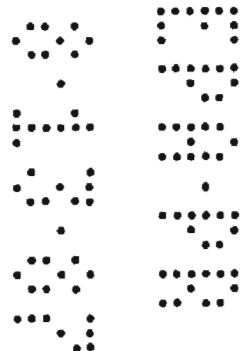
To disinfect: After cleaning, thoroughly wet surfaces using a mop, cloth, sponge or mechanical pump spray. Allow to air dry.

To prevent Mold and Mildew: Repeat application weekly or if new growth appears.

To eliminate odors: Apply as above.

Storage and disposal: Store at room temperature. Discard empty container in regular trash collection.

EPA Reg. No. 8383-3
EPA Est. No. 37615-MD-01



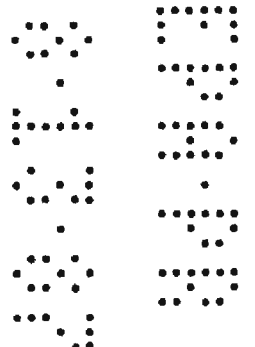
BACK PANEL

PASSES THE RIGID AOAC EFFICACY STANDARDS FOR HOSPITAL AND INSTITUTIONAL TYPE DISINFECTANTS. Permacide Brand (Ristex) Germicidal/Disinfectant provides 100% kill of most disease and odor-causing organisms such as Staphylococcus, Streptococcus, Salmonella, Pseudomonas, Escherichia coli, **Herpes types 1 and 2, Influenza A₂ (Japan 305/57 Asian Strain), Polio 1, Trichophyton (Athlete's Foot Fungus), molds, and mildew and the tubercle bacillus on non-porous surfaces. Acts quickly on germ-laden articles in patient rooms, operating rooms, emergency rooms, bathrooms and recovery rooms. When used as directed, will not harm instruments, equipment, furniture, floors, telephones, door handles, under sinks, diaper pails, garbage cans, linen hampers, ducts, windows, light switches, surgical carts, wheel chairs, walkers, counter tops, damp and musty enclosed areas and animal areas. Reduces the hazard of cross contamination.

A DEODORANT*: It provides continual antibacterial and antifungal activity (residual bacteriostatic, fungistatic) against odor-causing organisms in the presence of suitable moisture if not removed from surface. It is an active deodorant (bacteristat and fungistat) on paper, fabrics, plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

WARNING: Avoid contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

Sporicidin International
4000 Massachusetts Ave., N.W.
Washington, D.C. 20016



Technical Brochure

PERMACIDE BRAND
(RISTEX)
GERMICIDAL/DISINFECTANT

A Household and Institutional Disinfectant and Deodorizer for Contamination Control

Permacide Brand (Ristex) is a germicidal compound which contains bactericidal, fungicidal, virucidal and tuberculocidal properties against a broad spectrum of pathogenic organisms which may cause infection. It is especially adapted as a disinfectant for hospital use, and as a deodorizer for household and institutional articles and environmental surfaces.

USES: As a hospital disinfectant, it reduces the risk of contamination on treated surfaces and articles including thermometers, instruments, telephones, tubing, and other disposable and reusable supplies and equipment. It is a disinfectant which provides germicidal activity for household articles and environmental surfaces.

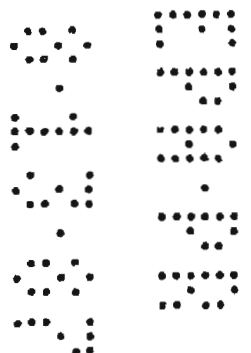
DIRECTIONS: Use full strength...
Immerse articles or wet surfaces thoroughly. Allow to dry.
After treatment, repeat if new mold and mildew occurs.
Clean surfaces prior to application.

ACTION:

- (1) A microbiocide that kills most disease and odor producing organisms (an active deodorant and self-sanitizer against odor-causing organisms for many uses).
- (2) Kills mold and mildew on contact.
- (3) Contains a surface tension reducing agent.
- (4) Contains no abrasives.
- (5) Non-staining.
- (6) Water soluble.
- (7) Kills:
 - Staphylococcus aureus
 - Pseudomonas aeruginosa
 - Salmonella choleraesuis
 - Trichophyton interdigitale
 - Group A alpha hemolytic Streptococcus
 - Group A beta hemolytic Streptococcus
 - Streptococcus viridans
 - Escherichia coli
 - Chaetomium globosum
 - Aspergillus niger
 - Pellicularia filamentosa
 - Influenza A₂ virus (Japan 305/57 Asian Strain)
 - Herpes simplex (types 1 and 2) (oral and genital)
 - Polio (type 1)
 - Mycobacterium tuberculosis
- (8) The germicidal activity of this product was demonstrated visually with electron microscope photos.
 - a. It dehydrates the bacterial cytoplasm.
 - b. It deactivates and alters the chromatin mass.
 - c. It destroys the bacterial cell mass and the membrane.
- (9) May be used on natural and synthetic hard surfaces made of plastic, latex, glass, finished wood, metal, porcelain, enamel and painted surfaces.

- (10) Kills **Influenza A₂ virus (Japan 305/57 Asian Strain), Polio type 1, Herpes Simplex types 1 and 2 (oral and genital) viruses, and the tubercle bacillus on articles and environmental surfaces.

Caution: Keep out of reach of children.



PERMACIDE BRAND RISTEX
Veterinary Germicidal Disinfectant

Bactericidal . Tuberculocidal . Fungicidal . Virucidal*

Prevents Mold and Mildew

Eliminates Odors

For Contamination Control

Active Ingredients Phenol 1.41%, Sodium Phenate 0.24%,
Essential Oils 0.25%

Inert Ingredients 98.10%

Keep Out Of Reach Of Children

WARNING

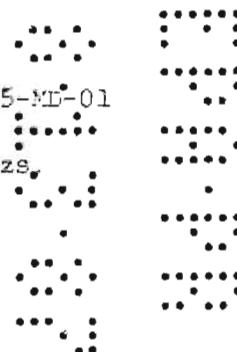
See First Aid and Additional Precautions on Left Panel

EPA Reg. No. 8383-3

EPA Est. No. 37615-MD-01

Net Wt. 22 ozs.

Sporicidin International
4000 Massachusetts Avenue, N.W.
Washington, D.C. 20016



PERMACIDE BRAND RISTEX VETERINARY GERMICIDAL DISINFECTANT

(Complete Hospital Level Disinfection)

For disinfection of instruments and equipment in the operating room and on surfaces in veterinary laboratories, animal hospitals, farm premises, animal housing, in research animal holding areas and for treating animal transportation vehicles and conveyances. It is bactericidal, fungicidal, and *virucidal against the organisms (including canine coronavirus and parvovirus) causing canine distemper, equine influenza, transmissible gastroenteritis, hog cholera, parainfluenza-3, bovine rhinotracheitis, bovine viral diarrhea, infectious bronchitis, Newcastle disease, Venezuelan encephalitis, equine rhinopneumonitis, feline rhinotracheitis, pseudorabies, equine enteritis.

It provides 100% hospital level disinfection against gram positive and gram negative bacteria, pathogenic fungi, and *Mycobacterium tuberculosis* var. *bovis* (BCG).

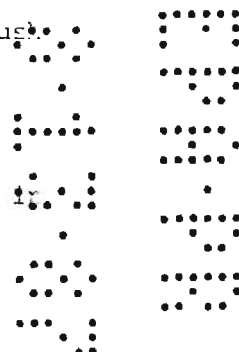
Special Uses:

Spray Cow's Teats:

Permacide Brand Ristex Veterinary Germicidal Disinfectant can be used for spraying cow's teats and will thus act as an aid in controlling the spread of bacteria that cause mastitis.

WARNING: Avoid contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

Storage and Disposal: Store at room temperature. Discard empty container in regular trash collection.



DIRECTIONS FOR USE

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

- I. Disinfecting Instruments, Equipment and Hard Surfaces in Veterinary Laboratories and Hospitals. Preclean surface, spray to completely wet articles or surfaces for 10 minutes with the solution.
- II. For Disinfecting Veterinary or Farm Premises and Animal Housing:
 1. Remove all animals and feed from premises, vehicles and other equipment.
 2. Remove all litter and manure, from floors, walls and surfaces of barns, pens, stall, chutes, and other facilities and fixtures occupied or traversed by animals.
 3. Empty all troughs, racks, and other feeding and watering appliances.
 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
 5. Spray to set all surfaces with the solution for a period of 10 minutes.
 6. Spray to wet all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
 7. Ventilate buildings, vehicles, and other closed spaces. Do not house livestock or empty equipment until treatment has been absorbed and dried.
 8. Thoroughly rinse all treated feed racks, mangers, troughs, automatic feeders, fountains, with potable water before reuse.

For Disinfection of Official Meat, Poultry, Rabbit and Egg Establishments

1. All food products and packaging material must be removed from the room or carefully covered and protected.
2. Remove any loose dirt, litter, etc. that might be lying on floor or attached to the equipment.
3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
4. Spray to completely wet all cleaned surfaces, instruments and equipment with the solution for a period of 10 minutes.
5. After disinfection, all equipment and/or instruments should be thoroughly rinsed with potable water before reuse.

For Spraying Teats as an Aid in Controlling Organisms that Cause Mastitis

Before and after cow is milked, spray each teat until wet. Before milking, dry sprayed teats with a clean paper towel. After milking, allow spray to dry. Teat spraying should start one week before the cow freshens. During drying off process, the teats should be sprayed once a day for three to four days.

202.0 Recommendations

202.3 Additional Data Required To Support Efficacy

- a. No efficacy data were submitted to support virucidal claims against Newcastle Disease Virus and Venezuelan equine encephalitis virus.

New castle disease virus, and Venezuelan equine encephalitis virus can infect man. Therefore, submit data as indicated in the attached DIS/TSS-7 enclosure or delete the claims.

203.0 Labeling

a. Primary Labeling

1. On the Back Panel revise the statement "Permacide Brand (Ristex) Germicidal/Disinfectant provides.....Staphylococcus, Streptococcus, Salmonella, Pseudomonas, Escherichia coli, **Herpes types 1 and 2, Influenza A₂ virus (Japan 305/57 Asian Strain), Polio 1, Trichophyton (Athlete's Foot fungus), molds, and mildew and the tubercle bacillus on non-porous surfaces" to read Permacide Brand (Risex) Germicidal/Disinfectant ProvidesStaphylococcus aureus, Streptococcus salivarius, Streptococcus pyogenes, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli, ** Herpes Simplex types 1 and 2, Influenza A₂ virus (Japan 305/57 Asian Strain), Polio 1, Trichophyton mentagrophytes (Athlete's Foot fungus), Mycobacterium tuberculosis and molds, and mildew on non-porous surfaces".
2. Under "A DEODORANT" revise the statement "It provides.....if not removed from surface" to read "It provides residual bacteriostatic and fungistatic activity against odor-causing organisms in the presence of adequate moisture if not removed from surface".
3. To reflect the proposed amendment revised primary labels with additional use directions (veterinary use) must be submitted.

b. Brand Name Labels

(Permacide Brand Ristex Veterinary Germicidal Disinfectant)

Agency does not review additional brand name labels. However, the following labeling revision are required:

1. Under "Disinfection of veterinary clinics, farm premises and animal housing or caging" include a statement "Do not use in milking stalls, milking parlors, or milk houses"
2. In lieu of data delete claims against Newcastle Disease Virus and Venezuelan Encephalitis virus.
3. On the Left Panel change "infectious bronchitis" to read "avian infectious bronchitis" and "parainfluenza 3" to read "bovine parainfluenza 3".
4. Claims for "cow's teats spray" is a drug claim subject to Food and Drug Administration (Bureau of Veterinary Medicine). In lieu of clearance from FDA delete the claims for use of this product on cow's teats in controlling organisms that cause Mastitis.
5. Under the heading "Active Ingredients" delete "Essential Oils 0.25%" and include "Sodium Borate 0.47%"

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BRAND
RISTEX GERMICIDAL/DISINFECTANT

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.PREVENTS MOLD AND MILDEW
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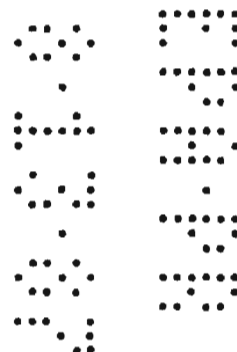
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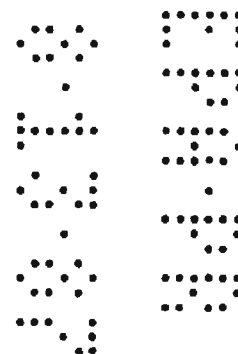
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EPA Reg. NO. 8383-3
EPA Est. No. 37615-MD-01



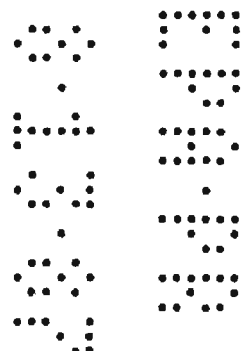
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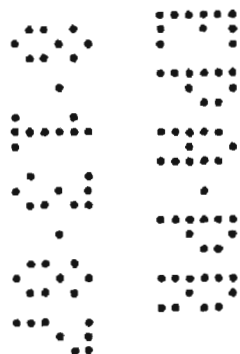
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 - a. It dehydrates the bacterial cytoplasm.
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Caution: Keep out of reach of children.



PERMACIDE BRAND RISTEX

Veterinary Germicidal Disinfectant

Bactericidal . Tuberculocidal . Fungicidal . Virucidal*

Prevents Mold and Mildew

Eliminates Odors

For Contamination Control

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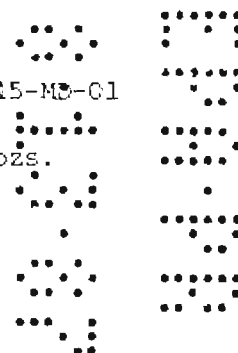
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(Complete Hospital Level Disinfection)

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It provides 100% hospital level disinfection against gram positive and gram negative bacteria, pathogenic fungi, and Mycobacterium tuberculosis var. bovis (BCG).

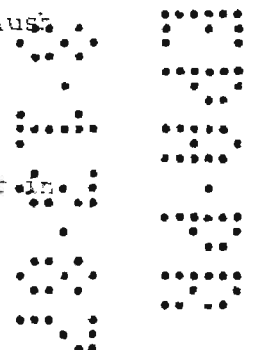
Special Uses:

Spray Cow's Teats:

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WARNING: Avoid contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

Storage and Disposal: Store at room temperature. Discard empty container in regular trash collection.



DIRECTIONS FOR USE

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- II. For Disinfecting Veterinary or Farm Premises and Animal Housing:
 1. Remove all animals and feed from premises, vehicles and other equipment.
 2. Remove all litter and manure, from floors, walls and surfaces of barns, pens, stall, chutes, and other facilities and fixtures occupied or traversed by animals.
 3. Empty all troughs, racks, and other feeding and watering appliances.
 4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
 5. Spray to set all surfaces with the solution for a period of 10 minutes.
 6. Spray to wet all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
 7. Ventilate buildings, vehicles, and other closed spaces. Do not house livestock or empty equipment until treatment has been absorbed and dried.
 8. Thoroughly rinse all treated feed racks, mangers, troughs, automatic feeders, fountains, with potable water before reuse.

For Disinfection of Official Meat, Poultry, Rabbit and Egg Establishments

1. All food products and packaging material must be removed from the room or carefully covered and protected.
2. Remove any loose dirt, litter, etc. that might be lying on floor or attached to the equipment.
3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
4. Spray to completely wet all cleaned surfaces, instruments and equipment with the solution for a period of 10 minutes.
5. After disinfection, all equipment and/or instruments should be thoroughly rinsed with potable water before reuse.

For Spraying Teats as an Aid in Controlling Organisms that Cause Mastitis

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Sporicidin **INTERNATIONAL**

4000 MASSACHUSETTS AVENUE, N.W. • WASHINGTON, D.C. 20016
(202) 244-6608 • TELEX 904069

August 10, 1987

Jeff Kempter, PM 32
Disinfectants Branch
Registration Division, TS 767C
EPA-OPTA-OPP, CM-2
401 M Street, S.W.
Washington, D.C. 20460

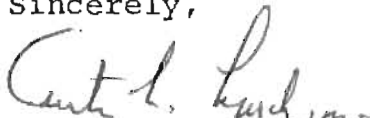
Re: Permacide Brand Ristex Germicidal Disinfectant
EPA Reg. No. 8383-3

Dear Mr. Kempter:

The labeling for the above product is being amended to include Veterinary uses. We are submitting five copies of that labeling as a formal amendment to the above registration in order that we may obtain EPA approval.

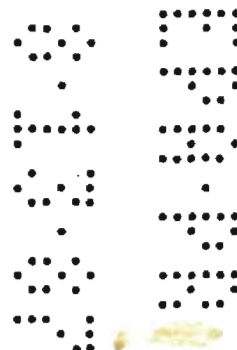
We do believe that you will find this submission in order. We therefore look toward receipt of a copy of the stamped accepted labeling at your earliest convenience.

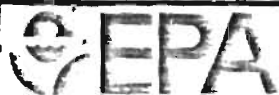
Sincerely,



Curtis L. Lynch, M.D., M.P.H.
Medical Director

Attachments
CLL:an




 U.S. ENVIRONMENTAL PROTECTION AGENCY
 OFFICE OF PESTICIDE PROGRAM (TS-767)
 WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE:

☐ REGISTRATION
☒ AMENDMENT

A

 Please read instructions
 on reverse before com-
 pleting

SECTION I

1. COMPANY PRODUCT NO. 8383-3	2. DATE August 10, 1987	3. PRODUCT MANAGER PM 32	4. PROPOSED CLASSIFICATION ☒ GENERAL ☐ RESTRICTED
5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code) Sporicidin International 4000 Massachusetts Avenue, N.W. Washington, D.C. 20016 ☐ CHECK IF THIS IS A NEW ADDRESS			

SECTION II

1. SUBJECT OF AMENDMENT ☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____ ☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____ ☒ OTHER (explain below) To add veterinary labeling

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN: CHILD-RESISTANT PACKAGING ☐ YES ☐ NO UNIT PACKAGING ☐ YES ☐ NO If YES, unit pkg. wt. _____ No. per container _____ WATER-SOLUBLE PACKAGING ☐ YES ☐ NO If YES, pkg. wt. _____ No. per container _____		2. TYPE OF CONTAINER ☐ METAL ☐ PLASTIC ☐ GLASS ☐ PAPER ☐ OTHER (Specify)
3. LOCATION OF NET CONTENTS ☐ LABEL ☐ CONTAINER	4. SIZE(S) OF RETAIL CONTAINER	
5. LOCATION OF LABEL DIRECTIONS ☐ ON LABEL ☐ ON MATERIAL ACCOMPANYING PRODUCT	6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT ☐ LITHOGRAPH ☐ OTHER (Specify) ☐ PAPER GLUED ☐ STENCILED	

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) NAME Curtis L. Lynch, M.D., M.P.H.		6. DATE APPLICATION RECEIVED (Stamped)
TITLE Medical Director	TELEPHONE NO. (Include Area Code) (202) 244-6606	
2. SIGNATURE <i>Curtis L. Lynch, M.D.</i>	3. TITLE Medical Director	
4. TYPE NAME Curtis L. Lynch, M.D., N.P.H.	5. DATE SIGNED August 10, 1987	