

FEB 25 1986

Barry Laboratories, Inc.
461 N.E. 27th Street
Pompano Beach, FL 33064

Attn: Aaron W. Barry

Subject: Merphene Germicidal Concentrate
EPA Reg. No. 3376-2
Submission dated February 12, 1986

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

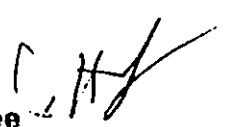
a. Add under the directions for use the following misuse statement: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely,


John H. Lee
Product Manager 31
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

Also available in the following sizes:

One (U.S.) gallon (128 Fl.oz.) size - Product No. 52-1
40 ml size Bottle - Product No. 50-40

CORRECTED COPY A

8 FL. OZ. (237 ML) SIZE

NO 50-8

(R)
M E R P H E N E
CONCENTRATE

E.P.A. Reg. No. 3376-2

BROAD SPECTRUM
ODORLESS GERMICIDE

CORRECTED COPY B

A Unique Formulation of Synthetic Cationic Surface Active Salts

Fungicidal Bactericidal Staphylocidal
Viricidal * Pseudomonacidal

Detergent Action - Built-in Rust Inhibitor

Merphene when diluted and used according to directions is a Professional Use Disinfectant for fine Surgical Blades and Instruments, Nonporous Environmental Surfaces in Hospitals, Clinics, and Nursing Homes where critical-care is needed.

Will not corrode or dull surgical blades or instruments. Use on non-porous painted surfaces, counter tops and polymer coated equipment as directed.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

CORRECTED COPY C

DANGER: KEEP OUT OF REACH OF CHILDREN

Corrosive. Causes eye damage and skin irritation. Do not get in eyes, skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

FEB 24 1986

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

3376-2

FIRST AID: 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 promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities or water. Avoid alcohol. Call a physician immediately.

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

RECEIVED

FEB 13 1986

Manufactured by
BARRY LABORATORIES, INC.

E.P.A. Est. 3376-FL-1 Registration Division (TS-767)

PANEL #2

CORRECTED COPY D

DIRECTIONS: MUST BE DILUTED BEFORE USE.

1. To prepare Merphene " use solution" for cold disinfection - mix Merphene Concentrate with clean potable water as follows

For Germicidal Viricidal* Activity Dilute (1:100) :
[* Herpes Simplex Type 2 and Influenza A2 (Asian) viruses]
Empty 10 ml into one liter of potable water.

For Fungicidal Activity Dilute (1:50) :
Empty 20 ml. Merphene Concentrate into one liter of potable water.

2. Clean instruments thoroughly of foreign matter, soap and detergents before immersion.

3. Immerse completely for at least 10 minutes. Flush and fill lumen of hollow instruments to avoid the entrapment of air bubbles. Rinse anything disinfected with sterile water and wipe dry with sterile gauze before use and use immediately or sterile wrap for future use.

NOTE: Surgical instruments will not be damaged by prolonged immersion, as an effective rust inhibitor is built into Merphene concentrate.

4. Change solution daily or oftener if diluted or discolored.

NOT RECOMMENDED FOR ALUMINUM INSTRUMENTS.

ACCEPTED
with COMMENTS
in EPA Letter to: _____

FEB 24 1986

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

CORRECTED COPY E

- ACTIVE INGREDIENTS:
- n-alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride 6.50%
 - diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.....3.25%
 - diisobutylcresoxyethoxyethyl dimethyl benzyl ammonium chloride.....3.25%
- INERT INGREDIENTS:.....87.00%

COPY F (UNCHANGED)

STORAGE AND DISPOSAL:

STORAGE: Keep away from heat.
DISPOSAL: Do not reuse concentrate container. Wrap and put in trash.

Pompano Beach, Florida 33064

COPY F - I.D. NO. 512-01

COPY G - LOT NO _____

NOTE: This photo copy is of a previously approved EPA printed label and is submitted only as a guide as to location of copy and the type styles. The copy in this label varies from the "corrected copy" attached. Only use "corrected copy" for current labeling details.

	PANEL 1	PANEL 2
Insert Corrected Copy A here →	<p>8 fl.oz./237 ml.size No. 50-8</p> <p>merphene E.P.A. Reg. No. 3376-2</p> <p>BROAD SPECTRUM GERMICIDAL CONCENTRATE</p>	<p>DIRECTIONS: MUST BE DILUTED BEFORE USE.</p> <p>1. To prepare Merphene "use solution" for cold disinfection — mix Merphene Concentrate with clean potable water as follows: (recommend new solution daily)</p> <p>For Germicidal Activity: Empty 40 ml. into one gallon (U.S.) of potable water or 10 ml. Merphene Concentrate to 32 oz. (1 quart, U.S.) water.</p> <p>For Fungicidal Activity: Empty 40 ml. into two quarts (64 oz., U.S.) of potable water, or 20 ml. Merphene Concentrate to 32 oz. (1 quart, U.S.) water.</p> <p>2. Clean instruments thoroughly of foreign matter, soil and detergents before immersion.</p> <p>3. Immerse completely for at least ten minutes. Change solution if discolored or diluted.</p> <p>Surgical instruments will not be damaged.</p> <p>NOTE: Prolonged immersion, as an effective rust inhibitor is built-in.</p> <p>NOT RECOMMENDED FOR ALUMINUM INSTRUMENTS</p> <p>ACTIVE INGREDIENTS</p> <p>n-alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl benzyl ammonium chloride 6.0%</p> <p>disobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 3.2%</p> <p>methylododecylbenzyltrimethylammonium chloride (40%) 3.2%</p> <p>methylododecylxylylene-bis-(trimethylammonium chloride) (10%) 1.0%</p> <p>INERT INGREDIENTS: 1.0%</p> <p>STORAGE AND DISPOSAL</p> <p>STORAGE: Keep away from heat.</p> <p>DISPOSAL: Do not reuse empty container (bottle, bucket). Wrap container and put in trash.</p>
Insert Corrected Copy B here →	<p>For Odorless Disinfection of Surgical, Dental Instruments and Nonporous Environmental Surfaces</p> <p>Fungicidal Viricidal Bactericidal Pseudomonacidal Staphylocidal</p> <p>A triple formulation of synthetic cationic surface-active salts and rust inhibitor. (See side panel.)</p>	
Insert Corrected Copy C here →	<p>DANGER Keep out of Reach of Children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.</p> <p>FIRST AID 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.</p> <p>If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.</p> <p>NOTICE OF PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.</p> <p>Manufactured by BARRY LABORATORIES, INC. E.P.A. Est. 3376-FL-1</p>	
	PANEL 1	PANEL 2



Attachment #3

Specifics regarding
Plastic
Container
for
MERPHENE
Concentrate

Capacity - 8 Fl. oz. (237 ml)
Dimensions as shown
Diameter "6"

Note Container at left
approx. actual size

Disregard any labeling
information appearing on
illustration of Bottle

See separate labeling
detail attached.

Barry Labs, Inc.
December 11, 1985

RECEIVED
EPA REGIONAL OFFICE
ATLANTA, GEORGIA

FEB 21 1986

This is a pesticide, as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, and is a pesticide, as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, registered under EPA Reg. No.