

MAR 12 1990

MDT Corporation
1777 E. Henrietta Rd
Rochester NY 14623

Attention: Raymond E. Bergan
Regulatory Affairs

Product Name: Harvey Vapo-Steril Solution
EPA Registration Number 10648-1
Submission Date Jan. 31, 1990

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. The address of record is: Rochester N.Y.

Your label declares California. Please revise.

b. The correct nomenclature for the first active is "Ethanol" only. Delete "specially denatured 3A."

c. Place the statement: "Contains Methanol" outside the ingredient.

d. Revise

"Vapo-Steril is a bacteriacidal compound for use in
Harvey Chemiclave Sterilizer for sterilizing operating
instruments."

e. read

Causes eye damage and may cause skin irritation.

f. Revise

Do not get in eyes or on skin

to read

Do not get in eyes, or on skin or on clothing.

g. Revise

Wear goggles or face shield

to read

Wear goggles or face shield when handling.

h. Add a Note to Physician statement to read:

Note to Physician

Probable mucosal damage may contraindicate
the use of gastric lavage.

i. Revise:

Directions

to read

Directions for Use

j. Place the new heading "Directions for Use" to appear directly
above the statement

"It is a violation of Federal law..."

Use quantity of Vapo-Steril) ...

to read ...

Use quantity of undiluted Vapo-Steril ...

1. Add the two subheadings

Container Disposal
Pesticide Disposal

to the Storage and Disposal section.

- m. As per phone conversation of March 6, 1990, the label declaration for Ethanol will be changed to 72.39%.

- n. Accordingly, the Inert Ingredient will be revised to 27.39%.

2. 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.

If any questions concerning this letter contact V. Gencarovs at 703-557-3663.

Sincerely yours,


Product Manager (31)
Antimicrobial Program Branch
Registration Division (N7505C)



Technology for Life

Vapo-Steril is a bactericidal compound for use in Harvey
Chemoclave sterilizers for sterilizing operative instruments.

HARVEY VAPO-STERIL® SOLUTION

ACTIVE INGREDIENTS:	72.38% Ethanol	72.38%
	(contains Methanol)	
	Formaldehyde	0.23%
INERT INGREDIENTS	27.39%	27.39%
TOTAL		100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See other precautionary statements on back panel

Manufactured by
MDT Biologic Company
19645 Rancho Way
Rancho Dominguez, California 90220, U.S.A.

NET CONTENTS

ONE GALLON (3.785 liters) U.S. MEASURE
EPA Reg. No. 10648-1 EPA Est. No. 10648-CA-1

350177-1 2/90

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 12 1990

Under the
Fungicide, Insecticide,
and Antimicrobial
Registration Act
10648-1

NOTICE:
ATTACHED ARTWORK MUST
BE RETURNED TO TECH-PUBS

5/15

BACK PANEL - TAB C

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

May cause eye and skin irritation. Do not get in eyes or on skin. Wear goggles or face shield. Harmful or fatal if swallowed. Avoid contamination of food.

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. Get medical attention if irritation persists.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat or open flame. VOLATILE SOLVENTS. Do not use Vapo-Steril in steam sterilizers.

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

DIRECTIONS

Use quantity of Vapo-Steril sufficient to fill reservoir tank. Refer to operating instructions accompanying each Harvey Chemicleave.

STORAGE AND DISPOSAL

Store in an upright position in a cool, dry location. Do not reuse Vapo-Steril. Used Vapo-Steril may be flushed down drain with plenty of water in most areas. If in doubt, contact your local authorities.

Do not reuse container. Triple rinse (or equivalent) container. Then, offer container for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Pesticide wastes are toxic. Improper disposal of excess pesticide or waste is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

350177-2 2/90

ACCEPTED
with COMMENTS,
in EPA Letter Dated:

MAR 12 1990

Under
Fungicide
as an
registered

10648-1

NOTICE:
ATTACHED ARTWORK MUST
BE RETURNED TO TECH-PUBS

