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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
71814-1	SEP 30 1999

NOTICE OF PESTICIDE:
x Registration
____ Reregistration
(under FIFRA, as amended)

Term of Issuance: CONDITIONAL

Name of Pesticide Product: Ster-Cid

Name and Address of Registrant (include ZIP Code):

GMS Marketing Services
191 Hempstead Turnpike
West Hempstead, NY 11552

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase EPA Registration Number "EPA Reg. No. 71814-1".

Signature of Approving Official:
Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Date: SEP 30 1999

EPA Form 6570-6

CONCURRENCES

SYMBOL								
SURNAME	7510C							
DATE	9/30/99							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

3. Enclosed is the Human Exposure Assessment for this product. Based on this exposure assessment (i.e., the dose and MOE calculations presented in Table 2.), there appears to be minimal potential for adverse dermal exposures to handlers when PPE is worn, (MOE = 345, exceeding the minimum criteria of 100 for acceptable dermal exposure risk). The dermal MOE for a person not wearing protective clothing is MOE = 34, however the use of PPE as required on the draft labeling/operator's manual will effectively mitigate the dermal exposure risks from STER-CID product use and STERIMED system cleaning, inspecting, and maintenance operations. Also, the results of this assessment indicate minimal potential for adverse inhalation exposures to handlers not wearing respirators as PPE (MOE = 8929, exceeding the minimum criteria of 100 for acceptable inhalation exposure risk).

Data submitted as product use information (data guidelines 875.1700 and 875.2700) and description of human activity (data guideline 875.2800) are acceptable and sufficient to characterize the exposure potential for occupational handlers of STER-CID. Based on the results of this exposure/risk assessment, RASSB recommends waiving all other application and post application data requirements applicable to the intended indoor use pattern for this product (e.g., dermal exposure: data guidelines 875.1200 and 875.2400, and inhalation exposure: data guideline 875.2500). RASSB reserves the right to request such data in the future if substantial changes are made to the STER-CID product formulation, use directions, or STERIMED system design, that would require the Agency to reassess the potential occupational exposures/risks.

4. The Agency performed a review to determine the adequacy of the Toxicology database to support the use of this product for the treatment of medical waste. The Agency has concluded from the available data that the proposed use of STER-CID in treatment of medical waste poses a reasonable certainty of no harm when used in accordance with label directions. It is noted that the present risk assessment contains conservative assumptions regarding risk from dermal and inhalation exposure to the STER-CID product, assumptions which may be changed in the future as more data become available and a more refined assessment is conducted. This review has been enclosed.

5. It is our understanding that the SteriMed brochure is no longer being distributed.

6. Revise the label as follows:

A. Add the following statement to the "Precautionary Statements" since Glutaraldehyde is a known skin sensitizer: "Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals."

B. Make the following revisions to the "Directions for Use" such that they will be clearer to the user and agree with the SteriMed Operating Manual:

1. Revise the sentence "Container opening must be directed into chemical holding tank in the SteriMed system." to

read "Container opening must be directed into chemical holding tank such that the threaded type cap is aligned with the hole in the deck."

2. Revise the sentence "Close the lid on the SteriMed system." to read "Leave the chemical container in this position and close the lid on the SteriMed system."

3. Revise the sentence "Follow chemical loading instructions outlined in the SteriMed Operating Manual." to read "Refer to the SteriMed Operating Manual for further instructions on how to operate the SteriMed system."

C. In the "STORAGE AND DISPOSAL" section make the following changes such that this section will be in agreement with PR Notice 83-3. Include the following information in the "Pesticide Storage" section: Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use." In the Pesticide Disposal Statement add the following: "...or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance." Revise the "Container Disposal" section as follows: "Triple rinse (or equivalent). Then offer for recycling, or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Or empty or used Ster-Cid container may be disposed of using the SteriMed system in the same manner as was used for the medical waste containers."

7. The following changes are recommended for the SteriMed Operating Manual to ensure consistency between the manual and the label.

A. On page one of the manual make the following revisions:

1. Delete the word "destroys" from the first section. This term infers that this product may be used to sterilize medical waste.

2. Revise the first sentence of the second section to read as follows: "Principle of Operation: Shredding and simultaneous chemical treatment with *a product registered for treating medical waste.*

B. On page six revise the statement beginning "Caution!! Protective clothing, rubber gloves..." to read as follows: "Caution!! Protective clothing, rubber gloves, particulate type mask and proper eye protection should be used, at all times, when handling chemicals *and when cleaning, inspecting, or maintaining the system.* Wash your hands..."

C. On page nine revise the statement beginning "Important!! Protective clothing, safety eyewear..." to read as follows: "Important!! Protective clothing, safety eyewear protection glasses, proper hand gloves for cuts and abrasion protection *as well as chemical protection* and particulate type respirators should be used at all times, while servicing the system *which includes cleaning, inspecting and maintaining the system.* Revise the similar statement at the beginning of page eleven in the

same manner.

D. On pages nine and twelve revise the last statement to end as follows so that the manual will agree with the stamped label for this product: "...accidentally exposed to the chemicals. *Get medical attention.*"

E. On page eleven the statement "Insert 200cc of registered and approved disinfectant into the treatment chamber, as well as spray the inside of the treatment chamber." must be followed by the sentence: "Refer to the label of the disinfectant product for the appropriate dilution and further instructions." Revise statement 3.4 and page seventeen in the same manner.

F. On page seventeen revise the following statements "Caution!! Rubber gloves..." to read as follows: "Caution!! *Protective clothing*, rubber gloves, *particulate type mask* and proper eye protection should be used, at all times, when handling chemicals *and when cleaning, inspecting, or maintaining the system.* Wash your hands..."

G. On page eighteen revise statements 5.1, 5.2, and 5.3 to include the sentence "Proper hand gloves for cuts and/or abrasion protection *as well as chemical protection* must be used."

Provide the Agency with a copy of the revised SteriMed Operating Manual.

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to the release of the product for shipment.

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure (stamped label, Human Tox and Human Exposure reviews)

CONCURRENCES

SYMBOL	7510C:T.Lantz:9/29/99:71814-1						
SURNAME							
DATE							

(front panel)

Ster-Cid

For Use Only with the SteriMed Equipment for Treatment of Medical Waste

ACTIVE INGREDIENTS:	%
Didecyl dimethyl ammonium chloride	7.80
Alkyl (50%C_{14}, 40%C_{12}, 10%C_{16})dimethylbenzyl ammonium chloride	17.06
Glutaraldehyde	10.72
INERT INGREDIENTS:	64.42
Total	100.00

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get immediate medical attention.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.
NOTE TO PHYSICIAN: Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Net Contents: 10 Liters

EPA Reg. No. 71814-
EPA Est. No.

Distributed by: GMS Marketing Services
191 Hempstead Turnpike
West Hempstead, NY 11552

ACCEPTED
with COMMENTS
In EPA Letter Dated:
SEP 30 1999
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
71814-1

(Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. May be harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing vapor. Wear goggles or face shield, rubber gloves and protective clothing when handling the product and when cleaning, inspecting or maintaining the system. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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(Side Panel)

DIRECTIONS FOR USE

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

Use Ster-Cid with the SteriMed system to treat medical waste in hospitals, medical/surgical/dental clinics, laboratories, biomedical research facilities and nursing homes. Open the top of the SteriMed System. Take one sealed Ster-Cid container and place it on the chemical container holding tray which is designed to hold the Ster-Cid container. Container opening must be directed into chemical holding tank in the SteriMed system. Open the Ster-Cid container and allow it to drain slowly into the SteriMed chemical holding tank. Close the lid on the SteriMed system. Follow chemical loading instructions outlined in the SteriMed Operating Manual. Then insert the medical waste bag and begin operation of the SteriMed system. One 10 L container of Ster-Cid is effective for 57 separate treatments, automatically dispensing 175 ml per treatment. The empty Ster-Cid container is replaced only when required to refill the SteriMed system. Please read and carefully follow the use instructions in the Operating Manual.

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or use of this product. Chemically treated medical wastes must be disposed of according to Federal, State and local regulations.

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PESTICIDE STORAGE

Store in a cool, dry area.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess 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 Control Agency, or the EPA Regional Office for guidance.

CONTAINER DISPOSAL

Do not reuse empty container. Empty or used Ster-Cid container may be disposed of using the SteriMed system in the same manner as was used for the medical waste containers.

NOTICE OF WARRANTY

NOTICE: Seller warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with the label directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use, storage or handling of this product in a manner other than as directed by label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to seller and buyer assumes the risk of any such use.

The terms of this Limited Warranty and Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or agent of the seller is authorized to vary or exceed the terms of this Limited Warranty and Disclaimer in any manner.