

71814-1

10-30-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 30 2003

Mr. R. Bruce Jaeger
Agent for GMS Marketing Services
2851 South Haven Road
Annapolis, MD 21401

SUBJECT: Ster-Cid
EPA Registration Number: 71814-1
Application Dated: July 30, 2003
Received Date: August 4, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- revise label language
- update to comply with PR Notice 2001-1

Conditions

Revise the label as follows:

1. Revise the "First Aid" statements to be in agreement with PR Notice 2001-1 as follows:
 - A. "IF IN EYES:" Delete the statement "Get medical attention." and replace with "Call a poison control center or doctor for treatment advice."
 - B. "IF ON SKIN OR CLOTHING:" Delete the statement "Get medical attention." and replace with "Call a poison control center or doctor for treatment advice."
 - C. "IF INHALED:" Add the following statement: "Call a poison control center or doctor for further treatment advice."

CONCURRENCES

SYMBOL	7510C							
SURNAME	J. Jaeger							
DATE	10/30/03							

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D. Delete all language in the "IF SWALLOWED:" section and revise to read exactly as follows:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person."

E. Add the following statement at the conclusion of the "First Aid" statement: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment."

2. Revise the "Pesticide Disposal" statement to include the following language: "...pesticide, spray mixture or rinsate is a..." such that your language is in agreement with PR Notice 83-3.

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:10/30/03:71814-1c

CONCURRENCES

SYMBOL								
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Ster-Cid

**For Use Only with the SteriMed and SteriMed Junior 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

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. Harmful if swallowed or inhaled. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals. 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.

Net Contents: 5 and 10 Liters

EPA Reg. No. 71814-1
EPA Est. No. 71355-BEL-001

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

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

OCT 30 2003

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

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FIRST AID	
If in eyes	<ul style="list-style-type: none"> o Hold eyelids open and rinse slowly and gently with water for 15-20 minutes. o Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. o Get immediate medical attention
If on skin or clothing	<ul style="list-style-type: none"> o Take off contaminated clothing. o Rinse skin immediately with plenty of water for 15-20 minutes. o Get medical attention.
If inhaled	<ul style="list-style-type: none"> o Move person to fresh air. o If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
If swallowed	<ul style="list-style-type: none"> o Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. o Do not induce vomiting or give anything by mouth to an unconscious person. o Call a doctor or get medical attention.
NOTE TO PHYSICIAN	
<p>Probable mucosal damage may contraindicate the use of gastric lavage. Aspiration may cause lung damage. Measures against circulatory shock, respiratory depression and convulsion may be needed.</p>	

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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NOV 30 2003

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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 and SterMed Junior systems to treat medical waste in hospitals, medical/surgical/dental clinics, laboratories, biomedical research facilities and nursing homes.

For Use With SteriMed: 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 such that the threaded type cap is aligned with the hole in the deck. Open the Ster-Cid container and allow it to drain slowly into the SteriMed chemical holding tank. Leave the chemical container in this position and close the lid on the SteriMed system. Refer to the SteriMed Operating Manual for further instructions on how to operate the SteriMed System. 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 cc (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 for SteriMed.

For Use With SteriMed Junior: Open the chemical holding tank cover located at the left side of the front panel of the SteriMed Junior. Open and remove the threaded type cap from the Ster-Cid container and replace it with the special funnel filler supplied with the unit. Insert the funnel filler into the opening of the chemical tank and tilt the container up to allow flow of the chemicals into the tank. Upon completion, remove the special funnel filler and wash thoroughly with running water. Place the empty chemical container into the treatment chamber to be shredded and disposed with the next treatment cycle. One 5 L container of Ster-Cid is effective for 142 separate treatments automatically dispensing 35 cc (ml) per treatment. Please read and carefully follow the use instructions in the Operating Manual for SteriMed Junior.

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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.

PESTICIDE STORAGE

Keep this product in a cool, dry area under locked storage sufficient to make it inaccessible to children and persons unfamiliar with its proper use.

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 Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

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CONTAINER DISPOSAL

Under the Federal Insecticide,
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amended, for the Pesticide
Registration Act of 1972

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Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling, or reconditioning, or puncture and dispose of immediately, by incineration, 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 and SteriMed Junior systems 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.