

71814-1

9-6-2001

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

GMS Marketing Services
191 Hempstead Turnpike
West Hempstead, NY 11552

ATTENTION: R. Bruce Jaeger
Agent for GMS

SEP 06 2001

SUBJECT: Ster-Cid
EPA Registration Number: 71814-1
Your Notification Dated: August 13, 2001
EPA Received Date: August 17, 2001

This is to acknowledge receipt of your notification as per PR Notice 93-10 to change the container size and associated labeling statements for this product. This application is acceptable.

The referenced PR Notice (98-10) allows for changes in package size when the dosage, concentration, frequency or method of application do not change and there is no increased exposure. Your addition of a 5 liter container and associated directions for the use of this container size in the SteriMed Junior appear to meet the criteria in PR Notice 98-10. This notification has been made part of the records for this file.

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

Sincerely,

DHE

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

7510C:T. Lantz:9/6/01:71814-1b

CONCURRENCES

SYMBOL	7510C							
SURNAME	<i>T. Lantz</i>							
DATE	9/6/01							

2/10

EPA	United States Environmental Protection Agency Washington, DC 20460	___ Registration ___ Amendment <u>X</u> Other: Notification	OPI Identifier Number 262229
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Application for Pesticide - Section I

1. Company/Product Number 71814-1	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ster-Cid	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) GMS Marketing Services 191 Hempstead Turnpike West Hempstead, NY 11552 <small>___ Check if this is a new address</small>		6. Expedited Review. In accordance with FIFRA Section 3c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 71814-1 Product Name <u>STER-CID</u>

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

"Me Too" Application.

Notification - (Sub Label, Split Label) Explain below. Notification of Directions for Use per PR Notice 98-10 Other - Explain

Explanation: Use additional page(s) if necessary. (For section I and Section II.) This Notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged in:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted	If "Yes", Unit No. per container Packaging wgt.	If "Yes", No. per container Package wgt.	

3. Location of Net Contents Information Label Container

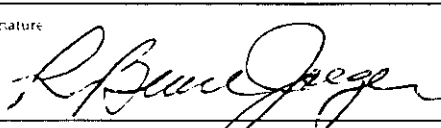
4. Size(s) Retail Container
5 L. and 10 L.

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which label is Affixed to Product
 Lithograph Other: _____
 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 R. Bruce Jaeger	Title President/Health & Environmental Horizons, Ltd	Telephone No. (Include Area Code) 301-261-8491
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Data Application Received (Stamped)
2. Signature 	3. Title: President/Health & Environmental Horizons, Ltd	
4. Typed Name: R. Bruce Jaeger	5. Date August 13, 2001	

3/10

Sub Label Changes

8/13/01 Section 3 Registration SubLabel

Ster-Cid
Page 1 of 4
(front panel)

Ster-Cid

ADDED

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

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: 5 Liters
EPA Reg. No. 71814-1
EPA Est. No. 71355-BEL-001

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



4/10

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. 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.

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.

5/10

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.

ADDED

6/10

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.

CONTAINER DISPOSAL

Do not reuse empty container. 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 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.

8/10

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9/10

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10/10

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