

71814-1

12/18/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Hillary Newman
Regulatory and Environmental Affairs
SteriMed Medical Waist Solutions, Inc.
23065 Commerce Dr.
Farmington Hills, MI 48335

DEC 18 2012

SUBJECT: SteriCid
EPA Registration Number: 71814-1
Application Dated: September 14, 2012
Receipt Date: October 9, 2012

Dear Ms. Newman:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable.

- Resubmission in response to Agency letter dated 06/27/12

Conditions

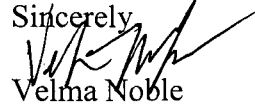
General Comments

Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

A stamped copy of the accepted labeling is enclosed. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347 0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510P)

Stercid™



Validity Code: XXXXXXXXX

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride	7.50%
Alkyl (50% C14, 40% C12, 10% C10) dimethylbenzyl ammonium chloride	17.96%
Glutaraldehyde	10.72%
	64.42%

OTHER INGREDIENTS:

TOTAL 100.00%

FOR USE ONLY WITH SteriMed
EQUIPMENT FOR THE TREATMENT
OF MEDICAL WASTE

MASTER LABEL

EPA Reg. No. 71814-1

EPA Est. No. 71355-BEL-1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 71814-1

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 eye protection where liquid could be splashed, wear rubber gloves, and protective clothing when handling the product and when cleaning, inspecting, or maintaining the system where skin contact or contamination is possible. Wash thoroughly with soap and water after handling, and before eating, chewing gum, drinking, using tobacco, or using the bathroom. Remove contaminated clothing and wash before reuse. Provide local exhaust or general room ventilation to minimize dust and/or vapor concentrations.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eyelids open, then rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 9-1-1 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • 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.
Have the product container or label with you when calling a poison control center, doctor, or going for treatment.	
NOTE TO PHYSICIAN	
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.	

Distributed by:

SteriMed Medical Waste Solutions, Inc.
 23065 Commerce Dr.
 Farmington Hills, MI 48335
 (248) 469-8780
www.sterimedsystems.com

EPA Reg. No. 71814-1

EPA Est. No. 71355-BEL-1

Net Contents: 5 Liters, 10 Liters, or 200 Liters

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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended by the Pesticide
 Act of 1972, registered under EPA Reg. No. 71814-1

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 sewer treatment plant authority or verifying that the effluent complies with the local sewage discharge ordinance. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Use SteriCid only with the SteriMed line of medical waste processors. Use this container of SteriCid only with the SteriMed System 70 (SteriMed-1) and/or SteriMed System 15 (Junior) to treat medical waste in hospitals, medical/surgical/dental clinics, laboratories, biomedical research facilities, nursing homes, blood banks, and dialysis clinics.

5 Liters & 10 Liters Containers

For Use With SteriMed System 70 (SteriMed-1): Open the top of the SteriMed System 70 (SteriMed-1). Take one sealed SteriCid container and place it on the chemical container holding tray which is designed to hold the SteriCid container. Container opening must be directed into the chemical holding tank such that the threaded type cap is aligned with the hold in the deck. Open the SteriCid container and allow it to drain slowly into the System 70 (SteriMed-1) chemical holding tank. Leave the chemical container in this position and close the lid on the System 70 (SteriMed-1). Refer to the System 70 (SteriMed-1) Operating Manual for further instruction on how to operate the System 70 (SteriMed-1). Then insert the medical waste and begin operation of the System 70 (SteriMed-1). The SteriMed System 70 (SteriMed-1) automatically dispenses 175 cc (ml) of SteriCid per treatment. One 5 L container of SteriCid is effective for 28 separate treatments. One 10 L container of SteriCid is effective for 56 separate treatments. The empty SteriCid container is replaced only when required to refill the System 70 (SteriMed-1). Please read and carefully follow the instructions for use in the System 70 (SteriMed-1) Operating Manual.

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For Use With SteriMed System 15 (Junior): Open the chemical holding tank cover located at the left side of the front panel of the SteriMed System 15 (Junior). Open and remove the threaded type cap from the SteriCid 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. The SteriMed System 15 (Junior) automatically dispenses 35 cc (ml) of SteriCid per treatment. One 5 L container of SteriCid is effective for 142 separate treatments. One 10 L container of SteriCid is effective for 284 treatments. Please read and carefully follow the instructions for use in the Operating Manual for System 15 (Junior).

55 Gallon Drum

For Use Only With SteriMed System 70 (SteriMed-1):

Storage and Use Location: Place this 55 gallon drum not more than 15 horizontal feet away from the System 70 equipment and not greater than 10 feet below the System 70.

- Using an OSHA approved drum dolly, locate the drum in a room that will not freeze or which exceeds 50°C, and which meets the distance criteria set forth Storage and Use Location directions as set forth in this label.
- Place the drum on a spill containment pallet (SteriMed recommended, not required by law).
- Remove the standard shipping plug from the drum (See Figure 1).
- Insert dip tube assembly into the shipping plug (See Figure 2).
- Tighten the dip tube assembly by turning the assembly clockwise (CW) using a standard drum wrench. (See Figure 3).
- Turn shipping plug counterclockwise (CCW) to remove. (Use a large, flat blade or #4 Phillips screwdriver). (See Figure 4).
- Insert quick disconnect chemical supply coupler into dip tube insert assembly. Note: there are two connection ports on the coupler. The top port is the SteriCid disinfectant chemical flow port and the lower port is the SteriCid vapor management port. (See Figure 5).
- Verify that the vapor management port has a check valve installed (Contact SteriMed for this part if valve is missing). (See Figure 6).
- Turn the coupler locking ring clockwise until tight (approximately 2 full turns). (See Figure 7).
- Connect 3/8" chemical line from System 70 (SteriMed-1) chemical dispensing pump inlet to the DrumQuik connector using a maximum length of approximately 15 feet of 3/8" chemical line from the DrumQuik and any necessary adapters to fit the conditions of the installing facility. (See Figure 8).
- Remove any trapped air from the chemical supply line between the drum and System 70 by purging the system (refer to System 70 SteriCid Drum Delivery Installation and Operators Manual).

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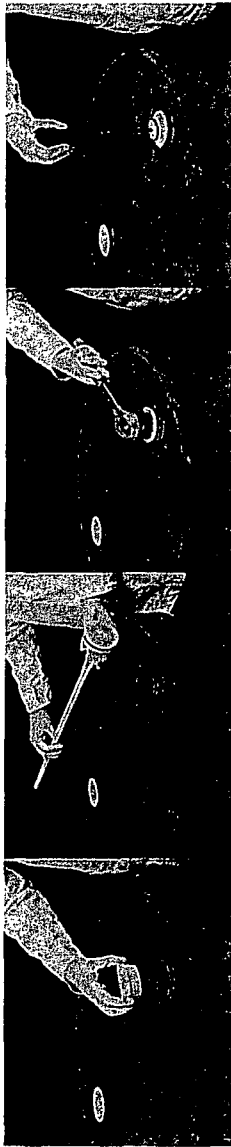


Figure 1

Figure 2

Figure 3

Figure 4

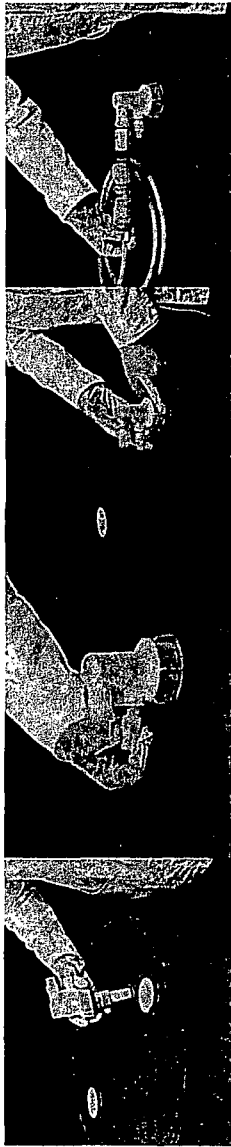


Figure 5

Figure 6

Figure 7

Figure 8

Refer to the System 70 (SteriMed-1) Operating Manual for further instructions on how to operate the System 70 (SteriMed-1). Load the untreated medical waste into the waste receiver for the System 70 and begin operation of the System 70 (SteriMed-1). One 55 gallon drum of SteriCid is effective for 1,189 separate treatments, automatically dispensing 175 cc (ml) of SteriCid per treatment. The empty SteriCid drum is replaced only when required. Please read and carefully follow the instructions for use in the System 70 (SteriMed-1) Operating Manual.

STORAGE

Do not contaminate water, food, or feed by storage, disposal, or use of this product. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. 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, well-ventilated area under protected storage, which is sufficient enough to make it inaccessible to children and persons unfamiliar with its proper use. Keep at room temperature to protect from freezing at 0°C and not exceeding 50°C. OSHA mandates that drums

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containing hazardous materials be labeled as a hazard with distinct warning labels that must be displayed until the drum is emptied, cleaned, or completely removed.

DISPOSAL

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 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.

5 Liters & 10 Liters Containers

Container Disposal:

The 5 L and 10 L SterCid containers are non-refillable. No rinsing of these container sizes of containers is required (i.e. dilution is not an appropriate means of disposal). Do not reuse empty container and store only in the original container. If burned, stay out of smoke. If empty or used, SterCid container may be disposed of using either of the SteriMed Systems in the same manner used for treating medical waste containers. If not shredded by a SteriMed System, the empty container may be offered for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

55 Gallon Drum

Container Disposal:

The disposal a 55 gallon drum container used for pesticide should conform and comply with the appropriate State Regulations and local mandates on pesticide container disposal.

Non-Refillable Container:

Do not reuse empty drum. Empty drums may only be disposed of as non-hazardous solid waste, if they meet certain conditions. An empty drum may be managed as a non-hazardous waste under the federal rule 40 Code of Federal Regulations section 261.7. This drum is not considered empty unless contains less than 3 % (1.5 gallons) or until all pourable liquid residue no longer pours when the drum is inverted.

However, the SterCid must be removed to the best of the generators ability through pumping, pouring, and aspirating. The drum may then be deemed and labeled "empty". Triple rinse with a liquid capable of dissolving the pesticide that the containers held or by another method which is proven to achieve equivalent removal. Then container must be punctured, shredded, crushed, or otherwise changed so as to prevent subsequent use or reuse. In accordance with the overriding State Regulations,

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"empty" containers may then be disposed of, recycled, reclaimed, reconditioned, reused per the appropriate regulations, or disposed of in a sanitary landfill provided that the chosen disposal method complies with State and local regulations.

SPILL MANAGEMENT

In the event of a chemical spill or serious leakage of SteriCid contact the hotline number below. SteriMed Medical Waste Solutions, Inc. is registered with INFOTRAC, so the hotlines are available to provide hazmat response services in the occurrence of any major spills. SteriCid is registered with INFOTRAC. Emergency Response hotline is a 24-hour emergency response telephone number required by the US Department of Transportation (DOT) in 49 CFR 172.604.

In case of Emergency Spill, Contact INFOTRAC: The Hazmat Solution Company

Emergency Response Hotline
1-800-535-5053 (U.S.A. & Canada)
1-352-323-3500 (International)
Customer I.D. for reference: 91933

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; nor does any warranty extend to use 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. REV11142012

UN 1760 Corrosive liquid, n.o.s. (benzalkoniumchloride, glutaraldehyde solution), Class 8.III

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