

12/20/95

PM 31

58779-1

P7173

Please read instructions on reverse before completing form.

Form Approved. GMB No. 2070-0060. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
245193

Application for Pesticide - Section I

1. Company/Product Number 58779-1	2. EPA Product Manager Marion J. Johnson, Jr.	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) STERIS 20 Sterilant Concentrate	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) STERIS Corporation 5960 Heisley Road Mentor, Ohio 44060 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION: Alternative brand names. STERIS 20TM Sterilant Concentrate (EPA Registration number 58779-1) will be sold under the following alternative brand names when marketed as a sanitizer for the treatment of biohazardous waste: 1) STERIS-SWTM 2) STERIS-LWTM

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Paul Zamecnik	Title V.P. Regulatory Affairs	Telephone No. (Include Area Code) 216-354-2600
Certification & Quality Systems 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. Date Application Received (Stamped)
2. Signature 	3. Title VP - REGULATORY AFFAIRS QUALITY SYSTEMS	
4. Typed Name Paul Zamecnik	5. Date 8/31/95	

Do Not Use After
 Lot Number
 Product No. S3000-20
 Net Contents 0.68 oz. (19.32 gm)
 EPA Reg. No. S8779-1
 MSDS No. 79-21-1

ACTIVE INGREDIENT Peroxyacetic acid (Peracetic acid) 35.0%
 INERT INGREDIENTS 65.0%
 TOTAL 100.0%

per container
 contains 2.24 ounces (63.7 gm) active ingredient

Bactericidal
 Sterilizing
 Disinfectant
 Steris-SW™
 Biohazardous Waste Decontaminant

THIS COMPONENT MUST BE USED ONLY WITH THE PEROXYACETIC ACID COMPONENT OF STERIS-SW™ Biohazardous Waste Decontaminant

ACTIVE INGREDIENT 0%
 INERT INGREDIENTS 100%
 Net Contents: 1.74 oz. (49.42 grams)

DANGER—KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. Corrosive, contact with STERIS-SW Decontaminant causes irreversible eye damage, including blindness, and irreversible destruction of skin tissue. High concentrations of vapor will cause lachrimation and irritate nose, throat, and lungs. Contact may cause an allergic reaction. If reaction occurs avoid further contact. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves. Wash thoroughly with soap and water after handling.

DISPOSAL. Wear goggles or face shield and rubber gloves. Dispose of leaking/damaged containers by placing the container in a sink in a well-ventilated area. Immerse container in water. Open container and flush with large quantities of water until container contents have dissolved. Dispose of thoroughly-rinsed container in proper receptacle.

MANUFACTURED BY

STERIS®



STERIS CORPORATION
 5960 Heisley Road • Mentor, Ohio 44060 USA
 216-354-2600

Protected by the Following Patents:
 U.S. 5,077,008; 5,209,909; 5,374,394; Can 1,321,137
 Other Domestic and Foreign Patents Pending
 EPA Est. No. 58779-OH-001

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Use STERIS-SW™ Biohazardous Waste Decontaminant only with the EcoCycle 10™ Processor. Place a sealed container of STERIS-SW Decontaminant into the processing chamber prior to cycle start. Follow the operating instructions located in the Operator Manual.

See the Operator Manual for a comprehensive listing of processing capability.

Do not attempt to manually open the STERIS-SW Decontaminant container.

STORAGE AND DISPOSAL

STORAGE. Store upright in a cool, dry place. Avoid exposure to extreme conditions such as heat, moisture, sunlight or contaminating substances.

DISPOSAL. Wear goggles or face shield and rubber gloves. Dispose of leaking/damaged containers by placing the container in a sink in a well-ventilated area. Immerse container in water. Open container and flush with large quantities of water until container contents have dissolved. Dispose of thoroughly-rinsed container in proper receptacle.

STERIS-SW™
Biohazardous Waste Decontaminant



DECONTAMINANT • SANITIZER • GERMICIDE

STERIS-SW Biohazardous Waste Decontaminant is a single-use chemical decontaminant concentrate validated for use in the EcoCycle 10™ Processor. STERIS-SW is suited to the decontamination of dry medical (<100 ml. blood content) waste such as syringes, needles, sharps, glassware, laboratory wastes, and other biohazardous materials—recommended for use in hospitals, medical/surgical/dental clinics or offices, laboratories, and biomedical research facilities.

DANGER
KEEP OUT OF REACH OF CHILDREN
See precautionary statement on side panel.

DANGER
KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. Corrosive. Contact with STERIS-SW™ Decontaminant causes irreversible eye damage, including blindness, and irreversible destruction of skin tissue. High concentrations of vapor will cause lachrimation and irritate nose, throat, and lungs. Contact may cause an allergic reaction. If reaction occurs avoid further contact. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Do not induce vomiting. Drink promptly a large quantity of egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.

FOR EYE CONTACT: Wash immediately with water for a minimum of 15 minutes, holding eyelids open. Get medical attention.

FOR SKIN CONTACT: Wash off skin immediately with large amounts of water. Remove and wash contaminated clothing. Get medical attention.

IF INHALED: Provide good ventilation with fresh air. If not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, convulsions may be needed.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flames.

ACTIVE INGREDIENT Peroxyacetic Acid (Peracetic Acid) 35.0%

INERT INGREDIENTS 65.0%

Contains 1.1 ounces (31.56 ml) active ingredient per container TOTAL 100.0%

Do Not Use After

Lot Number

Net Contents 3.18 oz. (90.37 gm)

MSDS No. 78-21-2

EPA Reg. No. S4779-1

Product No. S3050-20



Biohazardous Waste Decontaminant

STERIS-LW™

MANUFACTURED BY

STERIS®



STERIS CORPORATION

5960 Heislley Road • Mentor, Ohio 44060
USA
216-354-2600

Protected by the Following Patents:
U.S. 5,077,008; 5,209,909; 5,374,394; Can 1,321,137
Other Domestic and Foreign Patents Pending
EPA Est. No. 58779-OH-001

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Use STERIS-LW™ Biohazardous Waste Decontaminant only with the EcoCycle 10™ Processor. Place a sealed container of STERIS-LW Decontaminant into the processing chamber prior to cycle start. Follow the operating instructions located in the Operator Manual.

See the Operator Manual for a comprehensive listing of processing capability.

Do not attempt to manually open the STERIS-LW Decontaminant container.

STORAGE AND DISPOSAL

STORAGE. Store upright in a cool, dry place. Avoid exposure to extreme conditions such as heat, moisture, sunlight or contaminating substances.

DISPOSAL. Wear goggles or face shield and rubber gloves. Dispose of leaking/damaged containers by placing the container in a well-ventilated area. Immerse container in water. Open container and flush with large quantities of water until container contents have dissolved. Dispose of thoroughly-rinsed container in proper receptacle.

STERIS-LW™

Biohazardous Waste Decontaminant



DECONTAMINANT • SANITIZER • GERMICIDE

STERIS-LW Biohazardous Waste Decontaminant is a single-use chemical decontaminant concentrate validated for use in the EcoCycle 10™ Processor. STERIS-LW is suited to the decontamination of liquid (<1,000 ml, blood content) and dry medical waste such as syringes, needles, sharps, glassware, laboratory wastes, specimens, cultures and other biohazardous materials—recommended for use in hospitals, medical/surgical/dental clinics or offices, laboratories, and biomedical research facilities.

DANGER
KEEP OUT OF REACH OF CHILDREN
See precautionary statement on side panel

DANGER
KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS Corrosive. Contact with STERIS-LW™ Decontaminant causes irreversible eye damage, including blindness, and irreversible destruction of skin tissue. High concentrations of vapor will cause laceration and irritate nose, throat, and lungs. Contact may cause an allergic reaction. If reaction occurs avoid further contact. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED. Do not induce vomiting. Drink promptly a large quantity of egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.

FOR EYE CONTACT. Wash immediately with water for a minimum of 15 minutes, holding eyelids open. Get medical attention.

FOR SKIN CONTACT. Wash off skin immediately with large amounts of water. Remove and wash contaminated clothing. Get medical attention.

IF INHALED. Provide good ventilation with fresh air. If not breathing, apply artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

NOTE TO PHYSICIAN. Possible mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, convulsions may be needed.

PHYSICAL OR CHEMICAL HAZARDS. Do not use or store near heat or open flames.

THIS COMPONENT MUST BE USED ONLY WITH THE PEROXYACETIC ACID COMPONENT OF STERIS-LW™ Biohazardous Waste Decontaminant

ACTIVE INGREDIENT 0%

INERT INGREDIENTS 100%

Net Contents: 8.13 oz. (230.62 grams)

DANGER—KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS Corrosive. Contact with STERIS-LW Decontaminant causes irreversible eye damage, including blindness, and irreversible destruction of skin tissue. High concentrations of vapor will cause laceration and irritate nose, throat, and lungs. Contact may cause an allergic reaction. If reaction occurs avoid further contact. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves. Wash thoroughly with soap and water after handling.

DISPOSAL. Wear goggles or face shield and rubber gloves. Dispose of leaking/damaged containers by placing the container in a sink in a well-ventilated area. Immerse container in water. Open container and flush with large quantities of water until container contents have dissolved. Dispose of thoroughly-rinsed container in proper receptacle.