1043-121

04/27/2006

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs	EPA Reg. Number:	Date of Issuance:	
Antimicrobials Division (7510C) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460	1043-121	APR 27 2006	
NOTICE OF PESTICIDE:	Term of Issuance: CONDITIONAL		
X Registration			
Re-registration	Name of Pesticide Product:		
(under FIFRA, as amended)	GW002 Tertiary Blend		
Name and Address of Registrant (include 2IP code):			
Steris Corporation			
P. O. Box 147			
Saint Louis, Missouri 63166-0147		ł	
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Note Charge set to prevent encourse in a part of the the store of the store that a contract the store of the		s registration must merce. In pny	
On the basis of information furnished by the registrant, the above named registered/reregistered under the Federal Insecticide, Fungicide, and Rod	pesticide is hereb enticide Act, as a	y mended.	
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 Section 3(c)(7)(A) provided that you:			
1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4, or as required by registration review under FIFRA Section 3(g).			
2. Make the following labeling changes:			
a. Revise the EPA Registration Number to read, "EPA Reg. No. 1043-121"			
b. Place the appropriate EPA Establishment No. on the product labeling.			
Signature of Approving Official:	Date:	<u></u>	
MAnindell	APR 2	7 2006	
Marshall Swindell, Product Manager, Team 33,			
Regulatory Management Branch I, Antimicrobials Division			

EPA Form 8570-6

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The submitted Confidential Statement of Formula, is acceptable.

3. Revise the precautionary language as follows:

"Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or shielded safety glasses, coveralls, over long-sleeved shirt and long pants, socks, chemical-resistant gloves (such as butyl, nitrile, neoprene rubber, PVC polyethylene, or Vitron), chemicalresistant footwear, and a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides(MSHA/NIOSH approval number perfix TC-23C), or a canister approved for pesticides(MSHA/NIOSH approval number perfix (TC-14G), or a NIOSH approved respirator with an organic vapor(OV) cartridge or canister with any N, R, P, or HE prefilter. Wash thoroughly with soap and water after handing and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contamination clothing before reuse."

- 4. The statement, "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals," may be taken off the label because hydrogen peroxide products are not sensitizers according to the RED.
- 5. Revise the first aid statements to read as follows:

IF IN EYES

-Hold eye open and rinse gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

-Call a poison control center or doctor for treatment advice.

IF ON SKIN

-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

-Move person to fresh air.

-If person is not breathing, call 911 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

-Call a poison control center or doctor immediately for treatment advice.

-Have person sip a glass or water if able to swallow.

-Do not induce vomiting unless told to do so by a poison control center or doctor.

-Do not give anything by mouth to an unconscious person.

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6. Submit three copies of a final printed production label.

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

A stamped copy of the accepted label is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy at 703-308-6237.

Sincerely,

fell Marshall Swindell

Product Manager 33 Regulatory Management Branch 1 Antimicrobial Division(7510C)

Enclosure

GW002 Tertiary Blend Part A For Use Only with GW002 Parts B and C

For use in: Military Facilities Industrial Laboratories Pharmaceutical Manufacturing Facilities Industrial/Institutional Production Facilities

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO CORROSIVE

	FIRST AID
lf in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.
	-Call a poison control center or doctor for treatment advice.
lf swallowed	•Call 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.
lf on skin	 Take off contaminated clothing.
or clothing	•Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
lf inhaled	•Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give
	artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
	duct container or label with you when calling a poison control center going for treatment.
	NOTE TO PHYSICIAN
Probable mu	cosal damage may contraindicate the use of gastric lavage.

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ACCEPTED with COMMENTS in EPA Letter Dated:	••••	
APR 2 7 2006	•••••	:
Under the Federal Insecticide, Pangicide, and Rodenticide Act as	•••••	•
amended, for the pesticide, registered under EPA Reg. No.	•	•
1043-121	••••	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Harmful if swallowed. User should wash hands before eating, drinking, chewing gum, suing tobacco or using the toilet. User should remove contaminated clothing and wash before reuse.

Personal Protective Equipment PPE

Wear goggles, protective clothing and rubber gloves when handling this product. See GW002 Tertiary Blend art B label for proper protective equipment when handling the end use tertiary blend for this product.

Directions for Use: Use only in conjunction with GW002 Parts B and C. Follow all appropriate instructions for use on GW002 Part B label.

STORAGE AND DISPOSAL:

Environmental Hazards

Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency.

STORAGE AND DISPOSAL

Store containers upright at or below 77° F. Do not freeze. **DISPOSAL** Rinse containers with 20 parts water and then empty into sink with running water. **CONTAINER DISPOSAL** Rinse container with running water and dispose of with normal nonincinerated waste.

For chemical emergency, spill, leak, fire, exposure, or accident, call STERIS Corporation, St. Louis Operations,

day or night at 1-800-243-5799, extension 1395.

Manufactured by: STERIS Corporation 7501 Page Avenue St. Louis, MO 63133 USA 800-JIT-4-USE (800) 548-4873 www.steris.com

ACCEPTED with COMMENTS in EPA Letter Dated:

APR 27 2006

Under the Pederal Insecticide, Pungicide, and Rodenticide Art as smended, for the pesticide, registered under EPA Reg. No. 1043-121 5/9

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GW002 Tertiary Blend Sterilant/Disinfectant/Tuberculocide/Virucide/Fungicide Part B For Sterilization and Disinfection of Hard Non-Porous Surfaces

For use in: Military Facilities Industrial Laboratories Pharmaceutical Manufacturing Facilities Industrial/Institutional Production Facilities

Active Ingredients:

Hydrogen Peroxide	
Inert Ingredients	65%

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO OXIDIZER CORROSIVE

	FIRST AID
If in eyes	-Hold eye open and rinse slowly and gently with water for 15-20 minutes. -Remove contact lenses, if present, after the first 5 minutes, then continue missing the eye. -Call a poison combol center or doctor for treatment advice.
If swallowed	 Call 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 cold to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on skin or clothing	-Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Cull a poison control center or doctor for treatment advice.
If inhaled	•Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice. HOT LINE NUMBER.
	duct container or label with you when calling a poison control center going for treatment.
	NOTE TO PHYSICIAN
Probable mu	cosal damage may contraindicate the use of gastric lavage.

ACCEPTED with COMMENTS EFA Letter Dated:

APR 2 7 2006

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

1043-121

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse.

Personal Protective Equipment PPE

Applicators and all other handlers must wear:

- Coveralls over long-sleeved shirt and long pants

- Socks and chemical resistant footwear
- Goggles or face shield

- Chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton

- Respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MHSA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R,P, or HE prefilter.

Physical or Chemical Hazards

Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Do not confine B component or blended solution in a non-vented container. Avoid excessive heat, contamination, or contact with combustible materials. Clothing, shoes, or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. If allowed to dry in the materials, a fire may result. Discard shoes in a fireproof container.

IN CASE OF FIRE use water only.

CONTAIN SPILLS and dilute with 20 parts of water.

After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lbs. of SO2 equivalent per 500 ml of eroxide) may be used to destroy the peroxide.

Environmental Hazards

Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency. ACCEPTED with COMMENTS

EFA Letter Dated:

USES

APR 2 7 2006

Primarily intended	for use on surfaces such as:		AFR 2 7 2000
Plastic Items	Formica Surfaces	Floors	Under the Federal Insecticide,
Vinyl Surfaces	Bathroom Fixtures	Glass	Fungicide and Rodenticide Act as
Hard Surfaces	Stainless Steel Objects of	or Containers	amended, for the pesticide, registered under EPA Reg. No. / 0 44 3 - 1 2 1

Directions for Sterilization by Immersion: For use on hard, non-porous, pre-cleaned surfaces such as plastics, stainless steel objects or containers, or glass used by military facilities, laboratories and industrial/institutional manufacturers. Remove any obvious debris or organic material from the surface to be sterilized. Pre-clean surface with a detergent followed by a water rinse. To Component A add Component B then add Component C. Open the plastic vent on the lid of the A container and pierce the seal to allow venting. Reattach lid securely to container. Gently stir until thoroughly mixed. After mixing, transfer into a suitable tank for soaking items to be treated. Use caution to avoid contamination of the product prior to application. Do not store blended components; once blended, use immediately. Immerse the item to be sterilized in a sufficient volume of blended GW002 to cover the item and contact all surfaces requiring sterilization. Hold in the sterilizing solution for a minimum of 8 hours, then rinse with potable water until product residues are removed.

Sterilization of Manufacturing, filling and Packaging Equipment in Aseptic Processes: For use on hard, non-porous, pre-cleaned surfaces such as plastics, stainless steel objects or containers, or glass used by military facilities, laboratories and industrial/institutional manufacturers. Prior to use of this product, remove any obvious debris or organic material from the surface to be sterilized. Pre-clean surface with a detergent followed by a water rinse. To Component A add Component B then add Component C. Open the plastic vent on the lid of the A container and pierce the seal to allow venting. Reattach lid securely to container. Gently stir until thoroughly mixed. Circulate, or flood the sterilizing solution on or through the system. Use caution to avoid

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contamination of the product prior to application. Do not store blended components; once blended, use immediately. All surfaces should be exposed to the sterilizing solution for a minimum of 8 hours. Upon completion of the application process, rinse with potable water until product residues are removed. This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Directions for Use as a Disinfectant/Fungicide/Virucide: For use on hard, non-porous, pre-cleaned,

inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets. Prior to use of this product, remove any obvious debris or organic material from the surface to be cleaned. Pre-clean surface with a detergent followed by a water rinse. To Component A add Component B then add Component C. Open the plastic vent on the lid of the A container and pierce the seal to allow venting. Reattach lid securely to container. Gently stir until thoroughly mixed. Use caution to avoid contamination of the product prior to application. Do not store blended components; once blended, use immediately. Apply to surfaces using an appropriate application method such as mop, brush or coarse spray. Allow to remain on surface for 10 minutes. Rinse surfaces with potable water. **Sterilant Activity**: Blended GW002 components are effective as a sterilant when tested at a contact time of 8 hours at 20 C/68 F against *Bacillus subtilis and Clostridium sporogenes* utilizing the AOAC Sporicidal Activity fethod.

Disinfectant Activity: Blended GW002 components are effective as a surface disinfectant against Staphylococcus aureus and Salmonella choleraesuis when tested at a contact time of 10 minutes at 20 C/68 F utilizing the AOAC Use-Dilution Method.

Fungicidal Activity: Blended GW002 components are effective against Trichophyton mentagrophytes at a contact time of 10 minutes at 20 C/68 F utilizing the AOAC Fungicidal Activity Method.

Viracidal Activity: Blended GW002 components are effective against Polio virus Type 1, Adenovirus Type 2 and Influenza A virus in 10 minutes at 20 C/68 F utilizing the EPA approved virucidal assay method.

STORAGE AND DISPOSAL

Store containers upright at or below 77° F. Do not freeze. Do not expose to cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials, or flammable vapors.

PESTICIDE DISPOSAL

Triple rinse containers and dispose of the waste in an approved method. Hydrogen Peroxide is classified as a DOT oxidizer and a hazardous waste under U.S. EPA hazardous waste regulations and it is a violation of federal law to improperly dispose of pesticides.

CONTAINER DISPOSAL

Rinse container with running water and dispose of with normal nonincinerated waste.

For chemical emergency, spill, leak, fire, exposure, or accident, call STERIS Corporation, St. Louis Operations, day or night at 1-800-243-5799, extension 1395.

Manufactured for: STERIS Corporation 7501 Page Avenue St. Louis, MO 63133 USA 800-JJT-4-USE (800) 548-4873 www.steris.com

EPA Reg. No. 1043-RER EPA Est. No. ACCEPTED with COMMENTS EPA Letter Dated:

APR 2 7 2006

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. $1043 - 1 \ll 1$

GW002 Tertiary Blend Part C For Use Only with GW002 Parts A and B

For use in: Military Facilities Industrial Laboratories Pharmaceutical Manufacturing Facilities Industrial/Institutional Production Facilities

KEEP OUT OF REACH OF CHILDREN CAUTION

RECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes eye irritation. Do not get in eyes, on skin or on clothing.

Personal Protective Equipment PPE

Wear goggles or appropriate eye protection when handling this product. See GW002 Tertiary Blend Part B label for proper protective equipment when handling the end use tertiary blend for this product.

Directions for Use: Use only in conjunction with GW002 Parts A and B. Follow all appropriate instructions for use on GW002 Part B label.

STORAGE AND DISPOSAL:

Environmental Hazards

Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent ontaining this product to sewer systems without previously notifying the sewage authority. For guidance

ontact your State Water Board or Regional Office U.S. Environmental Protection Agency.

STORAGE AND DISPOSAL

Store containers upright at or below 77° F. Do not freeze.

DISPOSAL

Rinse containers with 20 parts water and then empty into sink with running water.

CONTAINER DISPOSAL

Rinse container with running water and dispose of with normal nonincinerated waste.

For chemical emergency, spill, leak, fire, exposure, or accident, call STERIS Corporation, St. Louis Operations, day or night at 1-800-243-5799, extension 1395.

Manufactured by: STERIS Corporation 7501 Page Avenue St. Louis, MO 63133 USA 800-JIT-4-USE (800) 548-4873 www.steris.com ACCEPTED with COMMENTS in EPA Letter Dated: APR 2 7 2006

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

-121