

1043-121

12-6-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 06 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Mike Sali
Regulatory Affairs for,
Steris Corporation
P. O. Box 147
Saint Louis, MO 63166-0147

Subject: GW0002 Tertiary Blend
EPA Registration Number 1043-121
Your Amendment Dated December 3rd, 2007
EPA Received Date December 3rd, 2007

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, is acceptable.

A stamped copy of the labeling is enclosed for your records.

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

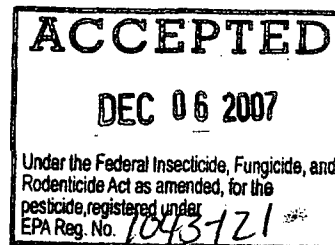
Sincerely,

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division(7510P)

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**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	
If in eyes	<ul style="list-style-type: none"> •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.
If swallowed	<ul style="list-style-type: none"> •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.
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 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	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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 Part B label for proper protective equipment when handling the end use tertiary blend for this product.

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

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

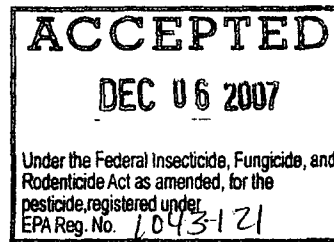
Rinse container with running water and dispose of with normal nonincinerated waste.

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.

STERIS Corporation

7501 Page Avenue ■ St. Louis, MO 63133 ■ USA

800-JIT-4-USE (800) 548-4873 ■ www.steris.com



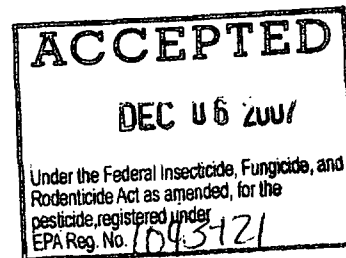
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**GW002 Tertiary Blend
Sterilant/Disinfectant/Virucide/Fungicide
Part B**

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.....35%

Inert Ingredients.....65%

Total.....100%

**KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO
OXIDIZER CORROSIVE**

If in eyes		<ul style="list-style-type: none"> •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		<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 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		<ul style="list-style-type: none"> •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 FIRST AID unconscious person.
HOT LINE NUMBER		
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.		
NOTE TO PHYSICIAN		
Probable mucosal damage may contraindicate the use of gastric lavage.		

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: 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 Viton), and chemical resistant footwear, and a respirator with an organic-vapor removing cartridge with a prefilter approved for

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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 N, R, P, or HE prefilter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical Hazards

Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. 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.

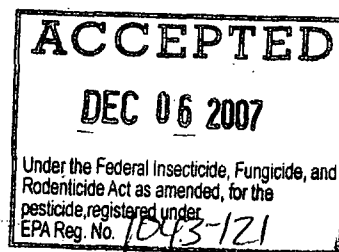
CONTAIN SPILLS and dilute with 20 parts of water.

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

USES

Primarily intended for use on surfaces such as:

- | | | |
|----------------|---------------------------------------|--------|
| Plastic Items | Formica Surfaces | Floors |
| Vinyl Surfaces | Bathroom Fixtures | Glass |
| Hard Surfaces | Stainless Steel Objects or Containers | |



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. Thoroughly pre-clean surface to be sterilized 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. Thoroughly pre-clean surface to be sterilized 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 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

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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* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) utilizing the AOAC Sporicidal Activity Method.

Disinfectant Activity: Blended GW002 components are effective as a surface disinfectant against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) 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* (ATCC 9533) at a contact time of 10 minutes at 20 C/68 F utilizing the AOAC Fungicidal Activity Method.

Virucidal Activity: Blended GW002 components are effective against Polio virus Type 1 (ATCC VR-1000), Adenovirus Type 2 (ATCC VR-846) and Influenza A virus (ATCC VR-544) 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.

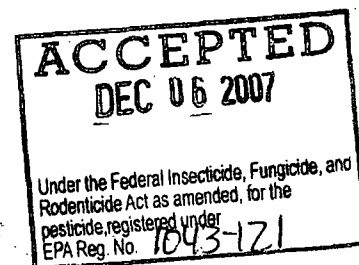
CONTAINER DISPOSAL

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-JIT-4-USE (800) 548-4873 ■ www.steris.com

EPA Reg. No. 1043-121
EPA Est. No. 1043-MO-002



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**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**

PRECAUTIONARY 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.

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.

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