

71871-3

3/30/2009

1098

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Advanced Sterilization Products  
33 Technology Drive  
Irvine, CA 92618

MAR 30 2009

AGENT: Lewis & Harrison  
122 C Street, N. W., Suite 740  
Washington, D. C. 20001

Attention: Robert S. Brennis

Subject: Sterrad Hydrogen Peroxide  
EPA File Symbol No. 71871-3  
Amendment Dated March 20, 2009

This will acknowledge receipt of your notification for the following additional brand names, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

**ADDITIONAL BRAND NAMES**

- "Sterrad Cassette Hydrogen Peroxide"
- "Sterrad 50 Cassette Hydrogen Peroxide"
- "Sterrad 100S Cassette Hydrogen Peroxide"
- "Sterrad 200 Cassette Hydrogen Peroxide"
- "Sterrad NX Cassette Hydrogen Peroxide"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this Notice, please contact Martha Terry at (703) 308-6217.

Sincerely,

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

2008

 <b>EPA</b>	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> <b>Other (Notification)</b>	OPP Identifier Number
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**Application for Pesticide - Section I**

1. Company/Product Number 71871-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Advance Sterilization Products/ Sterrad Hydrogent Peroxide</b>	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) <b>Envirox LLC</b> 1938 E. Fairchild Street Danville, IL 61832 <u><b>PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</b></u> <input checked="" type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> 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**

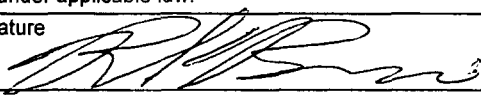
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 This is a simple notification for additional brand names and typographical corrections. We are adding the brand names **Sterrad Cassette Hydrogen Peroxide, Sterrad 50 Cassette Hydrogen Peroxide, Sterrad 100S Cassette Hydrogen Peroxide, Sterrad 200 Cassette Hydrogen Peroxide, Sterrad NX Cassette Hydrogen Peroxide.**  
 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 the 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 type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt    No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other
<b>*Certification must be submitted</b>			
6. Manner in Which Label is Affixed to Product			
<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name: Robert S. Brennis, Lewis & Harrison 122 C St. NW, Suite 740, Washington, DC 20001	Title Agent for Advance Sterilization Products	Telephone No. (Include Area Code) 202-393-3903 ext 20
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 <p style="text-align: center;"><b>(Stamped)</b></p>
2. Signature 	3. Title Agent for Advance Sterilization Products	
4. Typed Name Robert S. Brennis	5. Date March 20, 2009	

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# LEWIS & HARRISON

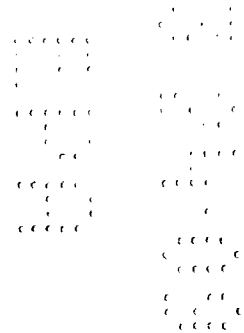
Consultants In Government Affairs

122 C Street, N.W., Suite 740  
Washington, D.C. 20001

telephone 202.393.3903  
fax 202.393.3906

March 20, 2009

U.S. Environmental Protection Agency  
Document Processing Desk (7504P)  
Room S-4900  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460-0001



**ATTENTION: Marshall Swindell**  
**Product Manager, Team 33**

**SUBJECT: Advance Sterilization Products**  
**Sterrad Hydrogen Peroxide**  
**(EPA Reg. No. 71871-3)**  
**Notification – Brand Names and correction of Typos**

Dear Mr. Marshall Swindell:

On behalf of **Advance Sterilization Products**, I am submitting a label notification for their product, **Sterrad Hydrogen Peroxide (EPA Reg. No. 71871-3)**. This is a simple notification to add five additional brand names. We are adding the brand names:

- Sterrad Cassette Hydrogen Peroxide
- Sterrad 50 Cassette Hydrogen Peroxide
- Sterrad 100S Cassette Hydrogen Peroxide
- Sterrad 200 Cassette Hydrogen Peroxide
- Sterrad NX Cassette Hydrogen Peroxide

This notification is also being submitted to correct some minor typographical errors. The phrase "See side panel for additional precautionary language" has been removed, since there is no side panel on the container. All of the language is contained on the main label. The authorized EC representative language has been removed since this language is only required for distribution in Europe and is not language that is appropriate for EPA registered product in the United States. Lastly, there is a phrase that states the amount of hydrogen peroxide in each cell which was stated incorrectly for the alternate language related to Sterrad NX. We have corrected the typographical error by including the correct language as stated in the other three sections of the alternate language.



# STERRAD®

## HYDROGEN PEROXIDE AQUEOUS SOLUTION STERILANT

FOR USE IN THE STERILIZATION OF  
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN  
DANGER

### STATEMENT OF PRACTICAL TREATMENT

**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 rinsing eye.

**If On Skin or Clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

**If Swallowed:** 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.

**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.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**Note To Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

<b>ACTIVE INGREDIENT:</b> Hydrogen peroxide .....	59.0%
<b>INERT INGREDIENTS:</b> .....	41.0%
<b>TOTAL:</b> .....	100.0%

EPA Registration No.: 71871-3  
EPA Establishment No.: \_\_\_\_\_

Net Contents: \_\_\_\_\_

LOT: \_\_\_\_\_

### PRECAUTIONARY STATEMENTS

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

### PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO<sub>2</sub> equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge 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.

Manufactured by:

 **ADVANCED STERILIZATION PRODUCTS®**  
a *Johnson & Johnson* company  
Division of Ethicon, Inc.

33 Technology Drive, Irvine, CA 92618-9824  
(888) STERRAD



©ASP, 2000

DO NOT REMOVE PLASTIC WRAP IF BAG HAS CHANGED FROM YELLOW TO RED. EXP. NOT FOR USE OR SALE AFTER (USE BY DATE HERE) (NOTE TO REVIEWER: The expiration date will not exceed 9 months from manufacturing date)

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## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- tissue culture equipment and materials
- laboratory equipment (including glassware) and instrumentation
- medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

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### For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise: Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- **Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.**

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- OR -

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### For Use In The STERRAD® NX Sterilizer Only.

One (1) Cycle/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise: Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® NX Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.

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- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: One is Standard cycle for 28 minutes and the other is Advanced cycle for 38 minutes
- **Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.**

- OR -

**For Use In The STERRAD® 50 Sterilizer Only.**

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz) [(1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

- OR -

**For Use In The STERRAD® 100S Sterilizer Only.**

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz) [(1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

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.

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### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Store upright at all times. Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

**PESTICIDE DISPOSAL: Bottles:** If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste. **Bottles and Cassettes:** Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or 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: Cassettes:** Discard empty container per hospital policy. **Bottles:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.