

71871-3

10/20/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 20 2010

Ms. Christina Swick
Regulatory Agent for,
Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Mail to: Lewis & Harrison
122 C street N. W., Suite 740
Washington, D.C. 20001

Subject: Sterrad Hydrogen Peroxide
EPA Registration Number 71871-3
Your Notification Dated September 22nd, 2010
EPA Received Date September 22nd, 2010

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, revise the Container Handling as per PR Notice 98-10, is acceptable.

The notification has been part of the permanent record of this file.

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

Sincerely,

A handwritten signature in black ink that reads "Marshall Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)



United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment
 Other NOTIFICATION

OPP Identifier Number

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) STERRAD® Hydrogen Peroxide	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Advanced Sterilization Products 33 Technology Drive Irvine, CA 92618 <u>PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</u> <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

- Amendment – Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application
 Notification – Explain below. Other – Explain below

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

Notification of in Accordance With PR Notice 98-10

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 EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Christina M. Swick Date: 9/22/10

THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Cassette	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" 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 Christina M. Swick, Lewis & Harrison 122 C Street, NW, Suite 740, Washington DC 20001	Title Agent	Telephone No. (Include Area Code) 202-393-3903 x16
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Certification

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 <u>Christina M. Swick</u>	3. Title Agent	6. Date Application Received (Stamped)
4. Typed Name Christina M. Swick, Lewis & Harrison, LLC	5. Date September 22, 2010	

**STERRAD®
HYDROGEN PEROXIDE
AQUEOUS SOLUTION STERILANT**

STERRAD® 100S™ Cassette	REF 10153
STERRAD® 50™ Cassette	REF 10154
STERRAD® 200™ Cassette	REF 10155
STERRAD® NX™ Cassette	REF 10156

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 1-877-208-6653 for emergency medical treatment information.

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

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS:..... 41.0%
TOTAL:..... 100.0%

EPA Registration No.: 71871-3

EPA Establishment No.: 071871-CA-001

Net Contents of STERRAD® 100S Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 50 Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 200 Cassette: Each cell contains NLT: 2246 mg
Net Contents of STERRAD® NX: Each cell contains NLT: 1750µL

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. SO₂ 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:

ASP ADVANCED STERILIZATION PRODUCTS®
 a *Johnson & Johnson* company
 Division of Ethicon, Inc.
 33 Technology Drive, Irvine, CA 92618-9824
 For Technical information call 1-888-783-7723

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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)

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 for 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 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.**

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [1750 µL (1800 µL ± 50 µL)] 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 into the STERRAD® NX 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® 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.**

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- 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 for 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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