

71871-1

1-24-2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 24 2001

Eliot I. Harrison
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: *Advanced Sterilization Products
CD-Cartridge
EPA Registration No. 71871-1
Notification Per PR Notice 98-10*

Dear Mr. Harrison:

This will acknowledge receipt of your notification to add non pesticidal claims, graphics and change the name of the chlorine dioxide generator to be used with the CD-Cartridge, submitted under the provisions of FIFRA Section 3 © 9. Based on a review of the submitted materials the following comments apply.

The notification is acceptable and has been made a part of the file for this product.

Sincerely,

*Wanda Y. Mitchell
Notification Coordinator
Regulatory Management Branch II
Antimicrobials Division (7510C)*

CONCURRENCES							
SYMBOL	7510C						
SURNAME	W. Mitchell						
DATE	1-24-01						

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EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number 274901
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Application for Pesticide - Section I

1. Company/Product Number 71871-1	2. EPA Product Manager Robert Brennis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CD-Cartridge	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Advanced Sterilization Products 33 Technology Drive Irvine, CA 92618-9824 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(1), 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) is necessary. (For Section I and Section II.)

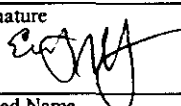
NOTIFICATION TO ADD NON-PESTICIDE LABEL ELEMENTS AND GRAPHICS IN ACCORDANCE WITH PR-NOTICE 98-10

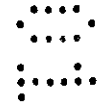
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR Part 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR Part 152.46, this product may be in violation of FIFRA and the registrant 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*Certification must be submitted</i>	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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify)	
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"/> 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 Eliot I. Harrison	Title Agent for Advanced Sterilization Products	Telephone No. (Include Area Code) (202) 393-3903
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 Agent for Advanced Sterilization Products	
4. Typed Name Eliot I. Harrison	5. Date December 20, 2000	



ISODOX™

Sterilization System

CD-Cartridge

REF 90001



FOR USE IN GENERATING CHLORINE DIOXIDE GAS
FOR INDUSTRIAL USE ONLY

ACTIVE INGREDIENT:	Sodium Chlorite	72.8%
INERT INGREDIENTS		27.2%
Total		100%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
If on Skin: Wash with plenty of soap and water. Get medical attention.
If Swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution or, if these are not available, drink large quantities of water. Avoid alcohol.
If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

EPA Registration No.: 71871-1
EPA Est. No.: 9150-RI-1

Distributed by

ASP ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824

©ASP, 2000

LC-90001-002 Rev A

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

DANGER. Corrosive. Causes eye and skin damage. May be fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and use only Neoprene gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS: This product contains a strong oxidizing agent. In the event the container is damaged, combustible material contaminated with the product's contents may burn rapidly. Do not expose to hot surfaces, sparks or open flame.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL: DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL. Storage: Avoid exposure to high temperatures during storage. Store remote from other chemicals and combustible materials. Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use 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: Do not throw expended column in the trash. Return used column to an authorized disposal facility, as per manufacturer's instructions.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product contains a sodium chlorite mixture which, when contacted with chlorine, generates chlorine dioxide. CD-Cartridge is for use by industrial sites where sterility conditions are critical for optimal performance. Use CD-Cartridge to sterilize manufacturing and laboratory equipment, environmental surfaces and implements such as: manufacturing vessels; beakers, test tubes and laboratory glassware; "clean rooms"; sterility testing isolators and pharmaceutical isolators. This product is for use in Advanced Sterilization Products' ISODOX™ Sterilization System ONLY and must be used by trained personnel. For proper generation and application of chlorine dioxide, you must follow the instructions in the ASP ISODOX Sterilization System Operator's Guide.



Net Weight: 11lbs. 10oz.
Sodium Chlorite, 5.1, UN1496, PG II

LOT

EXP

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ISODOX™

Sterilization System
CD-Cartridge

FOR USE IN GENERATING CHLORINE DIOXIDE GAS
FOR INDUSTRIAL USE ONLY

ACTIVE INGREDIENT: Sodium Chlorite	72.8%
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Total	100%

KEEP OUT OF REACH OF CHILDREN DANGER

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LOT

EXP 

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33 Technology Drive, Irvine, CA 92618-9824

©ASP, 2000

LC-90001-001 Rev. A

REF 90001

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OXIDIZING

Net Weight: 3 lb. 14 oz.

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