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 \bigcirc 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)

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CONCURRENCES						
SYMBOL	7510C	-				
SURNAME	M, tchell			************	•••••	
DATE	1-24-01		***************************************	*******		
EPA Form	1320-1A (1/90)		Printed on Recycled Pape		OFFICI	AL FILE COPY

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EPA Enviro	United States		Registrati			OPP Id	entifier Number
Enviro	nmental Protection	Agency	Amendme	ent		2	74901
	Washington, DC 20460		Other				
· ·	Appl	ication for Pe	sticide - Section 1				
. Company/Product Number	2. EPA Product Manager				3. Proposed (Classification	
71871-1	····-		t Brennis				
CD Contridge		Р <u>М</u> # 32				None 📉	Restricted
CD-Cartridge		52					
Name and Address of Applicant (Inc			lited Review. In accordan			ion 3(c)(3)(b)(1),	my product is
Advanced Sterilization F	roducts	similar or	similar or identical in composition and labeling to:				
33 Technology Drive		EPA Re	g. No.				
Irvine, CA 92618-9824		ļ	-				
Check if this is a ne	w addresss	Product	Name				
		Sectio	n – II				
Amendment - Explain below.			Final printed labe	ls in response	to Age	ncy letter dated	
Resubmission in response to Age	ency letter dated		"Me Too" Applica		0-		
Notification - Explain below.	-		Other - Explain b				
Explanation: Use additional p	bage(s) is necessary. (For Section I ar				<u></u>	
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FOR USE IN GENERATING CHLORIDE 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

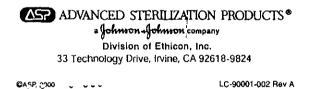
FIRST AID

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 artificiat respiration, preferably mouth-to-mouth. Get medical attention.

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

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REF 90001

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 pesilicide is toxic to fish and aquatic organisms. Do not discharge ellluent containing this product into takes, 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 sever 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 tabel 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 lacility, 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' ISODOX₁₄₄ 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



EXP 🕌

REF 90001

Sterlization System CD-Cartridge

FOR USE IN GENERATING CHLORIDE 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



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ADVANCED STERILIZATION PRODUCTS[®] a Johmon Johmon company

> Division of Ethicon, Inc. 33 Technology Drive, Irvine, CA 92618-9824

LC-90001-001 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 bum 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 laboling. 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_{TM} 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: 3 lb. 14 oz.

OXIDIZIN

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