13-119

2/11/2011

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

United States Environmental Protection Office of Pesticide Programs

STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147 FEB 1 1 2011

Attention: Michael G. Sarli

Subject: SPOR- KLENZ® RTU EPA Registration No: 1043-119 Notification Dated January 11, 2011

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

General Comments

The Notification is in compliance with PR Notice 98-10 and is acceptable. To change the Primary brand name to "Spor-Klenz Ready To Use" from SPOR-KLENZ® **RTU**. This information has been added to your file.

If you have any questions concerning this letter, please feel free to contact Zebora Johnson at (703) 308-7080.

Sincerely

Marshall Swinde

Product Manger (33) Regulatory Management Branch I Antimicrobial's Division (7501P)

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	United StatesEnvironmental Protection Ager Washington, DC 20460				Registration Amendment X Other		OPP Identifier Number	
	Ar	oplication for	Pesticide - Se	ction	Ī			
1. Company/Product Number 1043-119						3. Propose	Proposed Classification	
4. Company/Product (Name) SPOR-KLENZ [®] RTU			PM # 33		X No	one Restricted		
5. Name and Address of Applic	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:							
STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147			EPA Reg. No.					
Check if this is a new address	Product Name							
	······	Sec	tion - II					
Amendment - Explain Below Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated "Me Too" Applicaton X Notification - Explain below. Other - Explain below. Explanation: Notification of change in primary brand name to Spor-Klenz Ready To Use. Spor-Klenz Ready To Use.								
This notification is consisted been made to the labeling of willfully make any false sta and 40 CFR 152.46, this pr and 14 of FIFRA	ent with the provisions o or the confidential statem atement to EPA. I furthe	f PR Notice 98-1 nent of formula or r understand that	0 and EPA Regul f this product. I un if this notificatior	ations a ndersta n is not	at 40 CFR nd that it is consistent	a violation c with the term	of 18 U.S.C. Sec. 1001 to as of PR Notice 98-10	
		Sect	ion - III					
1. Material This Product will b			Water Coluble Deels			Trans of Courts!		
Child-Resistant Packaging Yes* X No	Unit Packaging Yes No X	Yes No X		S Metal Plastic 2 Glass		astic X ass		
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" No. per Paper Package wgt container Other (Sp			per her (Specify)		
		4. Size(s) Retail C 1 quart, 50 gallon	4. Size(s) Retail Container 1 quart, 50 gallon		5. Location of Label Directions			
Label X Container	bel X Container		On Label X On Labeling acco				companying product	
6. Manner in Which Label is Affixed to Product		Lithograph Paper glued X Stenciled			Other			
		Sect	ion - IV	A				
1. Contact Point (Complete item	s directly below for identification			ary, to pr	ocess this app	lication.)		
Name Michael G. Sarli	Title Manager, Regulatory Affairs			Telephone No. (Include Area Code) 314-290-4704				
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that a true is a complete is a complete in the statement may be punishable by fine or imprisonment or both under applicable law.								
2. Signature	3. Title				cière			
Mulsit.		Manager, Regulatory Affairs						
4. Typed Name Michael G. Sarli	5. Date					<u> </u>		
EPA Form 8570-1	· · · · · · · · · · · · · · · · · · ·	1/10/11				<u>I</u>		

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STERIS[®]

January 11, 2011

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Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) Regulatory Management Branch 1 Antimicrobials Division (7510C) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 Attn: Marshall Swindell, PM #33

Re: Notification for SPOR-KLENZ[®] RTU (EPA Reg. No. 1043-119) Change in Primary Brand Name in Accordance with PR Notice 98-10

Dear Mr. Swindell:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling 850 mL size (1 copy)
- Labeling 3.2 L size (1 copy)
- Labeling 50 gaL size (1 copy)

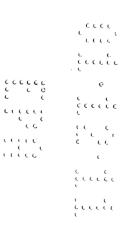
We request the primary brand name be changed to "Spor-Klenz Ready To Use."

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely, MDG

Michael G. Sarli Regulatory Affairs STERIS Corporation

Enclosures



s properly nimum of 0.0.5 ppm. Iume with hty before hty before on daily to o cleaned ds. Let air ds. urfaces):	surfaces e so as to a surface d surface of contact of contact of contact Surfaces. Surfaces. Itowed by Itowed by Itowed for ensed for	urs 20°C ftes 20°C ftes 20°C	s at 20°C fites 20°C nds 20°C o 49 part fites 21°C	Maintain Store ain Store and posed of a missate coording provi
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dvaging material dvaging material eroxic during bogg eroxic altoconce (000 cu. R. (2000 (2000 cu. R. (2000 (2000 cu. R. (2000 Surfact) Surfact) dr. Distored or Farmain on surfact or surfact) dr. Distored or surfact) dr. Distored or surfact) dr. Distored dr. Di dr. Distored dr. Distored dr. Distored dr.	itery solic.c. yo obs. Apply by do ox ditution (17	 C. sporogene: dial	(ATCC VR-907) U TCC 6538), U US 041	D DISPO orage of disposa- tract with combu- tract with combu- nergency, spill, the use of this pri- the use of this pri- the use of this pri- the use of this pri- sec annot be disp concersion and the disp concersion of the pri- concersion of the price of the price of the price of the price of the price of the price of the price of the price of the price of the price of the price of the price of the pri- of the pr
or carefully protect all food products and packaging materials. Ensure room is properly emittated. Vacata all gesometin from the <i>c.om</i> during togging cruft for 7 minimum of 2 hours after foogling or fould more the <i>c.om</i> during togging cruft for 7 minimum of 2 hours after foogling or fould more the <i>c.om</i> during togging cruft for 7 minimum of 2 hours after foogling or fould more the <i>c.om</i> during togging cruft for 7 minimum of 2 hours after foogling or fould more the <i>c.om</i> during togging cruft for 7 minimum of 2 hours after foogling or fould more the comparison in the food and that do the foodling of the foodling on the foodling of the food operations are sufficient. Not: 0.1 and 1.2 minimum of the foodling of the food perations are sufficient to not reuse solutions. Disposed of any durided for daily to ansure affectiveness. Sing SPOR-KLENZ Ready To Use unditued onto cleaned and non-provus surfaces. Sing SPOR-KLENZ Ready To Use unditued onto cleaned surfaces using a plasite spray budie. Apylo usergand on grande of 70 seconds. Let af 0 thready or times unditued water, drain. Apylo Singer 1 f bossible and allow to dri. DIRECTIONS FOR USE AS A CLEAUSERS.NITZER (2004 contact surfaces):	Using water or mechanical relation, rejinvo Prisidy water, cry coss fith from hard surfaces such as formles, stealed action, rejinvo Prisidy water, or mechanical strates such as formless stealed or wirking surfaces. Apply, by, John, mop or sponge so as to wet all surfaces throughly a freshly made StoX dilution (1) part product to 49 part water) of SPOR+KLENZ Fready for Uses, made using purified water, to the pre-desared surface for immerses pre-denated ferms to be sanitized in the solution. Allow 5 minutes of contract or immerses pre-denated ferms to be sanitized in the solution. Allow 5 minutes of contract product to 49 part water) the Let at rdy or rinse with purified water, to how 5 monuse of ormating time. Let at rdy or rinse with purified water, to more provus surfaces. Diffect TINS FOR USE as a cleaner/sanitizet. Use only on hard, non-porous surfaces fractiones and the accomplished by nising with water or by detegrent cleaning followed by a water rinse. Immerse hard, comportus surfaces in a sufficient volume of undituded SPOR-KLENZ Ready to rallow to arrive and surfaces must remain completely immersed for 30 minutes. Wipe dry or allow to arrive to a sufficient volume of or 30 minutes.	Sterilart/Sporicidal [B. subtilis (ATCC 19659), C. sporogenes (ATCC 3584)] Bactarical, Fundicial, Minucla 20°C (ATCC 3584)] Bactaricals (Fundicial, Minucla 20°C Sporiodial — Unchaption States [B. subtilis (ATCC 19659), C. sporogenes (ATCC 3584)] Estimonial anticrica (ATCC 10708)] Pseudomonas Aannonial anticrica (ATCC 10708)] Pseudomonas Aannonia anticrica (ATCC 10708)] Pseudomonas Aannonia anticrica (ATCC 10708)] Pseudomonas Annonia anticrica (ATCC 10708)] Pseudomonas Annonia anticrica (ATCC 15302) Hilvetri (Clinical Isolate)	Minute virus of moe (cuincal isolate) Winute paraintiperza virus (Clinical Isolate) Wurine provinus (Clinical Isolate) Wurine provinus (Clinical Isolate) Wurine paraintiper (Clinical Isolate) Manie parvovinus (Clinical Isolate) Aspergilus riger (ATCC 16404) Aspergilus riger (ATCC 10708) Cermical Story Disincerant [S. aureus (ATCC 6538), undiluted 30 seconds 20°C Mon-boot Contact Surface Samiber [S. aureus Mon-boot Contact Surface Samiber [S. aureus Matrice 370°C (1708)] Mon-boot Contact Surface Samiber [S. aureus Matrice 370°C (1708)] Mon-boot Contact Surface Samiber [S. aureus Matrice 370°C (1708)] Mon-boot Contact Surface Samiber [S. aureus Matrice 370°C (1708)] Matrice 370°C (1708)] Matrice 370°C (1708) Matrice 370°	STORAGE AND DISPOSAL Bo not contaminate water, food or feed by storage or disposal. Do not contaminate water, food or feed by storage or disposal. Pesticide Storage: Store in shipping cardon. Do not expose to direct sunfight. Maintain temperature below, 55° (24°C), Avoid contact with combustible materials. Store in original closed container. For chemical emergency, split, leak, fire, exposure and accident, call Chemitred, any on right flow 249.3600, 1703-577.3897. Pesticide Storage states in summing thom the use of this product may be disposed of norsite in a sanitary sewer or at an approved wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinste is a value of the factoration of factoral Law. If these wastes cannot be disposed of by use according the Hazardous Wastes resulting from the use of this product may be disposed of the Hazardous wastes cannot be disposed of by use according the Hazardous Wastes Pesticide or Environmental Control Agency, or the Hazardous Wastes Presticide or Environmental Control Agency, or the Hazardous Wastes Presticide or the mixture. Offer for recycling, if areilable. Container. Do not reuse or refill this container. Offer for recycling, if areilable. Cannot are the nearest EPA Hegional Office for Guidance. Container Disposa <u>s</u> . Nonrelitable container or mixtark. Fill the container and dorth, resuring at least one complete revolution, for 30 seconds. Stand the container on its effect and torth several times. Turny the container or the container on its and orbit is access. Repertatione equipment or a mix tark. Fill the container on the fact and torth several times. Turny the container or the add thit hade and torth several times. Turny the container or a fix tark or store rinsteals for tarter and or is asside and on it is back and thit hade and torth several times. Turny the normaline on its and and the task and thorth several times in the container of mix tark or store rinsteal for tarter and on the store and and the task and thorth several ti
y protect all food Vacate all person the foogling of int the togging of an int a using one and sing a resume A borous surfaces.	Lising water or mechanical action, reim usuch as formica, statiness steel or vivity, wet all surfaces throroughly, a freshly made of SPOR-KENZ Ready for Use, made or immerse pre-deamed terms to be sam nime. Let air dry or rinse with purified wat to be the reused as a cleaner/samitizer. DIRECTIONS FOR USE AS A SPOR Bernova any obvious debris or organic can often be accomptished by rinsing, a water rinse. Immerse hard, non-poro SPOR-ALENZ Ready to Use. Treated 5 30 minutes. Wipe dry or allow to ar dry. PRODU	Sporicidal (B. sub 564)) Bactericidal ane Non-porcesses anes Non-porcesses anes ArrCC Table Banterda ArrCC Table ArrCC Table A	Wurturule avraits of mice (climical isolate) Wurture parainfluenza virus yope 1 (35 Wurture norovirus (Clinical isolate) Wurture norovirus (Clinical isolate) Mouse parvovirus (Clinical isolate) Aspergitus riger (ATCC 10404) Germicada (ATCC 10708) Non-food Contact Surface Samitizer IS, MTCC 6538), K, pneumoniae (ATCC-	STOF Interninate water, I re Below 75% (is below 75%) (closed container, closed container, closed container, closed container, closed container, closed container, regrate Reprise and tip it back and remaining conter ensating at least ensuing at least ensuing at least ensuing at least ensuing conter enterning conter enterning at least ensuing conter enterning conter enterning at least ensuing a
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Harmful if Harmful if the toilet. 1 be used ce shield, estharies.	resources, ressort in resources, resources, resources resolutions	ms soiled arred from ECTTOUS CONTRCT dy to Use dy to Use	s labeling. + or other + or other to other aring and use. Test ampatible ampatible ampatible armonate, by To Use b used as	isual debra situa debra a the item a the item then for a mous and utem is not a the situal and the the and the

PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals.

SPOR-KLENZ[®] Ready To Use

The Technology of Clean[®] Cold Sterilant

STERIS[®]

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DANGER – PELIGRO. Corrosive. Causes irreversible eye damage. I absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid on skin. Wash hands before sering, drinking, chewing gum, using bbacco or using Hemow contaminated doriting and wash hands before reuse. Caution shout when applying indoors because pets may be at risk.

Personal Protective Equipment (PPE): Handlers must wear: Goggles or te and protective rubber gloves.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION A HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PET PHOTECTION 5 perficit barier protection items to be used when handing iter with bload or body fluids are disposable later, gloves, growns, masks and eye of cLEANING PROCEDURE: Bload and other body fluids function that surfaces and other bloady fluids should be autoclaved and other MATERIALS: Bload and other body fluids should be autoclaved and off according to federal and local regulations for inhectious wated disposal. C IMME: Leave surfaces completely immersed with undiluted SPOR-ALERIZ Bload or a minimum of 10 minutes. It is a violation of Federal law to use this product in a manner inconsistent with it

DIRECTIONS FOR STERILIZATION: SPOR-KLENZ Ready to Use is not to be a terminal statination any citical/semical relatical device. Amono any obvio or organic material from the surface to be straitized. This can often he accomp-inising with water or by detargent cleaning followed by a water first. Immerse the internet in a sufficient volume of undiuded SPOR-KLENZ Ready to Use the internet and fill all passages requiring sterilization. Hold in the sterilizing to Use minimum of 5-12 hours at 20°C termeture (GPF). Remove lense after 5-121 times with sterile volume or water shows levels of 10 ppm or less. The solutions be used and reused for up to 14 days in a manual system with 5-12 hours into

DIRECTIONS FOR BROAD SPECTRUM DISINFECTION/TUBERCULOS Sendal), Mouse paramits virus and Murrine paramitary inter paramitarus virus ty Sendal), Mouse paramits virus and Murrine aravitaris paramitareara virus ty Sendal), Mouse paravita virus and Murrine aravitare paramitarus virus ty Sendal), Mouse paravita virus and Murrine aravitate paramitational arguest used as a leminal high bread disrifectation on any challenger the be used as a leminal high bread of disrifectation on any challenger the breads at the minal high bread of disrifectation on any challenger arguest the accomplished by the form the surfaces to be disrifectad can often be accomplished by in the right with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrous surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrus surfaces, throroughly weiting surfaces with a disting followed by a water fines. Apply product to hard, porrus surfaces throroughly weiting surfaces with a disting the disting the disting followed by a water fines. Apply product to hard, porrus surfaces, throroughly weiting surfaces with a disting the di

product may be used in fogging as an adjunct either preceding or followir cleaning and disinfecting procedures for hard room surfaces. Prior to foggin FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECT

EPA Reg. No. 1043-119 EPA Est. No. 52252-MN-01

For Use in Pharmaceutical, Medical Device, Biotech and Cosmetic Manufacturing Facilities. Sterilant/Sporicidal, Bactericidal, Tuberculocidal, Fungicidal, *Virucidal, Non-food Contact Sanitizer Uses: Primarily intended for sterilization or disinfection of: stainless steel, plastic itoms and surfaces, hard surfaces e.g. countertops, floors, walls, bathroom fixtures, glass, formica, vinyl.

MK CONTINUE 189.25 Liters (50 gal.)

6525-P4

Environmental Hazards. This pesticide is toxic to birds, fish and aquatic inve Do not discharge effluent containing this product into lakes, streams, ponds, coeans, or public waters unless this product is pecifically identified and add a NPDES permit. Do not discharge effluent containing this product to sever without previously notifying the sevage plant authority. For guidance, contact, Water Board or Regional Office of the U.S. Environmental Protection Agency.

Physical and Chemical Hazards: This product contains an oxidizing agent.

"KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SUPFACES/O PREVIOUS/I SOILCE WTH BLOODBODILY LUIDS in name and care seting settings in which there is an expected Relihood of soling intarimate sufface with blood or body fluds, and in which the suffaces/objects likely to be solied to body fluts can be associated with the pountial for transmission of HIV-fimmundeficiency Vinus Type 1-associated with AIDS).

...1.00% 98.92%

Active Ingredients: Hydrogen Peroxide eroxyacetic Acid Inert Ingredients.

TOTAL

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO See side panel for precautionary statements.

DIRECTIONS FOR USE

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.

FIRST AID

If inhaled

Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes.
 Call a poison control center or doctor for treatment.

If on skin or on clothing

f in eyes

Hold eye open and rinse slowly and gently with water for 15-20 minutes. A Pernove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. • Call a poison control centrel or doctor for treatment advice.

Call poison control center or doctor immediately for treatment advice: + Have person bia a glass of water if able to swallow.
 Do not induce vomiting unless toid to do so by the poison control center or doctor.
 Do not give anything by mouth to an

If swallowed

HOT LINE NUMBER

unconscious person.

DO NOT USE AFTER EXPIRATION DATE. Do not allow SPOR-KLENZ I Use to mix with alkaline substances such as bleach (Sodium hypochlorite) oxidizing agents. Use puritied water (e.g. deionizet) for mating dilutors, clet rinsing. Some materials may be incompatible with SPOR-KLENZ Fleady To material prior to use. SPOR-KLENZ Ready To Use has been shown to be c with Polyving chloride, polypropytene, polyuretharine, aceborners, polystyrene, stanies steel. Reuse of diluted SPOR-KLENZ Ready To polystyrene, staniess steel. Reuse of diluted SPOR-KLENZ Ready is not recommended.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chemtrec at 800-424-9300 for emergency medical treatment information. For chemical emergency, split, leak, fire, exposure and accident, call Chemtrec, day or night 800-424-9300, 703-527-3887.

· EXB: MFD: Ŀ

Probable mucosal damage may contraindicate the use of gastric lavage.

NOTE TO PHYSICIAN