

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OCT 3 0 2009

Ms. Wendy McCombie Agent for, c/o Sterilex Corporation Lewis and Harrison 122 C Street, NW Suite 740 Washington, DC 20001

Subject: Sterilex Ultra Disinfectant Cleaner Solution 1

EPA Registration Number 63761-8

Your Notification Dated October 5th, 2009 EPA Received Date October 7th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to change the word "should" to "must" under the "Directions for Use" section on the adjuvant labeling as per request from Washington State Department of Registration, 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,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)

Please read instructions on reverse be		Form Approve	d, OMB No. 2070-000	50 45			
Ω EDA		☐ Regist	ration	OPP Identifier Number			
S EPA En	on Agency						
	Washington, DC 204	460			N I		
Application for Pesticide - Section I							
1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification							
63761-8			all Swindell				
4. Company/Product (Name)	01	PM#		_	None Restricted		
Sterilex Ultra Disinfection Cleaner Solution 5. Name and Address of Applicant (Include ZIP Code)		33 6 Evns	dited Basiass In		FIEDA Soction 2(a)(2)		
Sterilex Corporation		6. Expedited Review . In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling					
11409 Cronhill Drive		to:					
Suite L		EPA R	eg. No				
Owings Mills, MD 21117		Product Name					
Check if this is a new address			1 Toddet Name				
Section - II							
Amendment – Explain below.		,	Final printed la	bels in response to A	gency letter dated		
Resubmission in response to Agency letter dated			"Me Too" Application				
Notification - Explain below.	1	/F = = O = = 41	Other - Explain				
Explanation: Use additiona	al page(s) if necessary.	(For Section	on I and Section II	.)	•		
Notification	to update adjuvant	label. Ple	ease reference	cover letter for	r details.		
	tion of MINOR LABEL						
This notification is consistent with the							
the labeling or the confidential stater statement to EPA. I further understa							
				Notice 33-2 and 40 C	rik 152.40, tilis product may be		
in violation of FIFRA and I may be th	ne subject to enforcement act	tion and pena	Ilties under sections 12	2 and 14 of FIFRA.			
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LEWIS & HARRISON

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Consultants in Government Affairs

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

telephone 202.393.3903 fax 202.393.3906

direct 202.393.3903 ext. 11 wmccombie@lewisharrison.com

October 5, 2009

HAND DELIVERED

Document Processing Desk [NOTIFY]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION:

Marshall Swindell

Product Manager, Team 33

SUBJECT:

Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No. 63761-8)
Application For Notification of Minor Label Changes per PR Notice 98-10

Updated Adjuvant Labeling

This Submission is NOT Subject to PRIA fees

Dear Mr. Swindell:

On behalf Sterilex Corporation (Sterilex), I am submitting an Application for Notification for Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No. 63761-8) pursuant to the provisions of PR Notice 98-10.

Sterilex has updated the labeling for the adjuvant product, Sterilex Ultra Activator Solution. Sterilex has changed the word "should" to "must" on the label in the interest of improved product stewardship and per correspondence with Washington state. While the adjuvant product does not require registration or a stamped label, Sterilex would like to place a copy of the updated label on file for the Agency's review.

Please find enclosed the following documents in support of this Notification:

- Application for Pesticide Notification, which includes a signed statement certifying compliance with PR Notice 98-10; and,
- 2) Three (3) copies of the updated adjuvant label.

Thank you in advance for your assistance with this submission.

· Sincerely,

Wendy A. McCombie

Agent for,

Sterilex Corporation

Enclosures

cc: Mark Wozniak, Sterilex Corporation



Sterilex Ultra Activator Solution

An Activator for Sterilex Ultra Disinfectant Cleaner Solution 1.

This is a two-part product that must always be used with

Sterilex Ultra Disinfectant Cleaner Solution 1

PRINCIPAL FUNCTIONING AGENTS:

Soda Ash	6.0%
Potassium Carbonate	
Tetrasodium ethylene diamine tetraacetate (EDTA)	
CONSTITUENTS INEFFECTIVE AS SPRAY ADJUVANTS	83.1%
TOTAL	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMSESTIC ANIMALS.

DANGER. CORROSIVE - Causes burns. Wear suitable gloves and eye protection. Causes irreversible eye damage and skin burns. Harmful if swallowed. Ingestion causes burns of the upper digestive and respiratory tract. Harmful in contact with skin. Contact causes severe skin irritation and possible burns inhialation of vapors in high concentration may cause irritation of respiratory system. Harmful by inhalation:

DANGER KEEP OUT OF REACH OF CHILDREN

See Side Panel for Direction for Use and First Aid

For additional tips please visit v.ww.sterilex.com

For Technical Service Call 1-800-511-1659

Ultra Activator

DIRECTIONS FOR USE

This product must only be used with Sterilex's Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No 63761-8). This is a two-part product that must always be used with Sterilex Ultra Disinfectant Cleaner Solution 1. Refer to Sterilex's Ultra Disinfectant Cleaner Solution 1 for complete directions of use. Please refer to the Material Safety Data Sheet before use.

FIRST AID

EYE CONTACT: Immediate medical attention is required. In case of contact, immediately flush eyes with cool running water for at least 15 minutes. Remove contact lenses and continue flushing for at least 15 minutes. **SKIN CONTACT:** Wash skin with soap and plenty of water. Continue rinsing for

at least 10 minutes. Remove contaminated clothing and shoes. If symptoms persist, call a physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.

INHALATION: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician or Poison Control Center immediately,

ingestion: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Drink plenty of water. Call a physician or Poison Control Center immediately.

NOTE TO PHYSICIAN: Product is a corrosive material. Use of gastric lavage or emesis is contraindicated.

STORAGE AND DISPOSAL

STORAGE: Keep container tightly closed in a dry and well –ventilated place. Keep out of the reach of children. Keep in properly labeled containers. Store in cool area away from other chemicals.

DISPOSAL: Dispose of in an approved facility in accordance with local, state and Federal regulations.

DOT SHIPPING NAME:

Corrosive liquid, basic, inorganic, N.O.S. (Potassium carbonate, Sodium carbonate), UN3266, 8, PG III



FOR EMERGENCY MEDICAL INFORMATION IN THE USA, CALL: 1-800-328-0026. FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL 1-651-222-5352 (USA)

California Registration No. 63761-50001

The Sterilex® Corporation 11409 Cronhill Drive Owings Mills, MD 21117

Rev. 2 07/27/2009