

63761-8

10/30/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 30 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,

A handwritten signature in cursive script, appearing to read "M Swindell".

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

2094



EPA

United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment
 Other NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 63761-8	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilex Ultra Disinfection Cleaner Solution 1	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Sterilex Corporation 11409 Cronhill Drive Suite L Owings Mills, MD 21117	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 _____	
<input type="checkbox"/> Check if this is a new address		

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 to update adjuvant label. Please reference cover letter for details.

Notification of MINOR LABELCHANGES 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:

Date: **October 5, 2009**

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	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<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, 30 and 55 gallons		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"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Mark Wozniak (m.wozniak@sterilex.com)	Title Senior Scientist/R&D Manager	Telephone No. (Include Area Code) (410) 581-8860
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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 	3. Title Agent for Sterilex Corporation
4. Typed Name Wendy A. McCombie	5. Date October 1, 2009



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.

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

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.....	6.0%
Tetrasodium ethylene diamine tetraacetate (EDTA).....	4.9%
CONSTITUENTS INEFFECTIVE AS SPRAY ADJUVANTS.....	83.1%
TOTAL.....	100.0%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC 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. Inhalation 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 www.sterilex.com

For Technical Service Call 1-800-511-1659

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.

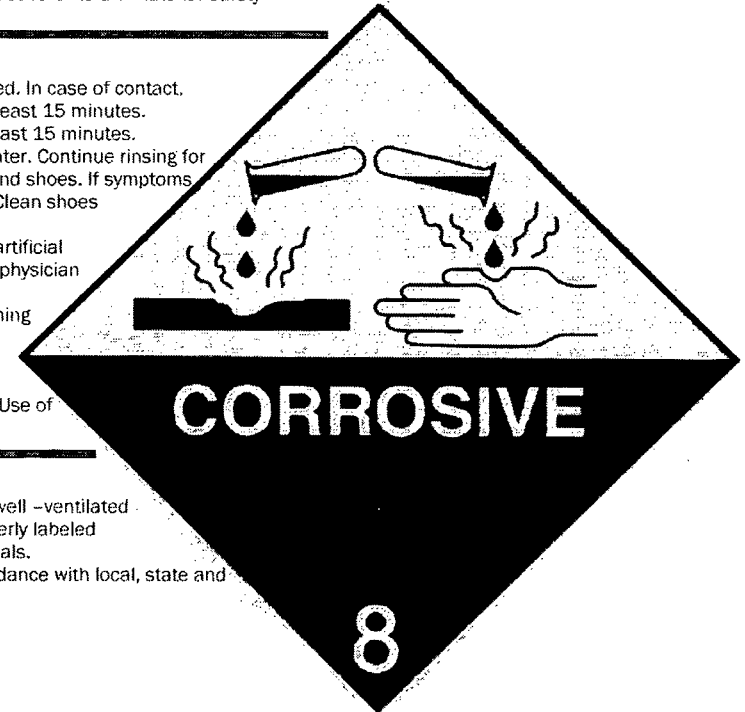
INGESTION: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Drink plenty of water. Call a physician or Poison Control Center immediately.

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.



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

Expiration Date: _____ / _____ / _____ Lot # _____

Rev. 2 07/27/2009

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