



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 22 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 April 6th, 2009
EPA Received Date April 6th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to update the labeling for the adjuvant product, 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 black ink, appearing to read "M Swindell".

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

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060



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 <input type="checkbox"/> Check if this is a new address	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 _____	

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) 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: **06 APRIL 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	
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 April 6, 2009		

LEWIS & HARRISON

Consultants in Government Affairs

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

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fax 202.393.3906

direct 202.393.3903 ext. 11
wmccombie@lewisharrison.com

April 6, 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 updated the warning language on the label in the interest of improved product stewardship. 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:

- 1) 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



Ultra Activator

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

DIRECTIONS FOR USE

This product should be used only 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.

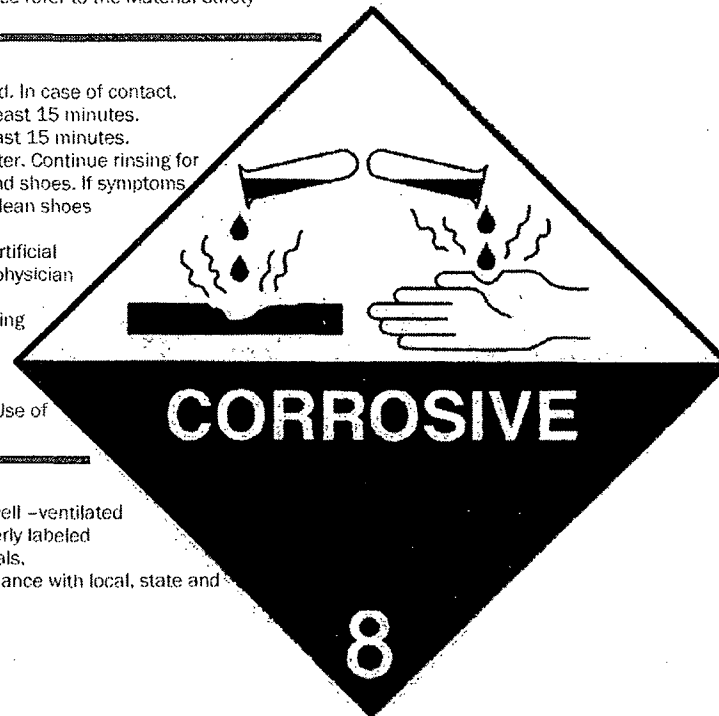
DISPOSAL: Dispose of in an approved facility in accordance with local, state and Federal regulations.

FOR EMERGENCY MEDICAL INFORMATION IN THE USA, CALL: 1-800-326-0026.
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

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



Expiration Date: _____ / _____ / _____ Lot # _____

Rev. 1 03/31/2009

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