63761-5 02/04/2005 1/3

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
63761-5	FEB 04 2005

Term of Issuance: Conditional

Name of Pesticide Product:
Sterilex Ultra Powder

Name and Address of Registrant (include ZIP Code):

Dr. Shira Kramer
Sterilex Corporation
11409 Cronhill Drive
Suite L
Owings Mills, MD 21117

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 63761-5".

   b. Delete the claim, "disinfects interior surface of dental unit water lines" because the Agency has not established a performance standard for this type of use.

   c. Revise the "First Aid" subheading by removing the phrase "If Powder" and replace it with the following subheadings as outlined in PR Notice 2001-1:

      "IF IN EYES, IF ON SKIN OR CLOTHING, IF SWALLOWED, and IF INHALED"

Signature of Approving Official:

Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

Date: FEB 04 2005

EPA Form 8570-6

3. The Agency has not developed a performance standard for dental unit waterlines. Once a method and performance standard has been established, you will be required to submit appropriate data to the Agency to maintain your product's registration.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

A stamped label is enclosed for your records. Submit two (2) copies of the revised final printed label for the record. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Acute Toxicology Data Evaluation
Stamped Label

Important Notice:
Before using Sterilex Ultra please read the following information.

1. This product is to be used in conjunction with regular testing of dental unit water.
2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra with the dental unit.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights.
2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatment.

How To Apply Sterilex Ultra Powder:

1. At the end of the workday, add eight (8) ounces of **HOT** water to a Sterilex measuring cup or other empty container.
2. Add one packet of Sterilex Ultra to the hot water. Use stirrer to mix or swirl to dissolve. Be sure all powder is dissolved. Pour pink liquid into an empty external dental unit water bottle. Do not use PET Bottles (See note for bottle requirements). Use within 24 hours after powder has been dissolved in water.
3. Run Sterilex Ultra mixture through the system until the pink mixture appears at the end of the A/W Syringe and Handpiece Line. Always remove the Handpiece.
4. Allow the mixture to sit in the unit overnight (Place the ends of waterlines into a sink or cuspidor in case any pink mixture drips overnight).
5. At the beginning of the next workday, discard any remaining mixture in external water bottle. Rinse the external water bottle with hot water.
6. Fill the external water bottle with hot water. Flush each line (A/W Syringe, Handpiece) until the bottle is empty.

ACCEPTED with COMMENTS In EPA Letter Dated: FEB 4 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 63761-5

STERILEX

Sterilex Ultra Powder

- Removes* biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Kills biofilm bacteria
- [redacted]
- Maintains dental unit water line effluent water <500 cfu/ml **

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PET) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches.

* Laboratory studies have shown >90% removal
** Control of bacterial contamination in the DUWL is affected by the quality of incoming water. Sterile water is recommended by OSAP.

Active Ingredients:

N-Alkyl(C_{14}95%,C_{12}3%,C_{16}2%) dimethylbenzylammonium chloride	10.0%
Sodium Carbonate Peroxyhydrate	29.75%
Other Ingredients	60.25%
TOTAL	100.0%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

(See side panel for additional precautionary and first aid statements)

STERILEX CORPORATION
11409 Cronhill Drive
Owings Mills, MD 21117
Phone: 1-800-511-1659 Fax: 410-581-8864

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Wear protective eyewear (goggles and/or face shield), protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

WHEN POWDER IS DILUTED: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid breathing vapor. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse

FIRST AID

IF POWDER GETS IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF POWDER GETS ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF POWDER IS 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, egg whites, gelatin, or if these are not available, drink large quantities of water. Avoid alcohol.

IF POWDER IS INHALED: 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT store about 30°C (or 86°F).
DISPOSAL: Do not reuse empty pouch, discard in trash.

Made in USA

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