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04/10/2000

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

EPA Reg. Number:

Date of Issuance:

63761-4

APR 10 2000

Term of Issuance:

Conditional

Name of Pesticide Product:

Ultra-Kleen Powder for Dental Water Lines

NOTICE OF PESTICIDE:

- Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sterilex
7-1 Gwynns Mill Court
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. 63761-4".
3. Please Note: If you decide to add public health organisms and/or biofilm claims to the label, you will not only be required to submit efficacy data, but Sodium percarbonate and Sodium carbonate will be considered as active ingredients and need to be registered.
4. Submit two copies of the revised final printed label for the record. A stamped copy of the label is enclosed for your records.

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 the product constitutes acceptance of these conditions.

Signature of Approving Official:


Velma Noble

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

Date:

APR 10 2000

ULTRA-KLEEN POWDER FOR DENTAL UNIT WATER LINES

Specially formulated to Clean and Control Bacterial Contamination in Dental Unit Water Lines (DUWL)

INDICATIONS FOR USE:

This product has been specially formulated and clinically proven to clean and control bacterial contamination in Dental Unit Water Lines.

Note: control of bacterial contamination in the duwl is affected by the quality of incoming water. Sterile water is recommended by OSAP.

Active Ingredient:

| | |
|---|--------|
| n-Alkyl(C ₁₄ 95%, C ₁₂ 3%, C ₁₆ 2%) dimethylbenzylammonium chloride..... | 10.0% |
| Other Ingredients..... | 90.0% |
| TOTAL | 100.0% |

KEEP OUT OF THE REACH OF CHILDREN

DANGER

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.

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

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Call 1-800-511-1659
For Technical Information

Patent #4847089, 4941989, 5320805, 5620527
SINGLE UNIT DOSE WT: 12.5 g

STERILEX CORPORATION
7-1 GWYNNS MILL COURT
OWINGS MILL, MD 21117

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

APR 10 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 63761-4

EPA REG. NO. 63761-4 U

EPA Est. No. 4875-NJ-001

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 nights starting on Monday.
2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after initial Start-up treatment.

HOW TO APPLY:

1. At the end of the workday, add eight (8) ounces of Hot Water to an empty external dental unit water container* (if you do not have an external container contact your dental distributor)
2. Add one packet of Ultra-Kleen to the Hot Water. Swirl to dissolve. (The solution will appear cloudy and all the powder may not dissolve.)
3. Run Ultra-Kleen Solution through the system until the pink solution appears at the AWW Syringe and Handpiece.
4. Allow the Ultra-Kleen Solution to sit in the unit overnight.
5. At the beginning of the next workday, discard remaining Ultra-Kleen Solution. Rinse the external water container with warm water.
6. Fill container with water. Flush each line (AWW Syringe, Handpiece) for one minute.

*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 is recommended. Do not use a bottle made of polyethylene terephthalate (PET).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. DANGER. Powder corrosive to skin and eyes. Powder causes irreversible eye damage and skin burns. Harmful if powder is swallowed. Wear goggles and/or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STORAGE AND DISPOSAL

STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT store above 30°C (or 86°F).

DISPOSAL: Do not reuse empty pouch, discard in trash.

Made in USA

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in EPA Letter Dated:

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