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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

May 16, 2016

DP BARCODE: 431704

MRID(s): 497567-06,-07,-08,-09,-10

SUBJECT: Sterilex Ultra Disinfectant Cleaner Solution 1

REG. NO. OR FILE SYMBOL: 63761-8

DOCUMENT TYPE: Acute Toxicity Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
069104	68397-01-5	n-Alkyl dimethyl ethylbenzyl ammonium chloride (C14 60%, C16 30%, C12 5%, C18 5%)
069154	85409-23-0	n-Alkyl dimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%)
000595	7722-84-1	Hydrogen Peroxide

TEST LAB: Tox Monitor Laboratories, Inc

SUBMITTER: Sterilex Corporation

GUIDELINE(s): 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600.

COMMODITIES: N/A

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** 5/16/2016

COMMENT: This product is for non-food use

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MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No. 63761-8
Product Name: Sterilex Ultra Disinfectant Cleaner Solution 1
DP Barcode: 431704

TO: Rose Kyprianou / Timothy Young
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Sterilex Corporation
Action code: (A676) Product Reregistration Decision
Due out date: May 17, 2016

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
n-Alkyl dimethyl ethylbenzyl ammonium chloride (C14 60%, C16 30%, C12 5%, C18 5%)	3.0
n-Alkyl dimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%)	3.0
Hydrogen Peroxide	6.3
Other Ingredient(s)	87.7
TOTAL	100.0

BACKGROUND:

The registrant is submitting 4 acute toxicity studies to support the reregistration of the subject product, Sterilex Ultra Disinfectant Cleaner Solution 1, EPA Reg. No. **63761-8**. MRID's are as follows: 497567-06 (81-1), 497567-07 (81-2), 497567-08 (81-3), and 497567-10 (81-6). The studies were conducted by Tox Monitor Laboratories, Inc (81-1,-2,-3,-6). The test material used in the studies was the subject product. The registrant provided also two waiver requests for Eye Irritation (81-4) and Skin irritation (81-5) studies in MRID 497567-09. The product is used to remove and control biofilm and other organic contaminants in water based systems.

The data package included:

1. Cover letter from Registrant to EPA, dated 10/28/2015
2. Application for pesticide registration, Form 8570-1
3. Basic Confidential Statements of Formula (CSF), dated 10/22/2015
4. Accepted label, dated 04/25/2013

FINDINGS:

1. The acute toxicity studies cited were previously reviewed by CTT for EPA Reg. No. 63761-3, DP431690 and found to be acceptable.
2. The acute toxicity profile for EPA Reg. No. **63761-8** can be extracted from the profile of EPA Reg. No. 63761-3 and it is as follows:

GRN	Study	MRID	Toxicity Category	Status
81-1	Acute Oral Toxicity	497567-06	III	Acceptable
81-2	Acute Dermal Toxicity	497567-07	II	Acceptable
81-3	Acute Inhalation Toxicity	497567-08	III	Acceptable
81-4	Primary Eye Irritation	497563-09	I	Waived
81-5	Primary Dermal Irritation	497563-09	I	Waived
81-6	Dermal Sensitization	497563-10	Not a sensitizer	Acceptable

CONCLUSION:

The acute toxicity requirements have been satisfied for the subject product EPA Reg. No. 63761-8.

LABELING:

ID #: EPA Reg. No.: 063761-00008 / Sterilex Ultra Disinfectant Cleaner Solution 1

SIGNAL WORD: DANGER

RESTRICTED USE CLASSIFICATION TRIGGERED:

The criteria for Restricted Use Classification have been met due to Toxicity Category I for primary eye and dermal irritation.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if absorbed through skin. Harmful if swallowed. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing (vapor, or spray mist). Wear protective eyewear such as goggles, face shield, or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Polyethylene or Polyvinyl Chloride (PVC), or Viton, selection Category A). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID:

IF 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 eye. Call a poison control center or doctor for treatment advice

IF ON SKIN OR CLOTHING: 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 SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact [insert phone number 1-800-xxx-xxxx] for emergency medical treatment information.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

Note to PM/CRM/Registrant:

The proposed label should contain a Note to Physician which addresses the Toxicity Category I for primary eye and dermal irritation. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.