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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

ANTIMICROBIALS DIVISION (AD)

June 7, 2016

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 63761-RN
DP Barcode: D432482
Product Name: Sterilex Ultra Step

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team (CTT)
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To: Eric Miederhoff PM 31/Cletis Mixon
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Sterilex Corporation

FORMULATION FROM LABEL:

PC Code	Active Ingredient(s):	% by wt.
069184	Alkyl (C_{14} 95%, C_{12} 3%, C_{16} 2%) dimethylbenzylammonium chloride	1.9
128860	Sodium carbonate peroxyhydrate	12.1
	Other Ingredient(s):	86.0
	Total:	100.0

BACKGROUND: Sterilex Corporation has submitted a label, a CSF (Confidential Statement of Formula), and a set of six acute toxicity studies for this non-integrated product for non-food use that is intended for industrial use. The studies include an acute oral toxicity study (MRID 49819803), an acute dermal toxicity study (MRID 49819804), an acute inhalation toxicity study (MRID 49819805), an eye irritation study (MRID 49819806), a dermal irritation study (MRID 49819807), and a skin sensitization study (MRID 49819808).

RECOMMENDATIONS:

1. The acute toxicity studies are **acceptable**.

2. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

3. The acute toxicity profile for File Symbol 63761-RN is currently,

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	49819803	III	Acceptable
Acute Dermal Toxicity	49819804	IV	Acceptable
Acute Inhalation Toxicity	49819805	IV	Acceptable
Primary Eye Irritation	49819806	I	Acceptable
Primary Dermal Irritation	49819807	II	Acceptable
Dermal Sensitization	49819808	Nonsensitizer	Acceptable

LABELING

1 The signal word is **DANGER**.

2. The precautionary statements must read, "Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wear coveralls over short-sleeved shirt, shoes, and chemical-resistant gloves. 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."

3. The first aid statements must read:

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.

-Call a poison control center or doctor for treatment advice.

If 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 swallowed:

-Call a poison control center or doctor immediately for treatment advice.

-Have a person sip a glass of water if able to swallow.

-Do not induce vomiting unless told to by a poison control center or doctor

-Do not give anything by mouth to an unconscious person.

4. The following first aid statements are optional:

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.

5. The **Note to Physician** "Probable mucosal damage may contraindicate the use of gastric lavage" must be added to the label because the product is toxicity category I for eye irritation.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100)

Product Manager: Eric Miederhoff
Reviewer: Chris Jiang
MRID No.: 49819803
Study Completion Date: Jan. 13, 2015
Study No.: 14-075-3

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Dose level: 5000 mg/kg, 2000 mg/kg

Species: Female Sprague-Dawley derived albino rats
Age: Ten weeks
Weight: 220 to 257 grams at study start
Source: Harlan Sprague Dawley, Indianapolis, IN

Conclusions:

1. **LD_{50} (mg/kg):** LD_{50}> 2000 mg/kg
2. **The estimated LD_{50} is greater than 2000 mg/kg.**
3. **Toxicity Category:** III **Classification:** Acceptable

Deviations from guideline 870.1100: Only females were used as females are more sensitive than males.

Results:

Reported Mortality – Limit Test

Animal Number	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
278	5000	X	X
279	2000	O	O
280	2000	O	O
281	2000	O	O
363	2000	O	O
364	2000	O	O

O = Survival; X = Death

Clinical signs:

5000 mg/kg: Clinical signs included stomach and gastrointestinal tract distended with gas and fluid and both slightly red in color. There staining around the anal area.

2000 mg/kg: All animals were active and healthy through the study.

Gross necropsies:

5000 mg/kg: The stomach and gastrointestinal tract distended with gas and fluid and both slightly red in color. There staining around the anal area.

2000 mg/kg: Gross necropsies were unremarkable.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200)

Product Manager: Eric Miederhoff
Reviewer: Chris Jiang
MRID No.: 49819804
Study Completion Date: Dec. 29, 2014
Study No.: 14-075-4
Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Dose level: 5000 mg/kg

Species: Five male and five female New Zealand albino rabbits
Age: Twelve weeks
Weight: ♂: 2.28 kilograms at study start; ♀: 2.62 to 2.98 kilograms at study start
Source: Kuiper Rabbitry, Gary, IN

Conclusions:

1. **LD_{50} (mg/kg):** Males: LD_{50}> 5000 mg/kg
   Females: LD_{50}> 5000 mg/kg
   Combined: LD_{50}> 5000 mg/kg
2. **The estimated LD_{50} is greater than 5000 mg/kg for males and females.**
3. **Toxicity Category:** IV **Classification:** Acceptable

Deviations from guideline 870.1200: Temperature, relative humidity, and air changes of the animal room were not reported.

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Combined
5000	2 / 5	1 / 5	3 / 10

Clinical signs:

5000 mg/kg: Clinical signs included stomach and gastrointestinal tract distended with gas and fluid and both slightly red in color. There staining around the anal area.

Gross necropsies:

5000 mg/kg: The stomach and gastrointestinal tract distended with gas and fluid. The stomach and gastrointestinal tract were both slightly red in color. There was staining around the anal area.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (870.1300)

Product Manager: Eric Miederhoff
MRID No.: 49819805

Reviewer: Chris Jiang
Study Completion Date: Feb. 9, 2015
Study No. 40061

Testing Laboratory: Product Safety Labs
Author: Daniel Merrill

Quality Assurance (40 CFR 160.12): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Gravimetric: 2.08 mg/L **Nominal:** 32.66 mg/L

Species: Five male and five female Sprague-Dawley derived albino rats
Age: Eleven to twelve weeks
Weight: ♂: 350 to 460 grams at study start; ♀: 224 to 248 grams at study start
Source: SAGE Labs

Summary:

1. **LC_{50} (mg/kg):** LC_{50}> 2.08 mg/L
2. **The estimated LC_{50} is greater than 2.08 mg/L.**
3. **MMAD:** 3.07 µm
4. **Toxicity Category:** IV **Classification:** Acceptable

Procedure (Deviations from 81-3): Due to the absence of Carolyn Lowe, this study was reassigned to Daniel Merrill.

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.08 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD (µm)	GSD (µm)	% particles < 3.3µm
2.08 mg/L	2.64	2.67	58.9
2.08 mg/L	3.50	3.03	44.3

Chamber Environment	
Chamber Volume (L)	6.7l Liters
Airflow (LPM)	30.0 LPM
Temperature (°C)	20 to 21
Relative Humidity (%)	15 to 16

Clinical Observations: Clinical signs for the animals included irregular respiration, red nasal discharge, moist rales, and red facial staining.

Gross Necropsy Findings: Gross necropsies were unremarkable.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (81-4, 870.2400)

Product Manager: Eric Miederhoff
MRID No.: 49819806

Reviewer: Chris Jiang
Study Completion Date: Jan. 12, 2015
Study No.: 14-075-1

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Dosage: 0.1 mL

Species: Three female New Zealand White rabbits
Age: Ten to twelve weeks
Weight: 3.23 to 3.52 kilograms at study start
Source: Kuiper Rabbitry, Gary, IN

Summary:

1. **Toxicity Category:** I
2. **Classification:** Acceptable

Deviations from Guideline 870.2400: None

Results:

Individual Scores for Ocular Irritation

Observations	Rabbit No. 269 (Female)						
	Time After Treatment						
	1 hr	24 hrs	48 hrs	72 hrs	168 hrs	336 hrs	504 hrs
I. Corneal Opacity	-	1	1	2	1	0	0
II. Iritis	1	2	2	2	1	0	0
III. Conjunctivae							
A. Redness	2	3	3	3	2	1	0
B. Chemosis	3	4	3	3	0	0	0
C. Discharge	3	3	3	3	1	0	0
Observations	**Rabbit No. 289 (Female)**						
	Time After treatment						
	1 hr	**24 hrs**	**48 hrs**	**72 hrs**	**168 hrs**	**336 hrs**	**504 hrs**
I. Corneal Opacity	-	1	1	1	1	1	0
II. Iritis	1	1	1	1	1	0	0
III. Conjunctivae							
A. Redness	2	3	2	2	2	1	0
B. Chemosis	3	3	2	2	1	0	0
C. Discharge	3	3	3	2	1	1	0
Observations	**Rabbit No. 290 (Female)**						
	Time After Treatment						
	1 hr	**24 hrs**	**48 hrs**	**72 hrs**	**168 hrs**	**336 hrs**	**504 hrs**
I. Corneal Opacity	-	1	1	1	2	2	2
II. Iritis	1	1	1	1	1	1	1
III. Conjunctivae							
A. Redness	2	3	3	3	3	2	1
B. Chemosis	2	3	2	2	2	2	0
C. Discharge	3	3	3	2	2	2	1

[1] – flourescein sodium used to evaluate the extent of corneal opacity.

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (870.2500)

Product Manager: Eric Miederhoff
MRID No.: 49819807

Reviewer: Chris Jiang
Study Completion Date: Dec. 31, 2014
Study No.: 14-075-2

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Dosage: 0.5 g

Species: Three female New Zealand White rabbits
Age: Ten to twelve weeks
Weight: 2.91 to 3.29 kilograms at study start
Source: Kuiper Rabbitry, Gary, IN

Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

Deviations from Guideline 870.2500: None

Results:

Individual Skin Irritation Scores following the 4-hour exposure

Animal	Erythema / Edema Time After Patch Removal						
	4.5 hrs	24 hrs	48 hrs	72 hrs	Day 7	Day 14	Day 21
256F	2/4	2/2	2/2	3/2	3*/2	1/0	0/0
257F	2/2	2/1	2/1	2/1	2*/1	0/0	0/0
268F	2/4	3/2	3/2	3/2	3*/2	1/0	0/0

* Coriaceousness

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OCSPP 870.2600)

Product Manager: Eric Miederhoff
MRID No.: 49819808

Reviewer: Chris Jiang
Study Completion Date: Jan. 19, 2015
Study No.: 14-075-5

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): A statement of GLP compliance was included.

Test Material: Sterilex FT Ultra Step, lot SB1-16C, white powder
Positive Control: 1-Chloro-2,4-dinitrobenzene

Species: Hartley albino guinea pigs
Weight: 303 to 461 grams at study start
Age: Young adult
Source: Kuiper Rabbitry, Gary, IN

Summary:

1. **This Product is not a dermal sensitizer.**
2. **Classification:** Acceptable

Procedure (Deviation From §81-6): No deviations occurred during the study

Procedure: After preliminary tests, the definitive study was undertaken. The Buehler method was tested for skin sensitization. Once each week for three weeks, either 0.4 mL at a 50% concentration or nothing was applied to the clipped left side of each animal using Hilltop Chambers that were secured in place with Micropore tape and secured with Kendall tape. After the exposure period, the chambers and the bindings were removed. The guinea pigs were scored at 24 and at 48 hours after each induction.
Two weeks after the final application, all animals were challenged with 0.4 mL of a 25% concentration of the test substance on the right side. The guinea pigs were scored at 24 and at 48 hours after challenge.

Results: At 24 hours after the first induction, the guinea pigs had diffuse erythema, slight erythema, and moderate erythema. At 48 hours after the first induction, the animals had slight erythema, diffuse erythema, and no reaction.
At 24 hours after the second induction, the guinea pigs had moderate erythema, diffuse erythema, and slight erythema. At 48 hours after the second induction, the animals had slight erythema, diffuse erythema, and no reaction.se erythema.
At 24 hours after the third induction, the guinea pigs had diffuse erythema, slight erythema, and moderate erythema. At 48 hours after the third induction, the guinea pigs had slight erythema, diffuse erythema, and no reaction. At 48 hours after the first induction, the animals had slight erythema, diffuse erythema, and no reaction.

At 24 hours after challenge, 2/20 animals had diffuse erythema. At 48 hours after challenge, no reaction was observed in any of the animals.

The historical positive control showed appropriate results.