EPA REGISTRATION NUMBER 63761-5 – Vol. 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 7 2005

April Zambelli-Weiner
Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

Subject: Sterilex Ultra Powder
EPA Registration No. 63761-5
Amendment Date: July 12, 2005
EPA Receipt Date: July 13, 2005

Dear Dr. Weiner,

The following amendment submitted in connection with registration under FIFRA, as amended, is unacceptable.

- Reconsideration of Sodium percarbonate as an active ingredient

Product Chemistry

The Agency believes that sodium percarbonate is an active ingredient in this formulation because it serves as a precursor to hydrogen peroxide. Hydrogen peroxide is important in removing the biofilm matrix by breaking the polysaccharide linkages. We believe the quaternary ammonium chloride will kill the bacteria but will not, by itself, remove the biofilm matrix from the hard surface of the dental unit waterline.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

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

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CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

August 10, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Sterilex Ultra Powder

DP Barcode: D320023 **Reg. No. Or File Symbol: 63761-5**
Manufacturing-use [] OR **End-use Product [X]**

TO: Velma Noble\Jacqueline McFarlane
PM Team No. 31

FROM: Chris Jiang, Chemist
Product Science Branch
Antimicrobials Division (7510C)

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

8/11/25

THRU: Michele Wingfield, Branch Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation for Sterilex Ultra Powder from label

Active Ingredient(s)	**% by wt.**
n-Alkyl (C_{14} 95%, C_{12} 3%, C_{16} 2%) dimethyl benzyl ammonium chloride	10.0 %
Sodium carbonate peroxyhydrate	29.75%

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BACKGROUND:

The registrant has submitted a rationale for why sodium carbonate peroxyhydrate (sodium peroxycarbonate) should be declared as an inert ingredient instead of an active ingredient.

FINDINGS:

1. The Agency believes that the sodium peroxycarbonate is an active ingredient because the quaternary compound would not be successful in killing the biofilm bacteria as the polysaccharide linkages would not be broken; therefore, the ingredient acts as an active ingredient as it helps the quaternary compound. Secondly, when sodium percarbonate comes into contact with water in the dental water lines, bubbles form which denote chemical activity; therefore, the chemical acts as an active and not as an inert ingredient. For these reasons, sodium peroxycarbonate cannot be declared as an inert ingredient.

RECOMMENDATIONS:

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 63761-5 to be unacceptable.

DP #: (320023) Decision #: 359459

DATA PACKAGE BEAN SHEET

Date: 04-Aug-2005

* * * Registration Information * * *

Registration: 63761-5 - STERILEX ULTRA POWDER

Company: 63761 - STERILEX CORP, THE

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Jacqueline Campbell-McFarlane JMCFAR02

Sent Date: 15-Jul-2005 Calculated Due Date: t3-Oct-2005 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: 069184, Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C t2, 2%C16)(10%)

128860, Sodium percarbonate(29.75%)

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 04-Aug-2005 Due Back:

DP Ingredient: 069184, Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2%C t6)

128860, Sodium percarbonate

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To		Date In	Date Out
Organization:	AD / PSB	8/5/05	
Team Name:	CTT	8/5/05	
Reviewer Name:	CHRIS	8/8/05	
Contractor Name:			

Last Possible Science Due Date: 29-Aug-2005

Science Due Date: 9/13/05

Sub-Data Package Due Date: 8/29/05

* * * Studies Sent for Review * * *

* * * Additional Data Package for this Decision * * *

* * * Data Package Instructions * * *

Registrant has submitted an augument as to why the active ingredient, sodium percarbonate, should be considered an i nert ingredient in this product's formulation.

Could you please review and comment.

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Send to Michele

Need a Receipt

Dennis Edwards/DC/USEPA/US
07/13/2005 08:10 AM

To Jacqueline Campbell-McFarlane/DC/USEPA/US@EPA
cc Velma Noble/DC/USEPA/US@EPA
bcc
Subject Fw: Sodium Percarbonate as an Inert

April Zambelli-Weiner <april@sterilex.com>
07/12/2005 02:58 PM
Please respond to april@sterilex.com

To Dennis Edwards/DC/USEPA/US@EPA
cc Shira Kramer <shira@sterilex.com>
Subject Sodium Percarbonate as an Inert

Dear Dennis:
In response to previous discussions regarding the problems with sodium percarbonate being classified as an active in Sterilex Ultra Powder, please find attached our summary argument of why sodium percarbonate is an inert ingredient in Sterilex Ultra Powder, as well as a supporting study. We appreciate your prompt review of these materials and look forward to your response. Please do not hesitate to contact me if you have any questions or require any additional information or materials. As always, thank you for your time and assistance.

Best Regards,
April

April Zambelli-Weiner, Ph.D.
Senior Research Scientist
The Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117
410-581-8860
fax 410-581-8864

april@sterilex.com Sodium Percarbonate Is an Inert Ingredient in Sterilex Ultra Powder 07.12.05.doc Nalco 6080323.pdf

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EPA Mag FIFO #63761-5

Page ____ is not included in this copy.

Pages 6 through 7 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

METHOD OF REMOVING BIOFILMS FROM SURFACES SUBMERGED IN A FOULED WATER SYSTEM

FIELD OF THE INVENTION

This invention relates generally to the field of water treatment technologies and, more particularly, to a method of removing biofilms from surfaces submerged in a fouled water system.

BACKGROUND OF THE INVENTION

Biofouling has always been problematic in industrial water systems such as cooling towers, heat exchangers and air washers, because it can adversely affect heat transfer efficiency and fluid frictional resistance, thereby subsequently reducing production rates. In addition, biofouling also plays an important role in microbiologically influenced corrosion.

The presence of microorganisms in industrial waters cannot be totally eliminated, even with the excessive use of chemical biocides. The most common way to control biofouling is through the application of toxic chemical biocides such as chlorine, bromine, isothiazolones, glutaraldehyde or other antimicrobials. These biocides are added in an attempt to kill both planktonic and attached microorganisms.

Some microorganisms attach to inert surfaces forming aggregates with a complex matrix consisting of extracellular polymeric substances (EPS). This consortium of attached microorganisms and the associated EPS is commonly referred to as a biofilm. Biocides have difficulty penetrating biofilms and removing them from surfaces. Although excessive biocide dosages may be able to control biofouling, the presence of biocides in effluent waters is usually environmentally unacceptable.

Mechanical treatments including scrapers, sponge balls, or "pigs" are also commonly used to remove biofilms. Acids, chelants and dispersants are likewise considered to be effective in causing the detachment of deposited materials. In addition, sidestream filtration devices, which continuously process 1–5% of the system water, have drawn increased interest lately. Nevertheless, these approaches are either too labor intensive and/or expensive.

Dispersants are sometimes applied along with biocides to enhance antimicrobial efficacy in industrial waters. The dispersants used in these applications will hereinafter be referred to as "biodispersants." Most biodispersants currently available on the market, such as block copolymer or terpolymer, have high molecular weights ranging from 1,000 to 15,000,000. These biodispersants attract fine foulant particles onto polymeric chains and form fluffy particles that are more readily detached from the fouled surfaces. It is also believed that these surface active compounds can increase the diffusion of biocide into the biofilm, and subsequently cause biofilm detachment.

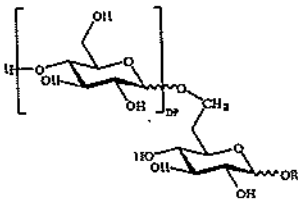
To date, biodispersants have not been used effectively without supplementation with biocides. As the United States Environmental Protection Agency (EPA) regulations and global concerns of biocide usage become more prevalent, high performance biodispersants having low toxicity are needed to control biofouling either with or without the addition of chemical biocides.

Accordingly, it would be desirable to provide a method of removing biofilms from surfaces submerged in water using a biodispersant which is effective both alone and with the use of a biocide. It would also be desirable to utilize a

biodispersant which is biodegradable and has a low toxicity. It would furthermore be desirable to employ a biodispersant which does not affect corrosion and scale inhibition programs used in industrial water treatment.

SUMMARY OF THE INVENTION

The method of the invention calls for adding to a fouled water system an alkyl polyglycoside having the chemical formula:

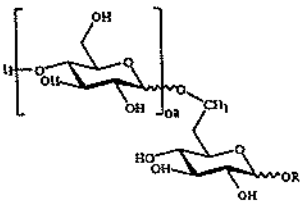


wherein R is a C_8–C_{18} alkyl chain and OP is from 0 to 3 carbohydrate units.

This method efficiently and effectively removes biofilms from surfaces submerged in the fouled water system. The method is also environmentally acceptable and economically appealing because the use of biocides can be minimized or eliminated, and the biodispersant utilized in the practice of the invention is biodegradable and has a low toxicity. Moreover, the method does not affect corrosion and scale inhibitor programs used in industrial water treatment.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a method of removing biofilms from surfaces submerged in a fouled water system. In accordance with this invention, an alkyl polyglycoside (APG) having the chemical formula:



wherein R is a C_8–C_{18} alkyl chain and the degree of polymerization (DP) is from 0 to 3 carbohydrate units, is added to the water system. Preferably, the alkyl chain is linear and the OP is from about 1.1 to 5.5.

Glucopon® 225 and Burco® NPS-225 (C_8, C_{10}), Glucopon® 425 (C_8–C_{16}) and Glucopon® 600 and 625 (C_{12}–C_{16}) are commercially-available APG products which may be used in the practice of the invention. (The Glucopon® products are available from Henkel Corporation of Ambler, Pa. and the Burco® product is available from Burlington Chemical Co., Inc. of Burlington, N.C.). It is believed that other APG products from other suppliers can also be used in the practice of the present invention.

It is preferred that the amount of APG which is added to the water system be in the range of about 0.1 ppm to about

10 ppm based on active ingredient, with about 1 ppm to about 10 ppm being most preferred. APG can be added to the water system by any conventional method, i.e., by slug, intermittently or continuously.

A biocide may also optionally be added to the water system in accordance with the practice of this invention. The biocide may be added by any conventional method either separately or in combination with APG. The biocides which may be used in the practice of the present invention include oxidizing biocides such as chlorine-based biocides, bromine-based biocides, peracetic acid, hydrogen peroxide and ozone; and non-oxidizing biocides such as isothiazolone, glutaraldehyde and quaternary amine compounds. The amount of biocide added to the water system is dependent upon the particular water treatment application and is generally known to those skilled in the art. However, it should be noted that the required amount of biocide is minimized when used in combination with APG.

In accordance with the method of this invention, biofilms are removed from all types of submerged surfaces, e.g., glass, metals, wood and plastics.

The method of the present invention may be used in an industrial water system or a recreational water system. The types of industrial water systems in which APG can be employed include, but are not limited to, cooling water systems, air washers, evaporative condensers, pasteurizers, air scrubbers, produce sanitizer streams, fire protection water systems and heat exchanger tubes.

The types of recreational water systems in which APG can be utilized include, but are not limited to, decorative fountains and full-body immersion systems such as swimming pools, spas and hot tubs.

The present invention takes advantage of the detergency and dispersancy of APG for use as a biodispersant. It was surprisingly found that when APG was added to a fouled water system, biofilms were effectively removed from the submerged surfaces. The APG biodispersant described herein exhibited superior performance as compared to other commercially-available biodispersants, and biofilm removal was achieved both with and without the addition of chemical biocides. It should be noted that when APG is used, lower amounts of toxic biocides are needed to achieve the same level of control. In addition, APG offers a low or non-toxic means to control biofouling and APG is biodegradable, thereby providing an environmentally-acceptable approach to water treatment. Moreover, the use of APG does not affect corrosion and scale inhibitor programs used in industrial water treatment.

EXAMPLES

The following examples are intended to be illustrative of the present invention and to teach one of ordinary skill how to make and use the invention. These examples are not intended to limit the invention or its protection in any way.

The biofilms used in the following Examples were generated from a mixed microbial consortium isolated from a cooling water deposit. The devices used to house the test bacterial biofilms were continuous flow stirred tank bioreactors. Both laminar and turbulent flow conditions were tested for product performance. Synthetic cooling water [400 ppm Ca, 200 ppm Mg, 400 ppm M alkalinity (all based on $CaCO_3$)] was used as make-up for the bioreactors. Bacterial biofilms were grown on glass and stainless steel surfaces for 96 hours at room temperature in order to reach steady state conditions. The thickness of the biofilms was approximately 500 μm.

The biofilms were then treated by continuously applying biodispersant for 24 hours in an attempt to remove the biofilms from the substrata. The area densities of the bacterial biofilms were measured with a protein assay. The biomass was expressed as μg protein per cm^2. The effectiveness of biofilm removal was determined by biomass loss during the treatment period. Conventional plate counts on tryptone glucose extract (TGE) agar were also employed to measure the viability of the bacterial population. The viable cell density of the biofilm bacteria was expressed as colony forming units (CFU) per cm^2 biofilm.

Example 1

Several surfactants were tested in laboratory biofilm reactors to evaluate their biofilm removal activities. Biomass removal activities of the biodispersants against bacterial biofilms were measured after 24 hours of continuous treatment. The APG tested was Glucopon® 425 (a mixture of C_8, C_{10} and C_{12-14}), a nonionic surfactant. NALCO® 7348, a nonionic ethylene oxide/propylene oxide (EO/PO) block copolymer, was also evaluated. The anionic surfactants used in this example were diphenyl disulfonate (Dowfax® available from Dow Chemical Company of Midland, Mich.), linear alkylbenzene sulfonate (LAS) and sodium octane sulfonate. A commercial biofilm cleaning product sold under the name Ultra-Kleen (available from the Sterilex Corporation of Owing Mills, Md.) was tested. A cationic surfactant, dimethyl amide polymer (DMAD), commercially sold by Duckman Laboratories, of Memphis, Tenn. was also included in this example. As shown below in Table 1, the biofilm removal for APG was significantly higher than for any of the other products tested.

TABLE 1

Biodispersant	Active Ingredient (ppm)	% Biomass Removal (protein as μg/cm²)	Log Reduction of Viable Biofilm Bacteria (CFU/cm²)
APG	10	46.15	0.73
EO/PO copolymer (NALCO® 7348)	10	0.00	0.00
diphenyl disulfonate	10	2.16	0.00
sodium octane sulfonate	50	0.00	0.09
sodium octane sulfonate	100	29.62	0.22
Ultra-Kleen	1000	39.36	1.83
13.3% LAS	100	0.00	0.00
DMAD	100	0.00	0.10

Note that a zero value was assigned if the attached biomass or the viable bacteria levels increased in the bioreactor. This phenomenon occurred if the biodispersant was ineffective.

Example 2

The effects of APG on corrosion rates were conducted with 4.5 ppm sodium tolyltriazole, 20 ppm 2-phosphonobutane-1,2,4-tricarboxylic acid (PBTC) and 18 ppm terpolymer of acrylic acid/acrylamide/sulfomethylacrylamide. The test water chemistry and alkalinity were maintained at 360 ppm $CaCl_2$, 200 ppm $MgSO_4$ and 220 ppm $NaHCO_3$. The pH was maintained at 8.7 and the temperature was set at 55° C. The APG concentration was 10 ppm. The tests were run in duplicate for 40 hours, and the corrosion rates were determined by electrochemical parameters. The addition of APG did not adversely affect corrosion control, as indicated by the low corrosion rates shown below in Table 2.

TABLE 2

APG Addition (ppm active ingredient)	Reaction Time (hours)	Corrosion Rate (mpy)
0	5	0.4
10	5	0.3
0	10	0.5
10	10	0.3
0	25	0.8
10	25	1.4
0	40	1.3
10	40	1.8

Example 3

The effects of APG on scale formation were evaluated. Scale formation was determined by solubility stress test which was run at 50° C. The scale inhibitors used in this study were 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) and 2-phosphonobutane-1,2,4-tricarboxylic acid (PBTC).

The scale formation, indicated by the low percent recovery of soluble Ca^{2+} after two hours, was slightly higher at 400 ppm $CaCO_3$ or Ca^{2+}/HCO_3 with 10 ppm APG in the system. APG did not affect scale formation when the calcium levels were raised to 600 ppm. Overall, as shown in Table 3, there was no significant difference on the scale formation either with or without APG applied at 10 ppm.

TABLE 3

ppm as $CaCO_3$ Ca^{2+}/HCO_3	ppm HEDP	ppm PBTC	ppm APG	pH	Percent Recovery of Soluble Ca^{2+}
300	5	0	10	7.8	32
300/300	0	10	10	7.9	103
300/300	5	0	0	8.1	27
300/300	0	10	0	8.5	101
400	5	0	10	8.0	38
400/400	0	10	10	8.1	81
400/400	5	0	0	8.1	79
400/400	0	10	0	8.3	45
500	5	0	10	8.2	25
500/500	0	10	10	8.0	42
500/500	5	0	0	7.9	21
500/500	0	10	0	8.0	33
600	5	0	10	7.5	9
600/600	0	10	10	8.0	10
600/600	5	0	0	8.0	17
600/600	0	10	0	8.1	28

Example 4

Synergism between APG and a stabilized bromine-based oxidizing biocide was determined with the calculation described by F. C. Kull, P. C. Eisman, H. D. Sylwestrowicz and R. L. Mayer, Applied Microbiology, vol. 9, pages 538–541, (1961) using the relationship:

$$\frac{Q_A}{Q_a} + \frac{Q_B}{Q_b} = \text{synergy index}$$

where:

Q_a=quantity of APG, acting alone, producing an endpoint.

Q_b=quantity of biocide, acting alone, producing an endpoint.

Q_A=quantity of APG in mixture, producing an endpoint.

Q_B=quantity of biocide in mixture, producing an endpoint.

If the Synergy Index is

<1, it indicates synergy

=1, it indicates additivity

>1, it indicates antagonism

Instead of using the conventional plate enumeration method, a bacterial luminescent test was employed to calculate the endpoints. A decrease in light emission depends on toxicant concentration in the test and is used to calculate the relative toxicity unit (RLU). This test gives rapid and sensitive detection of toxicants compared to conventional minimal inhibitory concentration (MIC) assays. Table 4 lists the synergy indices of several combinations of APG and stabilized bromine-based biocide (STB) tested in the laboratory. The concentrations expressed are mg/L for APG as active ingredient and mg/L as total chlorine for STB. The results shown in Table 4 demonstrate that all the APG/STB combinations tested were synergistic. It should be noted that APG by itself did not show significant toxicity to reduce bioluminescence readings. However, when combined with the biocides, APG dramatically improved the antimicrobial activity.

TABLE 4

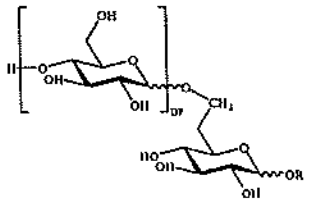
	Alkyl Polyglycoside (ppm)				
STB (ppm TRO*)	2.5	5	7.5	10	15
0.1	0.61	0.27	0.92	0.33	0.41
0.2	0.36	0.26	0.66	0.04	0.07
0.5	0.16	0.26	0.37	0.05	0.19
1.0	0.08	0.25	0.16	0.02	0.06
2.0	0.05	0.05	0.05	0.02	0.04
5.0	0.02	0.04	0.03	0.02	0.02

*TRO = Total Residual Oxidant (referring to chlorine here)

While the present invention is described above in connection with preferred or illustrative embodiments, these embodiments are not intended to be exhaustive or limiting of the invention. Rather, the invention is intended to cover all alternatives, modifications and equivalents included within its spirit and scope, as defined by the appended claims.

What is claimed is:

1. A method of removing biofilms from surfaces submerged in a fouled water system comprising the step of adding to the water system an effective amount of an alkyl polyglycoside having the chemical formula:



wherein R is a C_8–C_{16} alkyl chain and DP is from 0 to 3 carbohydrate units.

2. The method of claim 1 wherein the alkyl chain is linear.

3. The method of claim 1 wherein DP is from about 1.1 to 1.5.

4. The method of claim 1 wherein the alkyl polyglycoside is added to the water system in an amount of from about 0.1 ppm to about 50 ppm.

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5. The method of claim 1 wherein the alkyl polyglycoside is added to the water system in an amount of from about 1 ppm to about 10 ppm.

6. The method of claim 1 wherein the water system is an industrial water system.

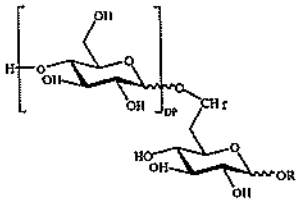
7. The method of claim 1 wherein the water system is a recreational water system.

8. The method of claim 1 wherein a biocide is optionally added to the water system.

9. The method of claim 8 wherein the biocide is an oxidizing biocide.

10. The method of claim 8 whrrein the biocide is a non-oxidizing biocide.

11. A method of removing biofilms from surfaces submerged in a fouled water system comprising the step of adding to the water system an effective amount of a biocide and an alkyl polyglycoside having the chemical formula:



wherein R is a C_8–C_{16} alkyl chain and DP is from 0 to 3 carbohydrate units.

12. The method of claim 11 wherein the alkyl chain is linear.

13. The method of claim 11 wherein DP is from about 1.1 to 1.5.

14. The method of claim 11 wherein the alkyl polyglycoside is added to the water system in an amount of from about 0.1 ppm to about 50 ppm.

15. The method of claim 11 wherein the alkyl polyglycoside is added to the water system in an amount of from about 1 ppm to about 10 ppm.

16. The method of claim 11 wherein the water system is an industrial water system.

17. The method of claim 11 wherein the water system is a recreational water system.

18. The method of claim 11 wherein the biocide is an oxidizing biocide.

19. The method of claim 11 wherein the biocide is a non-oxidizing biocide.

* * * * *

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 12 2005

Eric deLaubenefels
Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

Subject: Sterilex Ultra Powder
EPA Registration No. 63761-5
Amendment Date: June 9, 2005
EPA Receipt Date: June 14, 2005

Dear Mr. deLaubenefels,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions.

- Update label according to Agency letter dated 2/4/05

Conditions
Revise the label as follows:

1. Under First Aid, bold the subheading, "**IF IN EYES, IF ON SKIN, IF SWALLOWED,** and **IF INHALED.**"

2. Bold the headings, "**Storage and Disposal.**"

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

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CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,

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

Enclosure: Stamped Label

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CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

*U.S. Government Printing Office: 1992 — 620-888/40872

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 and Handpiece) until the bottle is empty.

ACCEPTED
WITH COMMENTS
AUG 12 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
- 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

EPA Reg. No. 63761-5

EPA Est. No. 21737-MN-01

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 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 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: 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 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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FQPA

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager	
PRODUCT REVIEWER: Jackie		RMB II TEAM ___
Description of Action: Label review		EPA File Symbol/Reg No. 63761-5
Decision No. 357312	Submission No. 779078	Fee for Service Action Code: ___
FQPA Action Code: 302	Non-FQPA Action Code: ___	Fee for Service Fee: $ ___

	MONTH	DAY	YEAR
APPLICATION DATE	5	13	2005
EPA PIN DATE	5	18	2005
REVIEWER ASSIGNED DATE			2005
DATE DUE FROM SCIENCE			2005
DATE DUE TO PM			2005

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.*

Label review — Give to Jackie

ATTACHMENTS: ☐ LABELING ☐ CSF(S) ☐ DATA ☐ OTHERS

B	For Arctic Slope Contract Only	
Contractor: Arctic Slope	Contract No.: 0332	ARCTIC SLOPE/MANAGER
Draft Task: Signature ___ ___ (Est. hrs)	Final Task: Signature ___ ___ (Total hrs)	

C Reviewer's Comments:

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STERILEX®

May 13, 2005

Document Processing Desk [AMEND]
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTENTION: Velma Noble
Product manager, Team 31

SUBJECT: ***Sterilex Corporation***
Sterilex Ultra Powder
EPA Registration Number 63761-5
Label Amendment to Revise Label Per EPA Letter

Dear Ms. Noble:

We are submitting a label amendment for **Sterilex Ultra Powder.** The sole purpose of this amendment is to revise the label in accordance with the comments from the EPA letter dated February 4, 2005. No other changes have been made to the product label.

Enclosed, please find the following documents:

1) Pesticide Application;
2) Three (3) copies of the revised product label.

If you have any questions, please contact me at 410-581-8860 or by e-mail at eric@sterilex.com.

Sincerely,

Eric de Laubenfels

Eric deLaubenfels, Ph.D.
Sterilex Corporation

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11409 CRONHILL DRIVE • SUITE L • OWINGS MILLS, MD 21117 • DIRECT 410-581-8860 • 1-800-511-1659 • FAX 410-581-8864 • www.sterilex.com

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	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
63761-5	Velma Noble	☐ None ☐ Restricted
4. Company/Product (Name) Sterilex Ultra Powder	PM# 31	

5. Name and Address of Applicant *(Include ZIP Code)*
Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

NOTE: PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW

☐ *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

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment to Update Label In Accordance with 02/04/2005 EPA Letter

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Eric deLaubenfels	Laboratory Director	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.

2. Signature	3. Title	6. Date Application Received
Eric de Laubenfels	Laboratory Director	(Stamped)
4. Typed Name: Eric deLaubenfels	5. Date: May 13, 2005	17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 1 2005

Dr. April Zambelli-Weiner
Sterilex
11409 Cronhill Drive, Ste. L
Owings Mills, MD 21117

Subject: Sterilex Ultra Powder
EPA Registration No. 63761-5
Notification Date: June 9, 2005
EPA Receipt Date: June 14, 2005

Dear Dr. Weiner,

This letter acknowledges receipt of the following notification under FIFRA section 3(c)9 and PR Notice 91-2.

- Addition of Non-Pesticidal Claim

General Comments

Based on a review of the submitted materials, your notification to add the claim, "Think Pink Once a Week, " is acceptable and apart of the records on file.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Tracy Lantz

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

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CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

FQPA

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager		
PRODUCT REVIEWER: Jackie		RMB II	TEAM ____
Description of Action: Notification		EPA File Symbol/Reg No. 63761-5	
Decision No. 359074	Submission No. 780546	Fee for Service Action Code: ____	
FQPA Action Code: 332	Non-FQPA Action Code: ____	Fee for Service Fee: $ ____	

	MONTH	DAY	YEAR
APPLICATION DATE	6	9	2005
EPA PIN DATE	6	14	2005
REVIEWER ASSIGNED DATE		—	2005
DATE DUE FROM SCIENCE			2005
DATE DUE TO PM			2005

Type of Data:	PSB Product Chemistry ☐	PSB Acute Toxicology ☐	PSB Efficacy ☐	RASSB Environmental Fate ☐	RASSB Ecological Effects ☐	RASSB Chronic Toxicology ☐	RASSB Exposure ☐

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.*

Notification - Give to Jackie

ATTACHMENTS: ☐ LABELING ☐ CSF(S) ☐ DATA ☐ OTHERS

B	For Arctic Slope Contract Only	
Contractor: Arctic Slope	Contract No.: 0332	ARCTIC SLOPE/MANAGER
Draft Task: Signature ____ ____ (Est. hrs)	Final Task: Signature ____ ____ (Total hrs)	

C Reviewer's Comments:

1.9

STERILEX®

09 June 2005

Document Processing Desk [NOTIFICATION]
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street South
Arlington, VA 22202

ATTENTION: **Velma Noble**
Product Manager, Team 31

SUBJECT: ***Sterilex Corporation***
Sterilex Ultra Powder
EPA Registration Number 63761-5
Notification of minor label change

Dear Ms. Noble:

We are submitting a notification for **Sterilex Ultra Powder**. The sole purpose of this notification is to inform the agency of the following minor label change to the above referenced product:

1. "Think Pink Once A Week" has been added to the label

Please find enclosed a copy of the revised label with the above change highlighted in yellow.

If you have any questions, please contact me at 410-581-8860 or by email at april@sterilex.com.

Sincerely,

April Zambelli-Weiner, Ph.D.
Senior Research Scientist
Sterilex Corporation

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11409 CRONHILL DRIVE • SUITE L • OWINGS MILLS, MD 21117 • DIRECT 410-581-8860 • 1-800-511-1659 • FAX 410-581-8864 • www.sterilex.com

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.

NOTIFICATION
Date Reviewed: 6/27/05
Reviewed By:

STERILEX

Sterilex Ultra Powder

Think Pink Once A Week

- 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

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
www.sterilex.com

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

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

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 63761-5	2. EPA Product Manager Velma Noble	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name) Sterilex Ultra Powder	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Sterilex Corporation 11409 Cronhill Drive, Suite L Owings Mills, MD 21117 ☐ 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:	

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of minor packaging and related label changes per PR Notice 98-10 consisting of the addition of "Think Pink Once A Week" to the label.

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 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No *Certification must be submitted	☐ Yes ☐ No If "Yes" Unit Packaging wgt. / No. per container	☐ Yes ☐ No If "Yes" Package wgt / No. per container	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	5, 30 and 55 gallons	☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name	Title	Telephone No. (Include Area Code)
April Zambelli-Weiner	Senior Research Scientist, Sterilex Corporation	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.

2. Signature	3. Title Senior Research Scientist, Sterilex Corporation	6. Date Application Received (Stamped)
4. Typed Name April Zambelli-Weiner	5. Date 7/18/05	32

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete White- EPA File Copy (original) Yellow- Applicant Copy

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

EPA Reg. Number: 63761-5

Date of Issuance: FEB 04 2005

Term of Issuance: Conditional

Name of Pesticide Product: Sterilex Ultra Powder

NOTICE OF PESTICIDE:

x Registration
__ Reregistration

(under FIFRA, as amended)

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 Rodeoticide 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

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 8, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol: 63761-L/ Sterilex Ultra Powder

DP Barcode: D310043

To: Velma Noble, PM 31 / Jacqueline Campbell-McFarlane
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

12/8/04

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: The Sterilex Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
N-Alkyl dimethylbenzylammonium chloride	10.0
Sodium Carbonate Peroxyhydrate	29.75
Other Ingredient(s):	60.25
Total:	100.00%

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I BACKGROUND: The Sterilex Corporation requests a waiver of the acute inhalation toxicity study requirement for its product, "Sterilex Ultra Powder". Supporting this request is "Final Report- Particle Size and Attrition Resistance for Ultra Kleen CW502". The study was conducted by the Celotex Corporation. This report is assigned MRID Number 463799-01.

This study report was conducted using "Ultra-Kleen CW502". The 3/30/2004 cover letter from regulatory consultants Lewis & Harrison states: "**Sterilex Ultra Powder** is identical to Ultra-Kleen CW-502 (EPA Reg. No. 63761-2) with respect to composition."

This study conducted was a particle size determination. According to the report, the following was carried out:

A The test samples were "screened using a 125 µm sieve to remove very fine particles from the sample as received."

B "50.0 grams of the sieved granules were transferred to bottles with 50. Grams of glass beads, samples A & B. The bottles were placed on the roller system which was adjusted to a speed of 100 ± 3 rpm. The bottles were allowed to rotate for 4500 revolutions, or forty-five minutes."

According to the report, both samples were over 99% resistant to attrition.

Particle Size Determination of Ultra Kleen CW502		
Particle Size (microns)	Lot C 9708013 9453	Lot 970801-1 9454
> 125	94.32	97.74
125 > x > 53	4.80	1.90
53 >	0.88	0.36

An acute toxicity review of 63761-L was conducted by CTT/PSB/AD on 6/11/2002. The results of that review were:

Study	Toxicity Category	Acceptability
acute oral toxicity	III	Acceptable
acute dermal toxicity	III	Acceptable
acute inhalation toxicity	II	Waived
primary eye irritation	I	Self-Validated
primary skin irritation	I	Self-Validated
dermal sensitization	Nonsensitizer	Waived

II RECOMMENDATIONS: PSB findings are:

CTT/PSB/AD waives the acute inhalation toxicity study for EPA File Symbol 63761-L.

The acute toxicity profile for File Symbol 63761-L is currently:

Study	MRID Number	Toxicity Category	Acceptability
acute oral toxicity	---	III	Acceptable
acute dermal toxicity	---	III	Acceptable
acute inhalation toxicity	463799-01	IV	Waived
primary eye irritation	---	I	Self-Validated
primary skin irritation	---	I	Self-Validated
dermal sensitization	---	Nonsensitizer	Waived

III LABELING:

1 The signal word for Registration Number 63761-L (the undiluted product) is "DANGER".

2 The Precautionary Statements for Registration Number 63761-L (the undiluted product) are:

"Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield). Wear protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or, using tobacco. Remove and wash contaminated clothing before reuse."

3 The First Aid Statements (derived from PR-Notice 2001-1) for Registration Number 63761-L (the undiluted product) are:

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 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:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to do so.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

4. CTT/PSB/AD still feels that the registrant needs to conduct a dermal sensitization study using the use dilution(s) of this product.

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

September 30, 2004 **HAND DELIVERED**

Document Processing Desk [RESPONSE[
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTENTION: Velma Noble
Product Manager, Team 31

SUBJECT: Sterilex Corporation
Sterilex Ultra Powder (EPA File Symbol 63761-L)
Response to Agency Letter Dated June 28, 2002

Dear Ms. Noble:

On behalf of Sterilex Corporation ("Sterilex"), we are responding to the Agency's June 28, 2002 letter (copy attached) regarding the registration application for **Sterilex Ultra Powder**. Each of the deficiencies and comments made in the Agency's letter are addressed below.

A) PRODUCT CHEMISTRY:

Agency Comment - Sodium percarbonate must be characterized as an active ingredient in this product formulation.

In response to the Agency's determination, we have prepared a new CSF for **Sterilex Ultra Powder**. The new CSF includes sodium percarbonate as an active ingredient. The new CSF is enclosed with this response package.

In addition, the product label has been revised to include sodium percarbonate as an active ingredient in the ingredient statement. Copies of the updated label are also enclosed with this response package.

B) ACUTE TOXICITY:

Agency Comment #1 - (paraphrased) Revise the precautionary statements as indicated.

The Precautionary Statements section has been revised as indicated by the Agency with the exception of the inhalation hazard statement. Copies of the updated label are enclosed with this response package.

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Sterilex is requesting that the respirator language not be required for the precautionary statements. **Sterilex Ultra Powder** is identical to Ultra-Kleen CW-502 (EPA Reg. No. 63761-2) with respect to composition. In effect, the formula for **Sterilex Ultra Powder** would be considered equivalent to an alternate formulation of Ultra-Kleen CW-502, and the [redacted] would have no effect on the overall toxicity of the product. The Agency determined that no respirator statement would be required for Ultra-Kleen CW-502 based on the particle size, and the same considerations would be applicable to **Sterilex Ultra Powder**.

We have learned that the particle size and attrition study that had been previously submitted for Ultra-Kleen CW-502 was never assigned a MRID number. We are, therefore, re-submitting the report so that a MRID number can be assigned for future reference. The report is included with this response.

Agency Comment #2 - (paraphrased) Revise the First Aid statement as indicated.

The First Aid statement has been revised as indicated by the Agency. Copies of the updated label are enclosed with this response package.

Agency Comment #3 - (paraphrased) Address the dermal sensitization data requirement.

Aside from the addition of a small amount of [redacted] **Sterilex Ultra Powder** is identical to Ultra-Kleen CW-502 (EPA Reg. No. 63761-2) with respect to composition. In effect, the formula for **Sterilex Ultra Powder** would be considered equivalent to an alternate formulation of Ultra-Kleen CW-502, and the [redacted] would have no effect on the overall toxicity of the product. The Agency determined that Ultra-Kleen CW-502 is a non-sensitizer. Therefore, the same determination would apply to **Sterilex Ultra Powder** based on the substantial similarity between the two products.

Since the neat powder is categorized as a non-sensitizer, diluting the product with water would not change the sensitization potential of the powder.

In addition, **Sterilex Ultra Powder** has been classified as Category 1 for eye and skin irritation. Therefore, **Sterilex Ultra Powder** is considered corrosive to the skin and eye tissue. The Agency has previously waived the requirement for skin sensitization data in the case of products that are found to be corrosive to the skin and eyes.

Agency Comment #4 - (paraphrased) Include use dilution labeling in italics after the general precautionary statements.

The italicized use dilution labeling has been added as indicated by the Agency. Copies of the updated label are enclosed with this response package.

C) EFFICACY:

(paraphrased) The claim "disinfects biofilm bacteria" is not acceptable based on the proposed performance standard, "90% of biofilm samples demonstrate <200

cfu/cm^2." Either submit data that supports the current disinfection standard or delete "disinfection of biofilm bacteria" claims from the label.

Per its discussions with Dennis Edwards, Sterilex has revised the biofilm claims for the **Sterilex Ultra Powder** label. The revised label now reflects the results of the laboratory testing for biofilm removal. Please note that Sterilex is willing to work with EPA further on the wording for these claims and would appreciate a telephone call or having a meeting to discuss any further recommended changes regarding the biofilm claims.

D) SUPPORTING DOCUMENTS:

In addition to the aforementioned attachment, please find enclosed the following documents to support the registration of **Sterilex Uttra Powder**:

1) Application for Pesticide Registration (OPP ID 297051);
2) Two (2) copies of the corrected Confidential Statement of Formula;
3) Corrected Formulator's Exemption Statement with corrected Confidential Statement of Formula;
4) Five (5) copies of the corrected product label; and,
5) Three (3) copies of the report

   Final Report: Particle Size and Attrition Resistance for Ultra Kleen CW502. (September 28, 2004) by Sterilex Corporation; 6 pages.

   MRID **46379901**

E) CONTACT INFORMATION:

Lewis & Harrison LLC is acting as the company contact and company agent for the purposes of this product registration. Accordingly, please direct all correspondence to us at 122 C Street NW, Suite 740, Washington DC 20001. If you have any questions, please contact me by telephone at 202-393-3903 ext. 13 or by e-mail at wmccombie@lewisharrison.com.

Sincerely,

Wendy A. McCombie
Agent for,
Sterilex Corporation

WAM/wm
Enclosures

CC: Eric deLaubenfels (Sterilex Corporation)

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FQPA

DATA PACKAGE BEAN SHEET

Date: 03-Nov-2004

* * * Registration Information * * *

Registration: 63761-L - STERILEX ULTRA POWDER

Company: 63761 - STERILEX CORP, THE

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# CM-2 308B

Risk Manager Reviewer: Jacqueline Campbell-McFarlane JMCFAR02

Sent Date: _____ Calculated Due Date: 05-Feb-2005 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (188) ADDITIONAL USE;NEW REGISTRATION;OLD INGREDIENT;ME-TOO;

Ingredients: 069184, Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2%C16)(10%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 03-Nov-2004 Due Back: _____

DP Ingredient: 069184, Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2%C16)

DP Title: Particle Size and Attrition Resistance

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out		
Organization:	AD / PSB			Administrative Due Date:	06-Feb-2005
Team Name:	CTT			Negotiated Due Date:	
Re. .wer Name:				Projected Completion Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Please review the Particle size study to address the inhalation data requirement. Also please respond to Registrants waiver request for dermal sensitization in the attached cover letter.

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STUDY TITLE:

Final Report-
Particle Size and Attrition Resistance for Ultra Kleen CW502

AUTHOR:

Sterilex Corporation

STUDY COMPLETION DATE:

September 28, 2004

PERFORMING LABORATORY:

Celotex Corporation Testing Services
10301 Ninth Street North
Saint Petersburg, Florida 33716

LABORATORY TEST IDENTIFICATION:

MTS Job No. 258230
MTS Job No. 258227

DATA SUBMITTER:

Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

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EPA Reg File #63761-5

Page____ is not included in this copy.

Pages 35 through 39 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Form approved. OMB NO. 2070-0060. Approval Expires 1-30-93

United States Environmental Protection Agency
Washington, D.C. 20460

EPA

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
	63761-L
Sterilex Corporation **11409 Cronhill Drive, Suite L** **Owings Mills, MD 21117**	Product Name **Sterilex Ultra Powder**
	Date of Confidential Statement of Formula (EPA Form 8570-4) **September 10, 2004**

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

a) **Sodium Carbonate Peroxyhydrate**
b) **Sodium Carbonate**
c) **n-Alkyl (C14 95%, C16 3%, C16 2%) dimethyl benzyl ammonium chloride dehydrate**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
a) Sodium Carbonate Peroxyhydrate	[redacted]	[redacted]
b) Sodium Carbonate		
c) n-Alkyl (C14 95%, C16 3%, C16 2%) dimethyl benzyl ammonium chloride dehydrate		

Signature	Name and Title	Date
	Wendy A. McCombie, Lewis & Harrison, Agent for Sterilex	September 10, 2004

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EPA Form 8570-27 (Rev. 7-91) White - EPA copy Yellow - Applicant copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 2 2004

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

Subject: Sterilex Protocol and Data to Support Biofilm Claims in Dental Unit Waterlines

Dear Dr. Kramer,

On June 15, 2004, the Agency met with Sterilex Corporation to discuss the proposed biofilm labeling claims in association with the comments from the expert panelist review of their protocol and data. The attendees of this meeting were Dr. Shira Kramer, Dr. Krishna Raman, Dr. Eric DeLaubenfels, and Dr. April Zambelli-Weiner of Sterilex Corporation along with Frank Sanders, Dennis Edwards, Michele Wingfield, Velma Noble, Nancy Whyte, Tajah Blackburn, Sanyvette Williams-Foy, Melba Morrow, and Jacqueline McFarlane of the USEPA.

The following are the minutes and next steps discussed at the meeting.

1. Sterilex felt that there was overwhelming data to support a "Biofilm Removal" claim. They believed their data demonstrates that over 85 % removal of biofilm is achieved using Ultra Kleen. The unresolved issue is what would be an adequate performance standard to describe to the action of the product. However, the Agency believes the claim implies 100% removal which is not achieved. It was suggested that Sterilex consider alternative language that better describe the level of action achieved by the product.

   Please Note: The Agency will need further discussions before this claim is allowed. Dr. Tomasino agreed to re-evaluate the University of Maryland data.

2. There was considerable discussion regarding the use of the term/claim, "Biofilm Disinfection." The Agency proposed that a "Kills/Elimates/Mitigate Biofilm Bacteria" would better define this product's action. It was agreed that Sterilex would re-evaluate this claim and submit alternatives.

3. The Agency accepted the "Prevention/Suppression of Biofilm Formation."

4. The use of the claim, "Disinfection of Dental Unit Waterlines," was discussed. The

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Agency believes that the AOAC Use Dilution Test is an inappropriate protocol to be used to demonstrate disinfection for this type of use site. The Agency and Sterilex agreed to re-examine this claim.

5. The "Maintenance of heterotrophic plate counts <200 cfu/ml dental waterlines" was revised. ANSI originally proposed this claim, but has revised it to <500 cfu/ml which corresponds to the drinking water standard. The Agency has no concerns with the revised claim.

If there are any issues that was not included in this letter, please notify the Agency in writing. 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)

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Dennis Edwards/DC/USEPA/US @EPA

06/18/04 03:27 PM

To: Frank Sanders/DC/USEPA/US@EPA, Michele Wingfield/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Stephen Tomasino/DC/USEPA/US@EPA, Nancy
cc:
Subject: Thank You

Dennis Edwards
Antimicrobials Division
703-308-8087
----- Forwarded by Dennis Edwards/DC/USEPA/US on 06/18/2004 03:06 PM -----

April Zambelli-Weiner <aprilzambelli@yahoo.com>

06/18/2004 02:25 PM
Please respond to april

To: Dennis Edwards/DC/USEPA/US@EPA
cc:
Subject: Thank You

Dear Dennis,
First I would like to thank you, on behalf of the team at Sterilex, for your efforts on our behalf and for facilitating the meeting on Tuesday. We have greatly appreciated your involvement and guidance in this process. Please also relay our thanks to Frank Sanders and the others in attendance at the meeting for the opportunity to meet with them and for their attention to the issues at hand.

As part of the R&D team at Sterilex, I am going to be increasingly involved in the regulatory affairs of the company. As such, I wanted to update you regarding the actions we have taken (and will be taking) as a result of the meeting. With regard to the wording of the claims, our response to the suggested changes at the meeting are as follows:

1. "Removal of Biofilm Matrix": We have discussed this claim at length and have attempted to arrive at alternative wording. However, it is the position of the team, including Shira, that there are lots of problems with attaching modifiers to this claim. We believe in doing so, the claim becomes too vague and misleading. We would like to reiterate our position that 100% matrix removal doesn't make sense in a dynamic system like DUWL, and to make such a claim would undoubtedly yield skepticism on the part of the end-user. We elaborate on the argument against 100% removal in our "Response to EPA Questions" included in the packet provided to the EPA on Tuesday. We would like to, again, request approval of the claim as it reads.
2. We agree with the EPA's suggestion of the claim to read: "Kills biofilm bacteria" (change from "disinfection" to "kill")

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3. "Prevention/Suppression of Biofilm Formation" It is our understanding that this claim is ok as submitted.
4. "Disinfection of DUWL." We believe that that the AOAC Use Dilution test supports this claim, as well as the field data from the Meiller study. In response to Dr. Tomasino's concerns about residual antimicrobial in the line at the time of sampling, I will re-fax the rinsing study to you for the record and to Dr. Tomasino for his perusal with some included commentary from Dr. DeLaubenfels on Monday.
5. "Maintains heterotrophic plate counts <500cfu/mL in dental unit water." It is our understanding that the EPA will accept this claim as it reads.

Please advise on any of this. We will be submitting updated materials for review by the end of next week. Again, thank you for your help and guidance.

Sincerely,

April

April Zambelli-Weiner, Ph.D.
Senior Research Scientist
The Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117
410-581-8860
fax 410-581-8864
april@sterilex.com

Sterilex Response to EPA Reviewer Comments

Sterilex Ultra Powder for Dental Unit Waterlines (EPA File Symbol 63761-L)
Sterilex Ultra Liquid B for Dental Unit Waterlines (EPA File Symbol 63761-A)

I. Response to Comments by Reviewer Rodney Donlan, Ph.D.

1. The comments received by Sterilex, dated January 6, 2004, refer only to two "additional" reports (Report by Dr. Ralph Leonard, and an Executive Summary of the University of Maryland Clinical Efficacy Study) reviewed by Dr. Donlan that were not submitted to him in the original packet that he evaluated in February, 2003. It is not clear what was contained in the original packet that he reviewed in February, 2003. Did Dr. Donlan ever receive the full study submitted by Dr. Timothy Meiller (Full report of the University of Maryland Clinical Efficacy Study)? Dr. Donlan's comments on the original packet that he reviewed in February, 2003 were also not sent to Sterilex. It would be helpful to see Dr. Donlan's comments to the packet sent to him by EPA in February, 2003.

2. Dr. Donlan objected to the use of scanning electron microscopy (SEM) for quantifying the degree of biofilm matrix removal after treatment with Sterilex Ultra.

   Sterilex chose to utilize the SEM method because it permits you to directly visualize the biofilm matrix. In the University of Maryland Clinical Efficacy Study, SEM's were performed on the dental unit waterline tubing prior to, and after treatment, as well as on control tubes that received no treatment. The degree of biofilm matrix removal was categorized, as follows: 100% removal (Gone); >90% removal (Negligible patchy biofilm); >85% removal (Biofilm patches); >75% removal (Thin layer). There were many replicate experiments conducted in order to ensure reliability and validity of results. In all cases, the microbial recovery results were consistent with the biofilm matrix removal results evaluated by SEM. In addition, there were four separate sets of experiments conducted at the University of Maryland, which included laboratory dental unit waterlines, as well as dental unit waterlines in actual clinical use. The results from all four sets of experiments were consistent. The SEM method for evaluating biofilm matrix removal was utilized in other studies submitted in support of this Registration, including the studies conducted at the University of Louisville, UCLA Medical Center (Thomas Lee, DDS, et al), and the University of Detroit, Mercy School of Dentistry. All study results were consistent, and supported the efficacy of Sterilex Ultra powder and liquid in removing biofilm from dental unit waterlines.

Sterilex performed separate microbiological studies to determine the efficacy of our products in killing microorganisms within the biofilm matrix, and in the effluent dental unit water. We believe that biofilm matrix removal and antimicrobial efficacy are two distinct functions that should be evaluated separately. In the University of Maryland Clinical Efficacy Study, (as well as all the other studies that were submitted to EPA in support of this registration), the biofilm matrix removal results, utilizing SEM, were confirmed by standard antimicrobial testing (culturing biofilms and effluent water).

Instead of utilizing SEM to evaluate biofilm matrix removal, Dr. Donlan suggested a method that incorporates image analysis of stained biofilms (Walker JT, Bradshaw DJ, Bennett AM, Fulford MR, Martin RV, Marsh PD. Microbial biofilm formation and contamination of dental-unit water systems in general dental practice. Appl Environ Microbiol 2000;66:3363-3367). In fact, this method neither qualitatively nor quantitatively directly measures biofilm *matrix* removal. The method suggested by Dr. Donlan measures viable organisms distributed in the biofilm matrix. If the test agent kills microorganisms, but leaves the matrix attached to the surface (as is the case with many antimicrobial products, which are not designed to hydrolyze or remove the matrix material), the method will yield false negative results. The method described in the Walker, et al paper is more relevant to a disinfection or microbial kill claim, not a biofilm matrix removal claim.

3. In Dr. Donlan's comments about the University of Maryland, he questioned how biofilm counts were determined during the course of treatment in the field study of 10 dental units. He also asked whether tubing samples were collected on each of the sampling dates and processed for biofilm (he referred to Table 5, but it is actually Table 4 in the Report). The method for enumerating biofilm counts is specified in the beginning of the paper, in the sections entitled "Experimental Design, Biofilm Assay", and "Experimental Design, Biofilm and Dental Unit Water Microbial Assay Plating Procedure". The same methods for determining biofilm counts were utilized in all four sets of experiments conducted at the University of Maryland. Therefore, the method was described once at the beginning of the paper. Regarding the frequency of sampling, it is clear in Table 4 that tubing samples were collected on each of the sampling dates and processed for biofilm.

II. Response to Comments by Reviewer Stephen Tomasino, Ph.D.

1. Dr. Tomasino concluded that "...the methods used to measure the various claims (removal, prevention/suppression) are scientifically sound for this type of product and use site."

2. Dr. Tomasino was not provided the AOAC Use-Dilution test results, which support a hard-surface disinfection claim.

3. Dr. Tomasino's primary concerns relate to the possible adoption of test methods employed in the studies submitted by Sterilex as "standard" test methods. He refers to the need for a standardized protocol and GLP procedures in order for the methods to be adopted by other laboratories as standard methods. He suggests that all parameters be standardized, including the use of a biofilm reactor to grow the biofilm in a controlled environment. Dr. Tomasino expresses his concern that the methods used in the Sterilex studies were "...too complex for a standard microbiology laboratory to conduct". Regarding the use of a biofilm reactor, the biofilm is actually easier to remove in a reactor (because it is an immature biofilm, and does not simulate the architecture of a dental unit waterline in a dental operatory).

   In response to Dr. Tomasino's comments, Sterilex is not proposing that the methods employed in the submitted studies be adopted as "standard methods" without further standardization. Sterilex submitted numerous studies, conducted by academic researchers using actual dental unit waterlines (including laboratory and clinical-use dental unit waterlines) to support the registration claims sought by Sterilex. The studies were not designed or conducted specifically for EPA registration purposes. However, the studies overwhelmingly confirm and support the registration claims sought by Sterilex, using stringent test conditions in actual clinical settings.

III. Sterilex Summary Position

1. Sterilex believes that the studies submitted in support of EPA Registration Applications 63761-L and 63761-A support the label claims relating to Removal, Prevention, and Suppression of Biofilm in Dental Unit Waterlines. Sterilex also believes that the submitted studies support the claims relating to Disinfection of Biofilm Bacteria (Kills Bacteria in Biofilms; Reduces Heterotrophic Bacterial Counts to <200 cfu/ml; Disinfects the Interior Lumen of the Dental Unit Waterline).

2. Sterilex agrees that the methods employed in the submitted studies require further standardization before they are adopted as a "standard" EPA test method.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 2 2004

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

Subject: Sterilex Ultra-Kleen Field Studies for Dental Waterlines

Dear Dr. Kramer,

The Agency has completed its re-review of your dental waterline field studies utilizing Dr. Rodney Donlan and Dr. Stephen Tomasino, as expert panelist. The experts disagreed on a number of issues, but they, both, agreed that the submitted data supported a "prevention of growth and suppression of biofilm" claim.

A key issue with the field studies was the inability to quantitatively evaluate biofilm formation as well as bacterial counts to adequately ascertain the degree of removal after product use. The panelists discussed the deficiencies in the test method or protocol that precluded a comparative analysis of the field studies presented. These deficiencies inhibited the repeatability and reproducibility by other laboratories which are intricate in protocol acceptance. They both called for a standardized approach to determining biofilm matrix removal before a matrix removal claim is accepted.

The following recommendations were by either one or both of the panelists:

a) In regard to biofilm removal, a method that incorporates image analysis of stained biofilms would be beneficial.

b) Efficacy testing using a laboratory-generated biofilm should be considered.

c) Test method validation is recommended using organizations such as ASTM and AOAC to ascertain the reliability and practicality of the method.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,

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

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CONCURRENCES								
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SURNAME								
DATE								

Rodney M. Donlan
Biofilm Laboratory Team Leader
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Mail Stop C-16
1600 Clifton Road, N.E.
Atlanta, GA
30333
(404) 639-2322
Email: rld8@cdc.gov

1/6/2004

Document Review Time: 16 hours

Letter Peer Review of Additional Efficacy Protocol Data Submitted on behalf of Sterilix Corporation

1. **Are the data from laboratory studies adequate to support a claim of biofilm matrix removal, prevention of biofilm growth and/or biofilm suppression?**

Two reports that were not included in the original packet evaluated in February 2003 were reviewed and my comments here pertain only to those two reports: a) Evaluation of Ultra-Kleen in Controlling DUWL Bacterial Contamination and Biofilm, submitted by Dr. Ralph Leonard, University of North Carolina, April 29, 1999, and b) Executive Summary, University of Maryland Clinical Efficacy Study, Sterilix Ultra-Kleen for Dental Unit Water Lines.

Report by Dr. Ralph Leonard, University of North Carolina.
Eight dental units were evaluated. Five were treated with Ultra-Kleen solution, three were untreated controls. Water samples were collected weekly over a one month period just prior to treatment, and processed. These samples were tested using the Millipore heterotrophic plate count (using the filter paddle), and by plating 1 ml of sample on 5% sheep blood agar, MacConkey's agar, and Sabouraud Dextrose agar. Plates were incubated at 35°C for 24-48 h and counted. Scanning electron microscopy of tubing sections was also performed.

Comments on the methods used for this study:

- 5% sheep blood agar will not determine the heterotrophic plate count. A medium such as Plate Count Agar or R2A agar should be used for this purpose. The author should consult Standard Methods for the Examination of Water and Wastewater, 20th edition, 1998, Method 9215 Heterotrophic Plate Count, American Public Health Association, for the proper medium.

- A one ml sample volume was added to each agar plate and excess sample was discarded prior to incubation of the plate. This is not a standard method. For spread plates, the proper method is to add no more than 0.5 ml of sample to the plate (reference Standard Methods above). The method used by this investigator would undoubtedly bias the results since an unmeasured portion of the sample would be discarded. It would be inaccurate to report results as CFU/ml.
- The Millipore HPC sampler method would be acceptable for measuring the heterotrophic plate count on dental unit water line samples, but there were flaws in the application of this method by the investigator: 1) the temperature of incubation was given as 25-35°C for 24-48 h. According to the technical information provided by Millipore Corporation ("Using Millipore Samplers in Dental Settings", http://www.millipore.com/publications.nsf/docs/TB094), the sampler should be incubated at 23-26°C for 7 days. This method has been evaluated by Karpay et al, 1999 (Karpay RI, Plamondon TJ, Mills SE. Comparison of methods to enumerate bacteria in dental unit water lines. Current Microbiol. 1999;38:132-134) and these investigators incubated all HPC samplers at 24°C for 7 days, 2) since serial dilutions of the samples were not made, it is impossible to determine the actual counts in several of the untreated samples (Table 2 of the report). The results for the treated samples (Table 1) were also difficult to interpret. For example, results provided for Units 8, 10, and 12, for the Week #4 samples were given as >10? What does this mean? How much higher than 10 were they?
- Scanning electron microscopy cannot be used to evaluate biofilm formation quantitatively. Please reference my comments on use of SEM to support claims of biofilm matrix in the report dated 3/14/03.
- In summary, the data in this report does not support the claims of biofilm matrix removal, prevention of biofilm growth and/or biofilm suppression.

Executive Summary, University of Maryland Clinical Efficacy Study, under the direction of Timothy Meiller, DDS, PhD.

Over a period of two years, 240 sections of dental unit tubing were collected from 40+ dental units after these units were dismantled. Water samples were collected from the dental units prior to tubing removal. The tubing sections were filled with "composite water" (water collected from the unit prior to tubing removal) and stored at 4°C prior to testing. To evaluate the effect of the treatment on biofilms, these tubing sections were drained of composite water then filled with the prescribed agent concentration for the designated treatment period. Following the treatment, tubing sections were flushed with sterile distilled water. Biofilms on the tubing sections were evaluated either using scanning electron microscopy or by culturing of the recovered biofilms on trypticase soy agar (TSA) medium and incubating plates at 25°C for 7 days then counting. Effluent water sample planktonic counts were measured using the same method (TSA, 25°C, 7 days). Untreated tubing sections were processed in an identical manner to the treated

samples. A field study was also performed in which the treatment was evaluated in 10 dental units used in clinical practice.

Comments

- The medium used to quantify biofilm and effluent microorganisms was trypticase soy agar (TSA). The recommended medium from Standard Methods for the Examination of Water and Wastewater for monitoring the heterotrophic plate count in drinking water is either plate count agar, mHPC agar, R2A agar, or NWRI agar. These lower nutrient media will provide higher colony counts of microorganisms in drinking water and dental unit water. However, TSA is considered a non selective medium and is recommended for monitoring hemodialysis water systems so it could be considered acceptable for this study. But higher numbers of microorganisms would probably be recovered using a low nutrient medium such as R2A agar.
- Scanning electron microscopy will provide *qualitative* evidence for the presence of biofilms but cannot be used to provide *quantitative* information. Please reference my discussion on this issue in my report dated 3/14/03.
- A study was performed on in-use dental units (field study). The results of this study, presented in Table 5, appear to support the results of the laboratory studies. However, it is unclear how biofilm counts were determined during the course of the treatment (as described on page 30). Were tubing samples collected on each of the sampling dates and processed for biofilm, as indicated in Table 5?
- In summary, the data provided in this report can support the claims that the treatment will prevent biofilm growth and/or suppress biofilm. The data do not support the claim that the treatment will result in biofilm matrix removal, since this claim is based upon evidence provided only by scanning electron microscopy.

2) To what degree are these three conditions satisfied by the data provided?

The data provided in the report by Dr. Ralph Leonard do not support any of the claims. The data provided in the report by Dr. Timothy Meiller support claims of prevention of biofilm growth and biofilm suppression.

3) If the data are not adequate, please identify deficiencies and provide advice on additional information that should be requested in order to satisfy any or all of the three biofilm claims.

The deficiencies in both reports have been specified in my comments above. To support claims of biofilm matrix removal, a method that incorporates image analysis of stained biofilms might be useful. Please reference Walker JT, Bradshaw DJ, Bennett AM, Fulford MR, Martin RV, Marsh PD. Microbial biofilm

formation and contamination of dental-unit water systems in general dental practice. Appl Environ Microbiol 2000;66:3363-3367 for a suggested method.

4) What information is provided by the field studies that would make them useful as ancillary, supportive data?

The field study results provided by Dr. Ralph Leonard were not helpful for the reasons indicated above. The results provided by Dr. Timothy Meiller appear to be supportive of the laboratory study.

5) Is sufficient data provided to supplement any of the claims mentioned in question number "1" (removal, growth prevention or suppression)?

The claims of growth prevention and suppression are supported by the data presented by Dr. Meiller.

6) If the data are insufficient, what information would be needed from field trials to support claims of removal, prevention, or suppression?

With the exception of the claims regarding matrix removal, the laboratory and field data reported by Dr. Meiller appear to be sufficient to support the claims.

Dennis

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

JAN 29 2004

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of the Sterilex Protocol and Data for Removal, Prevention and Suppression of Biofilm in Dental Unit Water Lines (DUWLs)

FROM: Stephen Tomasino, Ph.D. Stephen Tomasino
OPP Microbiology Laboratory
Biological and Economic Analysis Division

TO: Dr. SanYvette-Foy, Special Assistant to the Director
Antimicrobials Division
Office of Pesticide Programs

Per your request, I have reviewed Sterilex Corporation's test data to support product claims for control of biofilm associated with DUWLs. Data on disinfection using the AOAC Use-Dilution Test were not submitted. Answers and comments are provided below to the questions you have presented:

Question 1: Are the data from laboratory studies adequate to support a claim for biofilm matrix removal, prevention of biofilm growth and/or biofilm suppression?

- Generally speaking, the data support the claims (e.g., minumum 75% removal of biofilm and <200 cfu/mL effluent water); however, due to the lack of a standardized protocol (see response to question 3) and a comprehensive experimental design, it is not possible to compare or associate the level of efficacy across the studies presented. In addition, repeatability (within lab variability) and reproducibility (lab to lab variability) were not determined.

Question 2: To what degree are these three conditions satisfied by the data provided?

- *Biofilm matrix removal*: Based on the before/after treatment data presented, the use of the Sterilex products generally support the claim for reduction/removal of biofilm matrix and the planktonic populations of bacteria in effluent. SEM, as used in these studies, is a useful yet highly qualitative (i.e., degree of disruption or removal) tool. The microbial recovery data are more challenging to assess - microbial identification was not always performed and the culture assays were performed differently. Furthermore, the removal and/or neutralization of the product were not always confirmed. Additional experimentation is recommended per comments in Question 3.

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- *Prevention of Biofilm Growth or Suppression*: In the studies performed, the data generally supports the claim. Additional experimentation is recommended per comments in Question 3.

Question 3: If the data are not adequate, please identify deficiencies and provide additional information that should be requested.

- A standardized protocol is requested which specifically identifies the following parameters for testing: contact time, flow rate, lumen diameter of the DUWLs, water temperature, sample times, culture media, incubation conditions, neutralization verification, analysis of water quality for hardness and organic burden, identification of recovered microbes and identification of microbes in the composite water.
- Statistical analysis of within and between lab variability.
- Ruggedness testing - e.g., effect of organic burden on efficacy and regrowth of biofilm, slight differences in the use-dilution or contact time of product.
- Quantification (surface area covered) of biofilm before and after treatment using SEM.

Question 4: What information is provided by the field studies that would make them useful as ancillary, supportive data?

- Occurrence/frequency of biofilm in DUWL - distribution and surface area.
- Bacteria in biofilms - makeup of biofilms and planktonic populations in effluent.
- Association of water quality to biofilm buildup.

Question 5: Is sufficient data provided to supplement any of the claims mentioned in Question 1.

Yes, see comments in Question 1.

Question 6: If the data are insufficient, what information would be needed from field trials to support claims of removal, prevention or suppression?

- More locations - run "blind" tests to confirm laboratory test data.
- Provide standardized approach for monitoring the outcome of treatment.

Conclusions and Recommendations:

- It is the opinion of this reviewer that the methods used to measure the various claims (removal, prevention/suppression) are scientifically-sound for this type of product and use site. However, there are significant deficiencies in the test method protocol which impairs the comparative value of the data submitted and the ability of other testing labs to conduct/reproduce the methodology.
- Efficacy testing using a laboratory-generated biofilm (biofilm reactor) should be

considered; the test protocol presented here (materials) is too complex for a standard microbiology laboratory to conduct.

- I would strongly recommend a complete statistical analysis of the entire data set prior to continuing this project.
- Following the development of the test protocol, method validation is highly recommended. The reliability and practicality of this method has not been determined through standard method validation procedures. Method validation through organizations such as ASTM and AOAC should be pursued.

Please contact me if you have any questions regarding my comments or require further assistance on this project.

EPA Reg File # 6376/5

Page_____ is not included in this copy.

Pages 57 through 60 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

X Internal Deliberative

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 28 2002

Ms. Sally Hayes
Agent for Sterilex
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Sterilex Ultra Powder
EPA File Symbol: 63761-L
Submission Date: February 7, 2002
EPA Receipt Date: February 8, 2002

Dear Ms. Hayes,

The application referenced above submitted in connection with registration under FIFRA to register 63761-L is unacceptable.

Product Chemistry

The submitted product chemistry data in MRID No. 444897-01 satisfy registration requirements of Series 830 guidelines. The Confidential Statement of Formula dated January 18, 2002 is acceptable. It is in agreement with the label and in compliance with PR Notice 91-2.

We have reviewed your write-up explaining why "sodium percarbonate is not an active ingredient." In response, it has been determined that sodium percarbonate must be characterized as an active ingredient in this product formulation. First, the Agency is not dividing biofilm into public health and non-public health entities for this type of product. We consider biofilm to be a public health claim, and your product forms the hydrogen peroxide which is essential in removing the biofilm matrix from the dental water line. Secondly, "sodium percarbonate is only a perhydrate; it has the composition $Na_2CO_3.1.5H_2O_2$" according to Industrial Inorganic Chemistry, Butchner et. al. Sodium percarbanate is essentially hydrogen peroxide in a sodium carbonate matrix. Lastly, hydrogen peroxide is a versatile chemical which has the capability of reacting under acidic and basic conditions. If it follows a different reactivity route under acidic and basic conditions, it does not take away the nature of hydrogen peroxide.

You should note the there are several pending registration applications containing sodium percarbonate as the active ingredient. Also, a FR Notice was published citing the receipt of sodium percarbonate as a new active ingredient.

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CONCURRENCES

MBOL

Acute Toxicology

The following acute toxicity profile is for the undiluted product formulation:

Data Requirement	Means of Support	Status/ Tox. Category
Acute Oral Toxicity	Submitted study, MRID 445927-03	Acceptable/ III
Acute Dermal Tox.	Submitted study, MRID 445927-03	Acceptable/III
Acute Inhalation Tox.	Waived	II
Eye Irritation	Self-Validated	I
Skin Irritation	Self-Validated	I
Skin Sensitization	Waived	Non-sensitizer

Signal: **Danger**

Precautionary Statements
Hazard to Humans and Domestic Animals
Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Do not breathe dust vapor or spray mist. Wear protective eyewear (goggles or face shield.), clothing, and waterproof gloves. For handling activities, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Under the "First Aid" statements, you must address every route of exposure for the undiluted product. You must add labeling for "If inhaled":

If 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 assistance.

The following profile is in support of the use dilution of 12.5 grams in 250 ml of water:

Data Requirement	Means of Support	Status/ Tox. Category
Acute Oral Toxicity	Use dilution labeling rationale	IV
Acute Dermal Tox.	Submitted study, MRID 455786-02	Acceptable/IV
Acute Inhalation Tox.	Use dilution labeling rationale	III
Eye Irritation	Submitted study, MRID 455786-03	III
Skin Irritation	Submitted study, MRID 455786-04	III
Skin Sensitization		outstanding

The use dilution labeling for systemic toxicity routes such as acute oral and inhalation can be supported by calculations. Most systemic toxicity categories span an order of magnitude

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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CONCURRENCES

YMBOL								

whereas use dilutions are an order of magnitude or more, typically, bumping the systemic toxicity categories up by at least one. Using this rationale, the use dilution labeling for acute oral is bumped to tox. IV and acute inhalation is bumped to tox. III.

You should note that the use dilution labeling rationale does not support primary eye irritation, primary skin irritation, or dermal sensitization. You submitted studies for primary eye and skin irritation; however, dermal sensitization study was not submitted. You must address the dermal sensitization data requirement.

The following use dilution labeling must appear in italic after the general precautionary statements: *Causes moderate eye irritation. Harmful if absorbed through the skin and/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.*

Efficacy

We will not accept the proposed claim, "disinfects biofilm bacteria" based on the proposed performance standard, "90% of biofilm samples demonstrate < 200 cfu/cm^2." The Agency has an established performance standard that must be met when using the term, "disinfectant" on a label. You will either need to submit data that supports the our current disinfectant standard or delete "disinfection of biofilm bacteria" claims from the label. We will comment on the other claims proposed for this product after we have received comments from our "expert panel's" review of your protocol.

General Comments

This letter does not constitute registration, and the product cannot be lawfully marketed until it is registered. The Agency cannot complete its assessment of your product until the required data has been submitted and reviewed, and the Agency has accepted the proposed efficacy protocol. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Tracy Lynch

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

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Form Approved. OMB No. 2070-0060. Approval Expires 5-31-98.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
The Sterilex Corporation 7-I Gwynns Mill Court Owings Mill, MD 21117	63761-x
	Product Name Sterilex Ultra Powder
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 01/18/02

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

n-Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
n-Alkyl (C14 95%, C12 3%, C16 2%) dimethylbenzyl ammonium chloride dihydrate	[redacted]	[redacted]

Signature	Name and Title	Date
Sally Hayes	Sally Hayes, Agent	01/18/02

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

★ U.S. GPO: 1995-388-820/20413

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 11, 2002

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 63761-L/ Sterilex Ultra Powder
DP Barcode: D281534

To: Velma Noble, PM 31 / Jackie Campbell
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Sterilex Corporation

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
n-Alkyl dimethyl benzyl ammonium chloride dihydrate	10
Other Ingredient(s):	90
Total:	100%

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BACKGROUND: The Sterilex Corporation has submitted a set of three acute toxicity studies to support the registration of their product, "Sterilex Ultra Powder". The three studies were conducted by Product Safety Labs. The MRID Numbers are 455876-02 through 455876-04.

This submission includes an acute toxicology support scheme (MRID Number 455876-01). In this report, the registrants state that 63761-L is substantially similar to 63761-2. In order to have an acute toxicity profile for the use-dilution of 63761-L, the registrant has submitted an acute dermal toxicity study (455876-02), a primary eye irritation study (455876-03) and a primary skin irritation study (455876-04). As the product is diluted prior to use, these three studies were conducted on the diluted product. The registrant is citing the acute oral toxicity, acute dermal toxicity, and acute inhalation toxicity studies derived from 63761-2 to support the granular (undiluted) version of 63761-L.

A comment in the review of 63761-2 states that label should state: "May be fatal if inhaled." This will be recommended for 63761-L. The decision to retain this precautionary statement for acute inhalation toxicity category II will be left to the discretion of the Product Manager.

RECOMMENDATIONS: PSB findings are:

1. MRID Numbers 455786-02, -03 and -04: The acute dermal toxicity, primary eye irritation and primary skin irritation studies are acceptable. ***However, these studies are only acceptable to represent the acute dermal toxicity hazards posed by the product** at **a use-dilution of 12.5 grams to 250 mL of H2O.**

2. PSB/AD agrees that 63761-L is substantially similar to Registration Number 63761-2. The acute toxicity profile for 63761-L will be based upon that of 63761-2 (with the exception of the dermal sensitization study), with the addition of the 3 newly submitted studies to cover exposure to the use dilution.

3. PSB/AD requests that the registrant submit a dermal sensitization study to support the use-dilution of 63761-L. The problem is that apparently the dermal sensitization study was previously waived due to the primary skin irritation category (I) of the undiluted/ solid form of the product. The primary skin irritation study included with this submission (MRID Number 455786-04) was assigned toxicity category III. Thus, the dermal sensitization study cannot be waived due to the use-dilution being corrosive, it is not.

The acute toxicity profile for the (12.5 grams to 250 mL of water) use-dilution of File Symbol 63761-L is currently:

acute oral toxicity		No data submitted
acute dermal toxicity	*IV	Acceptable

acute inhalation toxicity		No data submitted
primary eye irritation	*III	Acceptable
primary skin irritation	*III	Acceptable
dermal sensitization		No data submitted

The acute toxicity profile for 63671-2 (from a 12/23/98 ESSB/AD review) is:

acute oral toxicity	III	Acceptable
acute dermal toxicity	III	Acceptable
acute inhalation toxicity	II	Waived
primary eye irritation	I	Self-validated
primary skin irritation	I	Self-validated
dermal sensitization	Nonsensitizer	Waived

LABELING:

1. The signal word for Registration Number 63761-L (the undiluted product) is "DANGER".

2. The Precautionary Statements for Registration Number 63761-L (the undiluted product) are:

   "Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Do not breathe dust vapor or spray mist. Wear protective eyewear (goggles or face shield). Wear protective clothing and waterproof gloves. For handling activities, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse."

3. The First Aid Statements (derived from PR-Notice 2001-1) for Registration Number 63761-L (the undiluted product) are:

   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 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:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to do so.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled (the PM may decide not to include acute inhalation toxicity category II First Aid Statements):

- 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.

4. No precautionary labeling can be recommended until the registrant properly addresses the dermal sensitization study for the use-dilution of 63761-L.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 31
MRID No.: 455876-02

Reviewer: Ian Blackwell
Study Completion Date: 11/21/01
Lab Study No.: 11191

Testing Laboratory: Product Safety Labs
Author: Daniel J. Merkel
Quality Assurance (40 CFR §160.12): Included

Test Material: Sterilex Ultra Powder, pink granular powder.

Species: Sprague-Dawley rats
Weight: males = 240-276 g; females = 200-210 g
Age: 8-9 weeks
Source: Ace Animals, Inc.

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5,000
   Females > 5,000
   Combined > 5,000

2. **The estimated LD_{50} is greater than 5,000 mg/kg of body weight.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2):
☞Prior to use, the test material was diluted to a use-dilution by placing 12.5g of the solid into 250 mL of water.

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: No abnormalities were observed.

Gross Necropsy Findings: No abnormalities were observed.

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

Product Manager: 31
MRID No.: 455876-03

Reviewer: Ian Blackwell
Study Completion Date: 11/21/2001
Report No.: 11192

Testing Laboratory: Product Safety Labs
Author(s): Daniel J. Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Sterilex Ultra Powder, pink granular powder
Dosage: 0.1 mL (of a 12.5 g to 250 mL H_2O dilution)
Species: New Zealand White rabbit
Sex: 2 males + 1 female
Weight: not reported
Age: young adult
Source: Davidson's Mill Farm

Summary:

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

Procedure (Deviations From §81-4):
☞The weight and age of the test animals were not reported.
☞The test material was diluted 12.5 g to 250 mL H_2O for testing.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	3/3	2/3	1/3	1/3	0/3	---	---
Iritis	0/3	0/3	0/3	0/3	0/3	0/3	—	—
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	0/3	0/3	—	—
Chemosis	0/3	0/3	0/3	0/3	0/3	0/3	—	—
Discharge	2/3	2/3	0/3	0/3	0/3	0/3	—	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31
MRID No.: 455876-04

Reviewer: Ian Blackwell
Study Completion Date: 11/21/2001
Lab Study No.: 11193

Testing Laboratory: Product Safety Labs
Author: Daniel J. Merkel

Quality Assurance (40 CFR §160.12): Included

Test Material: Sterilex Ultra Powder; pink granular powder
Dosage: 0.5 mL (of a 12.5 g to 250 mL H_2O dilution)
Species: New Zealand White rabbit
Age: young adult
Sex: 2 males + 1 female
Weight: not reported
Source: Davidson's Mill Farm

Summary:

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

Procedure (Deviations From §81-5):
☞The test material was diluted 12.5g to 250 mL H_2O.
☞The weights and ages of the test animals were not reported.

Results: One hour after the four hour exposure, 2/3 test animals displayed well-defined erythema with very slight edema; and on displayed very slight erythema only. Twenty-four hours after the exposure, 3/3 test animals displayed well-defined erythema with very slight edema. Forty-eight hours after exposure, 1/3 test animals displayed moderate-to-severe erythema, 2/3 well-defined erythema and 3/3 very slight edema. Seventy-two hours after exposure, 3/3 test animals displayed well-defined erythema with very slight edema. Seven days after exposure, 1/3 animals displayed very slight erythema. Ten days after the exposure, no irritation was observed.

Special Comments: None

FQPA

DP BARCODE: D281537

CASE: 071549
SUBMISSION: S611995

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/12/02

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 188 FQPA-OC-ME TOO ADDL USE
CHEMICALS: 069184 Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 10.0000%

ID#: 063761-L STERILEX ULTRA POWDER
COMPANY: 063761 STERILEX CORP, THE
PRODUCT MANAGER: 31 VELMA NOBLE 703-308-6233 ROOM: CS1 6W18
PM TEAM REVIEWER: JACKIE CAMPBELL 703-308-6416 ROOM: CS1 6W1
RECEIVED DATE: 02/28/02 DUE OUT DATE: 06/28/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 281537 EXPEDITE: Y DATE SENT: 03/12/02 DATE RET.: / /
CHEMICAL: 069184 Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : AD	3/12/02	/ /
BRAN: PSB	3/12/02	/ /
SECT: CTT	3/12/02	/ /
REVR : Chris	3/13/02	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 06/15/02
NEGOT DATE: 5/28/02
PROJ DATE: 5/14/02

* * * DATA REVIEW INSTRUCTIONS * * *

Product chemistry data in MRID Nos. 44897-1 and 44897-2 have been cited to support this product's registration. This product is identical to EPA Reg. No. 63761-4. The CSF is included for your review.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
281534	PSB/CTT	03/12/02	06/15/02	Y	Y	Y

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N/FT

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

B

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[✓] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 288624

Application for Pesticide - Section I

1. Company/Product Number: 63761-~~x~~ L	2. EPA Product Manager: V. Noble	3. Proposed Classification: [✓] None [ ] Restricted
4. Company/Product (Name): Sterilex Ultra Powder	PM#: 31	
5. Name and Address of Applicant (Include ZIP Code): Sterilex Corporation, 7-I Gwynns Mill Court, Owings Mills, MD 21117 [ ] Check if this is a new address	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 63761-4 Product Name: Ultra Kleen Powder for DUWL	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[✓] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Registration using old active

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[✓] Yes [ ] No	[ ] Yes [✓] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [✓] Other (Specify) Multilayer film
Certification must be submitted	If "Yes" Unit Packaging wgt. 0.44 oz. / No. per container 20	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[✓] Label [ ] Container	8.82 oz.	[✓] Label, package insert or box

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other Preprinted multilayer film

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sally Hayes	Agent for Sterilex Corporation	260-244-6270

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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received _____ (Stamped)

2. Signature: Sally Hayes	3. Title: Agent for Sterilex Corporation
4. Typed Name: Sally Hayes	5. Date: 01/18/02

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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

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2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
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2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

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1-5. Self-explanatory.
6. EPA Use Only.

75

N/FT

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [x] Registration
- [ ] Amendment
- [ ] Other

OPP Identifier Number: 288278

Application for Pesticide - Section I

1. Company/Product Number: 63761-*T	2. EPA Product Manager: V. Noble	3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): Sterilex Ultra Liquid J Solution 2	PM#: 31	
5. Name and Address of Applicant *(Include ZIP Code)*: Sterilex Corporation, 7-I Gwynns Mill Court, Owings Mills, MD 21117 [ ] *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 63761-4 Product Name: Ultra Kleen Powder for DUWLs	

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in ropsonse to Agency letter dated _____
- [x] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Registration using old active

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistent Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [x] Label [ ] Container	4. Size(s) Retail Container: 32 fluid oz.	5. Location of Label Directions: [x] Label or package insert

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [x] Other clear plastic label, glued to bottle

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Sally Hayes	Agent for Sterilex Corporation	260-244-6270

Certification

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4. Typed Name: Sally Hayes	5. Date: 01/30/02

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3. Proposed Classification - Specify the proposed classification of this product.
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5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1-5. Self-explanatory.
6. EPA Use Only.

11

* U.S. GOVERNMENT PRINTING OFFICE: 2001-620-288
20690

N/FT

B

SRC
Scientific & Regulatory
Consultants, Inc.

February 7, 2002

Ms. Velma Nobel, PM-31
Document Processing Desk (APPL)
OPP (7504C)
EPA
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Velma:

SUBJECT: Sterilex Ultra Liquid J Solution 2
EPA Reg. No. 63761-x

On behalf of Sterilex Corporation, enclosed is a submission for the above product. This product, when combined with Sterilex Ultra Liquid J Solution 1 (required per manufacturer's label directions), is substantially similar to a dilution of Ultra-Kleen Powder for Dental Unit Waterlines, EPA Reg. No. 63761-4.

Attached is a confidential discussion explaining why Sterilex Ultra Liquid J Solution 1 does not contain an active ingredient. The statement of formula for the non-antimicrobial Solution 1 is located in Volume 2. A label for Solution 1 is enclosed in Volume 1 for your review.

This product is designed to remove, disinfect and prevent biofilms in dental unit water lines. On December 6, 2001 Sterilex met with EPA to present a draft interim guideline for the determination of efficacy in Biofilm Matrix Removal, Disinfection of Biofilm Bacteria and Prevention/ Suppression of Biofilm Formation. The label claims for this product are based on the criteria proposed in the draft interim guideline presented at that meeting.

If any questions arise during the review of this submission, please contact me immediately.

Sincerely,

Sally Hayes (B)
Sally Hayes

cc: S. Kramer

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P.O. Box 1014 Columbia City, IN 46725 Phone: 219-244-6270 Fax: 219-244-6273

N|F7

B

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Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [x] **Registration**
- [ ] **Amendment**
- [ ] **Other**

OPP Identifier Number 288277 ~~259573~~

Application for Pesticide - Section I

1. Company/Product Number 63761-~~x~~ A	2. EPA Product Manager V. Noble	3. Proposed Classification [x] None [ ] Restricted
4. Company/Product (Name) Sterilex Ultra Liquid B Solution 2	PM# 31	
5. Name and Address of Applicant *(Include ZIP Code)* Sterilex Corporation 7-I Gwynns Mill Court Owings Mills, MD 21117 [ ] *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 63761-3 Product Name Ultra Kleen Solution 1	

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
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6. EPA Use Only.

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20690

EPA Reg File #6376-5

Page_____ is not included in this copy.

Pages 81 through 84 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 24, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Sterilex Ultra Powder

DP Barcode: D281537 **Reg. No. Or File Symbol: 63761-L**
Manufacturing-use [] OR **End-use Product [X]**

TO: Velma Noble\Jacqueline McFarlane
PM Team No. 31

FROM: Chris Jiang, Chemist CJ
Product Science Branch
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CTT Team Leader CJ for KPH
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele Wingfield, Branch Chief [signature] for Michele Wingfield 5/24/02
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation for Sterilex Ultra Powder

Active Ingredient(s)	**% by wt.**
n-Alkyl (C_{14} 95%, C_{12} 3%, C_{16} 2%) dimethyl benzyl ammonium chloride dihydrate PC Code: 069184	10 %

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BACKGROUND:

The registrant has submitted a package in support of a "me-too" registration (of 63761-4) of an end-use disinfectant to be used for the prevention and removal of biofilms in dental water lines. Because the chemical composition is identical to 63761-4, the registrant has chosen to support the registration of the product by citing their own data. The package includes a Confidential Statement of Formula, a label, and a data matrix.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 1/18/02) is consistent with that declared on the label.

2. All ingredients in the formulations are cleared for use in pesticides.

3. The percentages of the ingredients in the each of the formulations total 100.0.

4. The certified limits are calculated correctly and are **acceptable.**

9. The data for product chemistry cited in the data matrix is **acceptable.**

10. All waiver requests for required data (flammability, explodability, miscibility, and dielectric breakdown voltage) are granted. The other waiver requests (melting point, boiling point, water solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, and stability) are data requirements that are not required for end-use products.

11. The set of product chemistry data is complete. Please see the summary of the product chemistry data attached below.

RECOMMENDATIONS:

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 63761-L to be acceptable.

PRODUCT CHEMISTRY REVIEW

2. CONFIDENTIAL STATEMENT OF FORMULA

2a. Type of formulation and source registration
- Non-integrated formulation system [X]
- Are all TGAI used registered? Yes [X] No []

- Integrated formulation system []

- if "ME-TOO", specify EPA Reg. # of existing product: 63761-4

2b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [ ] NA [X]

2c. Physical state of product: Solid

2d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes [X] No [ ]

2e. NCs and CLs are acceptable: [X] Not acceptable [ ]

2f. Active ingredient (s)	NC	UCL	LCL
A. n-Alkyl (C_{14} 95%, C_{12} 3%, C_{16} 2%) dimethyl benzyl ammonium chloride dihydrate	10 %	10.50 %	9.50 %

2g. For products produced by an integrated formulation system:
- All impurities of toxicological significance have a UCL?
  Yes [ ] No [] Not applicable [ ]

- All impurities of $\geq$ 0.1% in the product have been identified?
  Yes [] No [ ] Not applicable [ ]

3. PRODUCT LABEL

3a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

3b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

3c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [ ]

3d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

3e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No [ ]

3f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [X]

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix)[1]	A	CSF dated 1/18/02
830.1600 Description of Materials	A	444897-01
830.1620 Manufacturing Process[2]	A	444897-01
830.1650 Formulation Method[3]	NA	
830.1670 Discussion of Impurities[4]	A	444897-01
830.1700 Analysis[5]	A	444897-01
830.1750 Certified Limits[6]	A	CSF dated 1/18/02
830.1800 Analytical Method for AIs[7]	A Titration	444897-02

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required,
G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information

[2]For MP/EP products produced by an integrated formulation system.

[3]For products from a TGAI or MP.

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated formulation system.

[6]If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Physical and Chemical Characteristics (Series 830, Part B)

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	White	444897-01
830.6303 Physical State	A	Solid	444897-01
830.6304 Odor	A	Odorless	444897-01
830.6313 Stability to Temps. Metal and Metal Ions	NR		
830.6314 Oxidation/Reduction	A	mod. oxid.	444897-01
830.6315 Flammability	W		
830.6316 Explodability	W		
830.6317 Storage Stability	A	acc. under D251552	444897-02
830.6320 Corrosion Character.	A	NC with HDPE	444897-01
830.7000 pH	A	10.8-10.9 (1% solution)	444897-01
830.7100 Viscosity	NA		444897-01
830.7300 Density/Specific gravity	A	1.105-1.120 g/mL	444897-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25°C.

In. nt Notice:
Before using Sterilex Ultra Powder 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 Powder 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.
3. If two or more weekly treatments are skipped, repeat 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 Powder 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 Powder mixture through the system until the pink mixture appears at the end of the A/W Syringe and Handpiece Line. Always remove the Handpiece before treating the line.
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.

EPA Reg. No.: 63761-x
Made in USA 011502

STERILEX
Solutions for Biofilm

Sterilex Ultra Powder

- Removes biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Disinfects biofilm bacteria
- Maintains dental unit water line effluent water <200 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.

* Control of bacterial contamination in the circulating water 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%) dimethyl benzyl ammonium chloride dihydrate...10.0%
Other Ingredients.....90.0%
TOTAL 100.0%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

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

STERILEX CORPORATION
7-I Gwynns Mills Court
Owings Mills, MD 21117
Phone: 1-800-511-1659 Fax: 410-581-8864

Net weight: 0.44 oz. (12.5 em)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. DANGER. Powder corrosive to skin and eyes. Powder causes irreversible eye damage and skin burns. *(After proper dilution, the product causes moderate eye irritation and minimal skin irritation.)* Harmful if powder is swallowed or absorbed through skin. *(After proper dilution, the product is not an ingestion or absorption hazard.)* Wear goggles and/or face shield, protective clothing and rubber gloves. *(After proper dilution, goggles, face shield, or gloves are not required.)* Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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: Remove 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. *(After proper dilution, oral ingestion hazards are not indicated.)*

STORAGE AND DISPSOSAL

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.

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FQPA

DP BARCODE: D281534

CASE: 071549 DATA PACKAGE RECORD DATE: 03/12/02
SUBMISSION: S611995 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 188 FQPA-OC-ME TOO ADDL USE
CHEMICALS: 069184 Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 10.0000%

ID#: 063761-L STERILEX ULTRA POWDER
COMPANY: 063761 STERILEX CORP, THE
PRODUCT MANAGER: 31 VELMA NOBLE 703-308-6233 ROOM: CS1 6W18
PM TEAM REVIEWER: JACKIE CAMPBELL 703-308-6416 ROOM: CS1 6W1
RECEIVED DATE: 02/28/02 DUE OUT DATE: 06/28/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 281534 EXPEDITE: Y DATE SENT: 03/12/02 DATE RET.: / /
CHEMICAL: 069184 Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : AD	3/12/02	/ /
BRAN: PSB	3/12/02	/ /
SECT: CTT	3/12/02	/ /
REVR : JMB	3/13/02	6/11/02
CONTR:	/ /	/ /

ADMIN DUE DATE: 06/15/02
NEGOT DATE: 5/28/02
PROJ DATE: 5/14/02

* * * DATA REVIEW INSTRUCTIONS * * *

This product is identical to 63761-4. MRID Nos. 445156-1 was cited for acute oral toxicity, and administration letter dated 9/21/98 cited for acute inhalation.

Please review the acute toxicology data in MRID Nos. 4558760-01 thru 455876-04 for Ultra Powder, a dental water line disinfectant.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
281537	PSB/CTT	03/12/02	06/15/02	Y	Y	Y

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Important Notice:
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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.
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6. Fill the external water bottle with hot water. Flush each line (A/W Syringe, Handpiece) until the bottle is empty.

EPA Reg. No.: 63761-x
Made in USA 011502

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Solutions for Biofilm

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- Removes biofilm from dental unit water lines
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* Control of bacterial contamination in the circulating water 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%) dimethyl benzyl ammonium chloride dihydrate...10.0%
Other Ingredients.....90.0%
TOTAL 100.0%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

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

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Owings Mills, MD 21117
Phone: 1-800-511-1659 Fax: 410-581-8864

Net weight: 0.44 oz. ~~(12.6 gm)~~

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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.

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[One of the following statements may appear on the product label, promotional material and/or box.]

Sterilex Ultra Powder is accepted as being safe and effective for the management of biofilm to provide unfiltered water containing not more than 200 colony forming units per mL of aerobic, mesophilic, heterotrophic bacteria in dental unit waterlines when used as directed. Council on Scientific Affairs, American Dental Association

Sterilex Ultra Powder is accepted as being safe and effective for cleaning deposits and controlling aerobic, mesophilic, heterotrophic bacterial contamination in dental unit waterlines when used as directed. Council on Scientific Affairs, American Dental Association

[Insert American Dental Association Seal of Approval]

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 204660

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 01/18/02	EPA Reg No./File Symbol 63761-x	Page 2 of 2
Applicant's/Registrant's Name & Address Sterilex Corporation, 7-I Gwynns Mill Court, Owings Mill, MD 21117	Product Sterilex Ultra Powder	

Ingredient n-Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate CAS No. 8001-54-5 68424-85-1 139-08-2

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1	Acute oral toxicity	44515601	Sterilex	Own	
81-2	Acute dermal toxicity	Waive	Sterilex	Own	
81-3	Acute inhalation	Admin. 9/21/98	Sterilex	Own	
81-4	Primary eye irritation	44515602	Sterilex	Own	
81-5	Primary dermal irritation	44515603	Sterilex	Own	
81-6	Dermal sensitization	Waive	Sterilex	Own	
81-2	Acute dermal toxicity (diluted)	Not yet assigned	Sterilex	Own	
81-4	Primary eye irritation (diluted)	Not yet assigned	Sterilex	Own	
81-5	Primary dermal irritation (diluted)	Not yet assigned	Sterilex	Own	
91	Biofilm Study	Not yet assigned	Sterilex	Own	
91	Biofilm Study	Not yet assigned	Sterilex	Own	
91	Biofilm Study	Not yet assigned	Sterilex	Own	
91	Biofilm Study	Not yet assigned	Sterilex	PL	
91	Biofilm Study	Not yet assigned	Sterilex	PL	
91-2	AOAC Use Dilution Method	Not yet assigned	Sterilex	Own	

Signature Sally Hayes	Name and Title Sally Hayes, Agent	Date 01/18/02

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 01/18/02	EPA Reg No./File Symbol 63761-x	Page 1 of 2
Applicant's/Registrant's Name & Address Sterilex Corporation, 7-I Gwynns Mill Court, Owings Mill, MD 21117	Product Sterilex Ultra Powder	

Ingredient n-Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydratetc CAS No. 8001-54-5 68424-85-1 139-08-2

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1	Product identity and composition	44489701	Sterilex	Own	
61-2	Description of beginning materials & mfg process	44489701	Sterilex	Own	
61-3	Discussion of formation of impurities	44489701	Sterilex	Own	
62-1	Preliminary analysis of product samples	44489701	Sterilex	Own	
62-2	Certification of ingredient limits	44489701	Sterilex	Own	
62-3	Analytical methods	44489701	Sterilex	Own	
63-2	Color	44489701	Sterilex	Own	
63-3	Physical state	4448970)	Sterilex	Own	
63-4	Odor	44489701	Sterilex	Own	
63-12	pH	44489701	Sterilex	Own	
63-14	Oxidizing/reducing action	44489701	Sterilex	Own	
63-7	Bulk density	44489701	Sterilex	Own	
63-17	Storage stability	44489702	Sterilex	Own	
63-18	Viscosity	44489701	Sterilex	Own	
63-20	Corrosion characteristics	44489701	Sterilex	Own	

Signature Sally Hayes	Name and Title Sally Hayes, Agent	Date 01/18/02

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registratio and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sterilex Corporation, 7-I Gwynn Mills Court, Owings Mills, MD 21117	EPA Registration Number/File Symbol 63761-x 5
Active Ingredient: n-Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate	Date: 01/18/02
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Dental Unit Water Lines	Product Name Sterilex Ultra Powder

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
Sally Hayes	01/18/02	Sally Hayes, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

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

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2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra Powder 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.

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2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatment.
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5. At the beginning of the next workday, discard any remaining mixture in external water bottle. Rinse the external water bottle with hot water.
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EPA Reg. No.: 63761-x
Made in USA 011502

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- Prevents and suppresses formation of biofilm in dental unit water lines
- Disinfects biofilm bacteria
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* Control of bacterial contamination in the circulating water is affected by the quality of incoming water. Sterile water is recommended by OSAP.

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n-Alkyl (C_{14} 95%, C_{12} 3%, C_{16} 2%) dimethyl benzyl ammonium chloride dihydrate... 10.0%
Other Ingredients.....90.0%
TOTAL 100.0%

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

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(After proper dilution, oral ingestion hazards are not indicated.)

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98

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[Insert American Dental Association Seal of Approval]

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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.
3. If two or more weekly treatments are skipped, repeat 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 Powder 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 Powder mixture through the system until the pink mixture appears at the end of the A/W Syringe and Handpiece Line. Always remove the Handpiece before treating the line.
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.

EPA Reg. No.: 63761-x
Made in USA 011502

STERILEX
Solutions for Biofilm.

Sterilex Ultra Powder

- Removes biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Disinfects biofilm bacteria
- Maintains dental unit water line effluent water <200 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.

* Control of bacterial contamination in the circulating water 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%) dimethyl benzyl ammonium chloride dihydrate...10.0%
Other Ingredients.....90.0%
TOTAL 100.0%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

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

STERILEX CORPORATION
7-I Gwynns Mills Court
Owings Mills, MD 21117
Phone: 1-800-511-1659 Fax: 410-581-8864

Net weight: 0.44 oz. (12.5 gm)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. DANGER. Powder corrosive to skin and eyes. Powder causes irreversible eye damage and skin burns. *(After proper dilution, the product causes moderate eye irritation and minimal skin irritation.)* Harmful if powder is swallowed or absorbed through skin. *(After proper dilution, the product is not an ingestion or absorption hazard.)* Wear goggles and/or face shield, protective clothing and rubber gloves. *(After proper dilution, goggles, face shield, or gloves are not required.)* Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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: Remove 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. *(After proper dilution, oral ingestion hazards are not indicated.)*

STORAGE AND DISPSOSAL

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.

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[One of the following statements may appear on the product label, promotional material and/or box.]

Sterilex Ultra Powder is accepted as being safe and effective for the management of biofilm to provide unfiltered water containing not more than 200 colony forming units per mL of aerobic, mesophilic, heterotrophic bacteria in dental unit waterlines when used as directed. · Council on Scientific Affairs, American Dental Association

Sterilex Ultra Powder is accepted as being safe and effective for cleaning deposits and controlling aerobic, mesophilic, heterotrophic bacterial contamination in dental unit waterlines when used as directed. Council on Scientific Affairs, American Dental Association

[Insert American Dental Association Seal of Approval]

FOR OFFICIAL USE ONLY

FILE SYMBOL
6376/2
REGISTRATION NO

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
1/23/02		

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

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(JULY 1970)

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USDA-AR

EPA Reg File #1037615

Page_____ is not included in this copy.

Pages 103 through 105 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

✓ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.