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DATA MATRIX

Date September 6, 2018	EPA Reg. No./File Symbol **63761-8**	Page 1 of 11
Applicant's/Registrant's Name & Address: **Sterilex, LLC, 111 Lake Front Drive, Hunt Valley, MD 21030**	Product **Sterilex Ultra Disinfectant Cleaner Solution 1**	

Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Properties					
830.1550/61-1	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	
830.1550	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.1600/61-2	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	
830.1600	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.1620	Waiver Request for Product Property Data Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-30932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-008	49756703	Sterilex, LLC	OWN	
830.1650/61-2	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	
830.1650	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.1670/61-3	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	
830.1700/62-1	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	

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	John Reilly Manager of Regulatory Affairs	September 6, 2018

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Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1750/62-2	Product Chemistry for Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: UK1/PC001	46033501	Sterilex, LLC	OWN	
830.1750	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.1800/62-3	Product Identity, Composition, and Analysis Test Guidelines Physical/Chemical Properties Test Guidelines: Sterilex Ultra Liquid B Solution 2.	45604701	Sterilex, LLC	OWN	
830.1800/62-3	Ultra-Kleen Solution 1: Product Chemistry, Product Identity and Composition, Analysis Certification of Product Ingredients.	44592701	Sterilex, LLC	OWN	
830.1800/62-3	Product Chemistry Data in Support of Registration of FMC Corporation's B-CAP 70 (Active Ingredient Hydrogen Peroxide): Preliminary Analysis, Certification of Limits, and Enforcement Analytical Methods: Lab Project Number: FMC-H2O2-70-62-98.001	44824403	FMC Corporation	OLD	
830.1800	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.6302/63-2	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6302	Sterilex Ultra Disinfectant Cleaner Solution 1: Product Properties; Study No. SC 15-002	49756702	Sterilex, LLC	OWN	
830.6303/63-3	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6303	Physical and Chemical Characteristics	49756704	Sterilex, LLC	OWN	

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Applicant's/Registrant's Name & Address: **Sterilex, LLC, 111 Lake Front Drive, Hunt Valley, MD 21030**	Product **Sterilex Ultra Disinfectant Cleaner Solution 1**	

Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	of Sterilex Ultra Disinfectant Cleaner Solution 1: Physical State, Oxidation/Reduction, Viscosity and Relative Density; Study No. 5810-09				
830.6304/63-4	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6314/63-14	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6314	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Physical State, Oxidation/Reduction, Viscosity and Relative Density; Study No. 5810-09	49756704	Sterilex, LLC	OWN	
830.6315	Waiver Request for Product Property Data Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-30932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-008	49756703	Sterilex, LLC	OWN	
830.6316	Waiver Request for Product Property Data Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-30932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-008	49756703	Sterilex, LLC	OWN	
830.6317/63-17	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6317/63-17	Final Report: Storage Stability of Sterilex Ultra Disinfectant Cleaner	46793301	Sterilex, LLC	OWN	

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Applicant's/Registrant's Name & Address: **Sterilex, LLC, 111 Lake Front Drive, Hunt Valley, MD 21030**	Product **Sterilex Ultra Disinfectant Cleaner Solution 1**	

Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Solution 1				
830.6317/63-17	Storage Stability of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: BATCH/ED/III/202/1	47239301	Sterilex, LLC	OWN	
830.6317	Interim Report – Sterilex Ultra Disinfectant Cleaner Solution 1 3, 6 month Storage Stability, Corrosion and pH Data; Study No. SC 15-013	49756705	Sterilex, LLC	OWN	
830.6319	Waiver Request for Product Property Data Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-30932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-008	49756703	Sterilex, LLC	OWN	
830.6320/63-20	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.6320/63-20	Final Report: Storage Stability of Sterilex Ultra Disinfectant Cleaner Solution 1	46793301	Sterilex, LLC	OWN	
830.6320	Interim Report – Sterilex Ultra Disinfectant Cleaner Solution 1 3, 6 month Storage Stability, Corrosion and pH Data; Study No. SC 15-013	49756705	Sterilex, LLC	OWN	
830.6321	Waiver Request for Product Property Data Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-30932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-008	49756703	Sterilex, LLC	OWN	
830.7000/63-12	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project	46360001	Sterilex, LLC	OWN	

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Applicant's/Registrant's Name & Address: **Sterilex, LLC, 111 Lake Front Drive, Hunt Valley, MD 21030**	Product **Sterilex Ultra Disinfectant Cleaner Solution 1**	

Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Number: 040317, 040412, 04021				
830.7000	Interim Report – Sterilex Ultra Disinfectant Cleaner Solution 1 3, 6 month Storage Stability, Corrosion and pH Data; Study No. SC 15-013	49756705	Sterilex, LLC	OWN	
830.7100/63-18	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.7100	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Physical State, Oxidation/Reduction, Viscosity and Relative Density; Study No. 5810-09	49756704	Sterilex, LLC	OWN	
830.7300/63-7	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Final Report. Project Number: 040317, 040412, 04021	46360001	Sterilex, LLC	OWN	
830.7300	Physical and Chemical Characteristics of Sterilex Ultra Disinfectant Cleaner Solution 1: Physical State, Oxidation/Reduction, Viscosity and Relative Density; Study No. 5810-09	49756704	Sterilex, LLC	OWN	
Toxicity					
870.1100/81-1	Acute Oral Toxicity in Rats-Median Lethal Dosage Determination: Ultra-Kleen Liquid Solution: Lab Project Number: 97-8409-21	44592703	Sterilex, LLC	OWN	
870.1100	Acute Oral Toxicity Study in Rats of	49756706	Sterilex, LLC	OWN	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Sterilex Ultra Disinfectant Cleaner Solution 1; Study No. 15-031-3				
870.1200	Acute Dermal Toxicity Study in Rabbits of Sterilex Ultra Disinfectant Cleaner Solution 1; Study No. 15-031-4	49756707	Sterilex, LLC	OWN	
870.1300	Acute Inhalation Toxicity Study in Rats of Sterilex Ultra Disinfectant Cleaner Solution 1; Study No. 15-031-6	49756708	Sterilex, LLC	OWN	
870.2400/81-4	Primary Eye Irritation in Rabbits without Rinsing: Ultra Kleen Liquid Solution: Lab Project Number: 96-8010-21	44592704	Sterilex, LLC	OWN	
870.2400	Waiver Request for Product Toxicology Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-90932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-009	49756709	Sterilex, LLC	OWN	
870.2500/81-4	Primary Skin Irritation Study in Rabbits: Ultra-Kleen Liquid Solution: Lab Project Number: 96-8009-21	44592705	Sterilex, LLC	OWN	
870.2500	Waiver Request for Product Toxicology Requirements (Antimicrobials) in Response to Quaternary Ammonium Data Call-in PDCI-069104-90932 and PDCI-069154-30949 for EPA Product Registrations 63761-3 and 63761-8; Study No. SC 15-009	49756709	Sterilex, LLC	OWN	
870.2600	Skin Sensitization Study in Guinea Pigs of Sterilex Ultra Disinfectant Cleaner Solution 1; Study No. 15-031-5	49756710	Sterilex, LLC	OWN	
Efficacy					

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Series 810	Sterilex Ultra Powder: Efficacy Discussion	45587605	Sterilex, LLC	OWN	
	AOAC Use Dilution Method: Ultra-Kleen CW-502HW: Final Study Report: Lab Project Number: 5045: SL112697.UD1.	45587606	Sterilex, LLC	OWN	
	Final Report for the Evaluation of Alkaline Peroxide Agent in the Disinfection/Disruption of Biofilm in Dental Unit Waterlines. Unpublished study prepared by University of Maryland.	45611601	Sterilex, LLC	OWN	
	Final Report for the Evaluation of An Alkaline Peroxide Agent in the Disinfection/Disruption of Biofilm in Dental Unit Waterlines. Unpublished study prepared by University of North Carolina at Chapel Hill.	45611602	Sterilex, LLC	OWN	
	Final Report for the Evaluation of An Alkaline Peroxide Agent in the Disinfection/Disruption of Biofilm in Dental Unit Waterlines.	45611603	Sterilex, LLC	OWN	
	Evaluation of A Hydrogen Peroxide Disinfectant for Dental Unit Waterlines. Journal of the American Dental Association 132 (Sep.):1287-1291.	45611604	Sterilex, LLC	OWN	
	Controlling Biofilm and Microbial Contamination in Dental Unit Waterlines. Journal of the California Dental Association 29:679-684	45611605	Sterilex, LLC	OWN	
	Efficacy Discussion: Sterilex Ultra Liquid B Solution 2	45604705	Sterilex, LLC	OWN	

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Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable): Enterobacter aerogenes, Staphylococcus aureus: Sterilex Ultra Disinfectant Cleaner Solution 1: Serilex Ultra Activator Solution: Final Report. Project Number: SLX01110311/NFS, A12359	49010901	Sterilex, LLC	OWN	
	AOAC Use-Dilution Method: Sterilex Ultra-Kleen Liquid Solution: Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis: Final Study Report. Project Number: 12958, SRC08022702/UD/1	46033502	Sterilex, LLC	OWN	
	AOAC Use-Dilution Test: Sterilex Ultra-Kleen Liquid: Escherichia coli: Final Study Report. Project Number: 12799, SRC08012202/UD/1.	46033503	Sterilex, LLC	OWN	
	AOAC Use-Dilution Method: Sterilex Ultra-Kleen Liquid: Listeria monocytogenes: Final Study Report. Project Number: 12798, SRC08012202/UD/2	46033504	Sterilex, LLC	OWN	
	AOAC Use Dilution Method: Ultra-Kleen Solution 1 and Ultra-Kleen Solution 2BHW: Final Study Report: Lab Project Number: 5510: SRC030698.UD	45604706	Sterilex, LLC	OWN	
	AOAC Use-Dilution Method: Ultra-Kleen Solution 1, Ultra-Kleen Solution 2: Zygosaccharomyces bailii: Final Study Report. Project Number: A01660, SLX01060903/UD	46561001	Sterilex, LLC	OWN	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Avian Influenza A (H3N2) Virus (Avian Reassortant): Sterilex Ultra Disinfectant Cleaner Solution 1. Project Number: A03805, SLX01121905/AFLU/1	46870101	Sterilex, LLC	OWN	
	Disinfectant Efficacy Testing for Sterilex Ultra Disinfectant. Project Number: M19238, M19239	47114501	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1282; S. aureus ATCC 6538	49756711	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1283; P. aeruginosa ATCC 15442	49756712	Sterilex, LLC	OWN	
810.2200	GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces; Study No. GLP 1287; Influenza A (H3N2), Strain A/Victoria/361/2011, ATCC/IRR FR-1061	49756713	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1289; A. niger ATCC 6275	49756714	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1290; L. monocytogenes ATCC 15313	49756715	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1291; S. enterica ATCC 10708	49756716	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1297; E. coli ATCC 35150	49756717	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1298; Z. parabailii ATCC 56075	49756718	Sterilex, LLC	OWN	

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Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP 1322; S. aureus ATCC 33591 (MRSA)	49756719	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP1269	49809101	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP1271	49809102	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP1272	49809103	Sterilex, LLC	OWN	
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP1302	49809104	Sterilex, LLC	OWN	
810.2200	GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces; Study No. GLP1274	49809105	Sterilex, LLC	OWN	
810.2200	GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces; Study No. GLP1287	49809106	Sterilex, LLC	OWN	
810.2200	GLP Evaluation of the Virucidal Efficacy of Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution on Inanimate, Nonporous Environmental Surfaces; Study No. GLP1314	49809107	Sterilex, LLC	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces; Study No. A17336	49809108	Sterilex, LLC	OWN	
810.2200	Virucidal Hard-Surface Efficacy Test: New Castle Disease Virus; Study No. 971-102		Sterilex, LLC	OWN	This submission
810.2200	GLP AOAC Use-Dilution Method; Study No. GLP1836		Sterilex, LLC	OWN	This submission

Signature	**Name and Title:** John Reilly Manager of Regulatory Affairs	**Date** September 6, 2018

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

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date September 6, 2018	EPA Reg. No./File Symbol **63761-8**	Page 11 of 11
Applicant's/Registrant's Name & Address: **Sterilex, LLC, 111 Lake Front Drive, Hunt Valley, MD 21030**	Product **Sterilex Ultra Disinfectant Cleaner Solution 1**	

Ingredient(s): **n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride; n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chloride; Hydrogen Peroxide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	GLP Single Tube Method for Measuring Disinfectant Efficacy against Biofilm Grown in the CDC Biofilm Reactor; Study No. GLP1910		Sterilex, LLC	OWN	This submission
810.2200	GLP Single Tube Method for Measuring Disinfectant Efficacy against Biofilm Grown in the CDC Biofilm Reactor; Study No. GLP1914		Sterilex, LLC	OWN	This submission
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces; Study No. A24854		Sterilex, LLC	OWN	This submission
810.2300	GLP AOAC Use-Dilution Method; Study No. GLP1312; E. aerogenes ATCC 13048	49756720	Sterilex, LLC	OWN	

Signature	Name and Title:	Date
	John Reilly Manager of Regulatory Affairs	September 6, 2018