Study Title Antibacterial Activity and Efficacy of SARIN Energy Solution's Test Device Item #11042 SES-UVCTR-110-R

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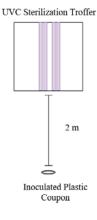
Purpose

The purpose of this study was to determine the antimicrobial efficacy of SARIN Energy Solution's UVC sterilizing device UVC Sterilization Troffer #11042 SES-UVCTR-110-R

Test Device Information

Name of Test Devices:	UVC Sterilization Troffer
Manufacturer:	SARIN Energy Solutions
Mode of Action:	UVC Light (Germicidal)

Instructions for use were included with the device. The sponsor was consulted for any further questions regarding the operation of the device. Note: The photo on this page depicts the study setup with the item UVC Sterilization Troffer #11042 SES-UVCTR-110-R. The distance from the unit to the test item was measured with a measuring tape.



Test Organism Information

The test microorganism(s) selected for this study: *Escherichia coli* ATCC 25922 *Staphylococcus aureus* ATCC 14458

Escherichia coli is a gram negative, facultative anaerobic, rod-shaped, coliform bacterium commonly found in the environment, foods, and gastrointestinal tract of people and animals. Although most *E. coli* are harmless, some strains can cause severe illnesses such as hemolytic uremic syndrome (HUS), a condition leading to kidney failure.

Staphylococcus aureus is a gram positive, facultative anaerobic, sphere-shaped bacterium commonly residing in the skin and/or nose of healthy individuals. *Staphylococcus aureus* can cause a multitude of diseases including skin infections (cellulitis, abscesses, furuncles etc.) and respiratory diseases such as pneumonia. Methicillin-resistant *Staphylococcus aureus* (MSRA) is a particularly difficult pathogen to treat as it is resistant to some common antibiotics.

Summary of the test procedure

- The test microorganisms are propagated in the appropriate liquid broth
- Cell suspensions of the test microorganism are prepared to achieve a concentration of at least 6 log10 CFU/mL
- A known volume of inoculum was used to inoculate plastic coupons to study the surface disinfection efficacy of the UVC unit
- The inoculated surface was dried in the biosafety cabinet and exposed to different UVC doses using different time treatments at various distances
- The UVC device is turned on for 10 minutes before treatment and samples are exposed to the UVC light for different treatment parameters.
- The survival bacteria were harvested, transferred to neutralizing medium, spread plated on media plates for enumeration and incubated in optimal incubation conditions
- After 24h incubation, the microbial populations are recorded, and log reductions are calculated
- All the experiments were conducted in duplicates and repeated on two different days

Testing Parameters

Culture Growth Media	Tryptic Soy Broth	Culture Growth Time	24 hours \pm 2 hours
Carrier Type	Plastic coupon	Inoculum Volume	0.100 mL
Contact Times and	60 min and 120 min	Contact Temperature	Ambient $(25^{\circ}C \pm 2^{\circ}C)$
		_	
Distance	2m		
Harvest Media	Phosphate Buffered	Enumeration Media	Tryptic Soy Agar
	Saline		
Incubation Temperature	$35^{\circ}C \pm 2^{\circ}C$	Incubation Time	24 hours \pm 2 hours
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Study Notes

The UVC intensity of the item UVC Sterilization Troffer #11042 SES-UVCTR-110-R was measured at 2m using a UVC sensor that only measures light intensity at 253.7 nm. The surface area of the inoculated plastic tokens was 17.35 cm². All microbial disinfection data reported in this document is preliminary and not peer-reviewed.

Control Results

The sterility of the media used to grow and enumerate bacterial cells was tested and confirmed sterile. Also, the growth of the bacterial cells was confirmed using the target morphology of the cells grown on the media plates.

Calculations

To quantify the bacterial disinfection achieved using the UVC device, the following calculations were done to determine the inactivation.

 $CFU/mL = (Average plate count) \times 1:10$ serial dilution factor

CFU/carrier = (Average plate count) x 1:10 serial dilution factor x volume inoculated

Percent reduction = $\frac{(A - B)}{A} \times 100$

Log₁₀ Reduction = log₁₀ (A/B) Where: A = Number of viable test microorganisms on the control test surface

B = Number of viable test microorganisms on the test surface after treatment

<u>Results of the Study</u> - (UVC Sterilization Troffer #11042 SES-UVCTR-110-R)

Target Microorganism	Contact Time	Carrier Distance	UV Intensity (µW/cm ²) at 253.7 nm	Log ₁₀ CFU/mL ± Standard Deviation	Reduction Compared to Control
<i>E. coli</i> ATCC 25922	Time Zero	N/A	N/A	7.51 ± 0.14	N/A
	60 min	2m	175.0	6.59 ± 1.85	99.9999 %
	120 min	2m	175.0	Not Detected	~99.99999 %
<i>S. aureus</i> ATCC 14458	Time Zero	N/A	N/A	7.77 ± 0.22	N/A
	60 min	2m	175.0	Not Detected	~99.99999 %
	120 min	2m	175.0	Not Detected	~99.99999 %