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**EN 13727: BACTERICIDAL EFFICACY ————— FINAL TEST REPORT**

Contact Person: **KYLE MOORE**  
Company: **BLULYTE (PTY) LTD**  
**7 DIPKA ROAD**  
**STIKLAND INDUSTRIAL**  
**CAPE TOWN**  
**7530**

Lab Number : **M20-12106**  
Order reference : **BLU026**  
Sample Date : **25/09/2020**  
Submit Date : **25/09/2020**  
Report Date : **12/10/2020**

**Disclaimer:**

The results reported relate only to the samples tested and is expressed on an 'as received' basis unless specified otherwise. The test report shall not be reproduced except in full, without written approval of the Laboratory.

**SANS 53727:2011 - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area.**

<b>Product Identification:</b>	<b>BLULYTE HOCL</b>
<b>Active Substances:</b>	HYPOCHLOROUS ACID

<b>Batch Number:</b>	NOT SUPPLIED
<b>Expiry Date:</b>	NOT SUPPLIED
<b>Storage Conditions:</b>	AMBIENT OUT OF DIRECT SUNLIGHT
<b>Recommended Diluent:</b>	NONE

<b>Appearance of Product:</b>	SUITABLE FOR TESTING
<b>Diluent Used in Test:</b>	STERILE DISTILLED WATER
<b>Product Concentrations:</b>	NEAT
<b>Appearance of Dilutions:</b>	HOMOGENOUS SUSPENSION
<b>Interfering Substances:</b>	0,3G BOVINE SERUM ALBUMIN
<b>Appearance during Test:</b>	HOMOGENOUS SUSPENSION
<b>Method:</b>	DILUTION NEUTRALIZATION
<b>Neutralizer / Rinsing Liquid:</b>	UNIVERSAL NEUTRALISER

<b>Analysis performed by:</b>	J. JACOBS
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## **Conclusion:**

### **Validations and Controls:**

All validations and controls were within specification during the test

BLULYTE HOCL was able to eliminate >99,999% of *S.aureus*, *P.aeruginosa* and *E.hirae* in a 5 minute contact period under simulated clean conditions with the addition of 0,3g/L bovine serum albumin as required by SANS53727 at the lowest tested concentration of 200ppm.

The product BLULYTE HOCL complies with the minimum performance requirement of SANS53727 for use in medical areas.



Johan Jacobs  
Technical Advisor

<b>Organism:</b>	<b>Staphylococcus aureus ATCC6538</b>	<b>Replicate:</b>	<b>1 OF 2</b>
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<b>Test Date:</b>	30/09/2020	<b>Test Temp.</b>	20 °C	<b>Incubation Temp.</b>	37 °C
<b>Test conditions:</b>	CLEAN	<b>Contact time:</b>	5 MINUTES	<b>Analyst:</b>	J. JACOBS

<b>Organism suspension</b>	10 <sup>-6</sup>	>300	<b>Organism suspension (N)</b>	4.85 X 10 <sup>8</sup>	Log	8.69	
		>300	<b>Test suspension (N<sub>o</sub>)</b>	4.85 X 10 <sup>7</sup>	Log	7.69	
	10 <sup>-7</sup>	46	<b>7.17 ≤ LgN<sub>o</sub> ≤ 7.70?</b>	Yes		Control	Pass
		51	<b>Validation suspension</b>	107	113	Control	Pass

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
<b>Experimental condition control (A)</b>	93	101	97	Yes	Pass
<b>Neutralizer control (B)</b>	86	94	90	Yes	Pass
<b>Methoc Validation (C)</b>	81	89	85	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration	200ppm
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<b>Organism:</b>	<b>Staphylococcus aureus ATCC6538</b>	<b>Replicate:</b>	<b>2 OF 2</b>
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<b>Test Date:</b>	08/10/2020	<b>Test Temp.</b>	20 °C	<b>Incubation Temp.</b>	37 °C
<b>Test conditions:</b>	CLEAN	<b>Contact time:</b>	5 MINUTES	<b>Analyst:</b>	J JACOBS

<b>Organism suspension</b>	10 <sup>-6</sup>	>300	<b>Organism suspension (N)</b>	3.65 X 10 <sup>8</sup>	Log	8.56	
		>300	<b>Test suspension (N<sub>o</sub>)</b>	3.65 X 10 <sup>7</sup>	Log	7.56	
	10 <sup>-7</sup>	34	<b>7.17 ≤ LgN<sub>o</sub> ≤ 7.70?</b>	Yes		Control	Pass
		39	<b>Validation suspension</b>	84	89	Control	Pass

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
<b>Experimental condition control (A)</b>	71	74	72.5	Yes	Pass
<b>Neutralizer control (B)</b>	68	75	71.5	Yes	Pass
<b>Methoc Validation (C)</b>	53	61	57	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration	200ppm
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**Organism:** Pseudomonas aeruginosa ATCC15442 **Replicate:** 1 OF 2

**Test Date:** 06/10/2020 **Test Temp.** 20 °C **Incubation Temp.** 37 °C  
**Test conditions:** CLEAN **Contact time:** 5 MINUTES **Analyst:** J. JACOBS

Organism suspension	10 <sup>-6</sup>	195	Organism suspension (N)	2.06 X 10 <sup>8</sup>	Log	8.31	
		209		Test suspension (N <sub>o</sub> )	2.06 X 10 <sup>7</sup>	Log	7.31
	10 <sup>-7</sup>	23	7.17 ≤ LgN <sub>o</sub> ≤ 7.70?		Yes	Control	Pass
		27	Validation suspension		55	62	Control

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
Experimental condition control (A)	49	53	51	Yes	Pass
Neutralizer control (B)	41	46	43.5	Yes	Pass
Methoc Validation (C)	34	40	37	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration: 200ppm

**Organism:** Pseudomonas aeruginosa ATCC15442 **Replicate:** 2 OF 2

**Test Date:** 09/10/2020 **Test Temp.** 20 °C **Incubation Temp.** 37 °C  
**Test conditions:** CLEAN **Contact time:** 5 MINUTES **Analyst:** J JACOBS

Organism suspension	10 <sup>-6</sup>	231	Organism suspension (N)	2.27 X 10 <sup>8</sup>	Log	8.36	
		224		Test suspension (N <sub>o</sub> )	2.27 X 10 <sup>7</sup>	Log	7.36
	10 <sup>-7</sup>	26	7.17 ≤ LgN <sub>o</sub> ≤ 7.70?		Yes	Control	Pass
		19	Validation suspension		59	50	Control

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
Experimental condition control (A)	52	44	48	Yes	Pass
Neutralizer control (B)	41	48	44.5	Yes	Pass
Methoc Validation (C)	37	34	35.5	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration: 200ppm

<b>Organism:</b>	<b>Enterococcus hirae ATCC10541</b>	<b>Replicate:</b>	<b>1 OF 2</b>
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<b>Test Date:</b>	06/10/2020	<b>Test Temp.</b>	20 °C	<b>Incubation Temp.</b>	37 °C
<b>Test conditions:</b>	CLEAN	<b>Contact time:</b>	5 MINUTES	<b>Analyst:</b>	J. JACOBS

<b>Organism suspension</b>	10 <sup>-6</sup>	>300	<b>Organism suspension (N)</b>	3.2 X 10 <sup>8</sup>	Log	8.51
		>300	<b>Test suspension (N<sub>o</sub>)</b>	3.2 X 10 <sup>7</sup>	Log	7.51
	10 <sup>-7</sup>	27	<b>7.17 ≤ LgN<sub>o</sub> ≤ 7.70?</b>	Yes	Control	Pass
		37	<b>Validation suspension</b>	74	71	Control

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
<b>Experimental condition control (A)</b>	68	59	63.5	Yes	Pass
<b>Neutralizer control (B)</b>	63	55	59	Yes	Pass
<b>Methoc Validation (C)</b>	51	47	49	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration	200ppm
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<b>Organism:</b>	<b>Enterococcus hirae ATCC10541</b>	<b>Replicate:</b>	<b>2 OF 2</b>
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<b>Test Date:</b>	09/10/2020	<b>Test Temp.</b>	20 °C	<b>Incubation Temp.</b>	37 °C
<b>Test conditions:</b>	CLEAN	<b>Contact time:</b>	5 MINUTES	<b>Analyst:</b>	J JACOBS

<b>Organism suspension</b>	10 <sup>-6</sup>	>300	<b>Organism suspension (N)</b>	3.8 X 10 <sup>8</sup>	Log	8.58
		>300	<b>Test suspension (N<sub>o</sub>)</b>	3.8 X 10 <sup>7</sup>	Log	7.58
	10 <sup>-7</sup>	41	<b>7.17 ≤ LgN<sub>o</sub> ≤ 7.70?</b>	Yes	Control	Pass
		35	<b>Validation suspension</b>	83	91	Control

	V <sub>c1</sub>	V <sub>c2</sub>	$\bar{X}$	$\bar{X} \geq 0.5XN_{v0}$	Control
<b>Experimental condition control (A)</b>	85	79	82	Yes	Pass
<b>Neutralizer control (B)</b>	73	66	69.5	Yes	Pass
<b>Methoc Validation (C)</b>	63	69	66	Yes	Pass

Concentration	V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub>	Log N <sub>a</sub>	Log <sub>red</sub>	% Kill Rate	Compliance
80% @ 400ppm	0	0	<10	<1	>5	>99.999%	PASS
60% @ 300ppm	0	0	<10	<1	>5	>99.999%	PASS
50% @ 250ppm	0	0	<10	<1	>5	>99.999%	PASS
40% @ 200ppm	0	0	<10	<1	>5	>99.999%	PASS
10% @ 50ppm	>300	>300	>3000	>3.45	<5	<99.99%	FAIL

Lowest Effective concentration	200ppm
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