



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Product name: Sta-Kill SK

Batch or ref no: 12/02/2014

Manufacturer or supplier: Bio-Productions Ltd. 72 Victoria Road,
Victoria Industrial Estate, Burgess Hill, RH15 9LZ

Sample ref: 14B/130 **Date received:** 18 February 2014

Date tested: 19 February 2014 **Certificate date:** 21 February 2014

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Analysis required: EN 13727:2012, Chemical disinfectants and antiseptics -
Quantitative suspension test for the evaluation of
bactericidal activity of chemical disinfectants for
instruments used in the medical area - Test method and
requirements (phase 2, step 1)

Storage conditions: Room temperature

Appearance of product (solution): Clear pink liquid

Active substance(s) and their concentration(s): Not declared

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Experimental conditions:

Concentration(s) of product tested: 1:5 v/v

Product diluent: Sterile hard water (300mg/l CaCO₃)

Test organism(s): Methicillin-resistant
Staphylococcus aureus (NCTC 12493)

Contact time(s): 5 minutes

Test temperature: 20°C ± 0.5°C

Test conditions: Dirty

Interfering substance: 3.0g/l bovine albumin +
3.0ml/l sheep erythrocytes

Neutralising solution: 3% Polysorbate 80, 3g/l Lecithin,
1g/l L-histidine, 1g/l L-cysteine

Incubation temperature: 37°C ± 1°C

Conclusion:

When tested at a concentration of 1:5, this sample of Sta-Kill SK passes the requirements of EN 13727 for bactericidal activity in 5 minutes at 20°C under dirty conditions against Methicillin-resistant *Staphylococcus aureus* (NCTC 12493).

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Results: Methicillin-resistant Staphylococcus aureus (NCTC 12493)

Validation and controls:

Validation suspension (N_{v0})			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
Vc1	149	$\bar{x} =$	Vc1	141	$\bar{x} =$	Vc1	136	$\bar{x} =$	Vc1	139	$\bar{x} =$
Vc2	151	150	Vc2	144	142.5	Vc2	146	141	Vc2	146	142.5
$30 \leq \bar{x} (N_{v0}) \leq 160$? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x} (A) \geq 0.5 \times \bar{x} (N_{v0})$? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x} (B) \geq 0.5 \times \bar{x} (N_{v0}$ or $N_{VB}/1000$) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x} (C) \geq 0.5 \times \bar{x} (N_{v0})$? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension (N_{VB})			Vc1	136	$\bar{x} =$	$30 \leq \bar{x} (N_{VB}/1000) \leq 160$? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no					
			Vc2	145	140.5						

**Test suspension:
(N and N_0)**

N	Vc1	Vc2	\bar{x} wm = 3.59×10^8 ; lg N = 8.56
10^{-6}	306	>330	$N_0 = N/10$; lg $N_0 = 7.56$
10^{-7}	60	65	$7.17 \leq \lg N_0 \leq 7.70$? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Control of weighted mean counts			Quotient = 5.09
			Between 5 and 15 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Product test conc.	Contact time	Diln. step	Vc1	Vc2	lg $N_a =$ lg (\bar{x} wm x10)	lg R (lg $N_0 = 7.56$)	Status
1:5	5 mins	10^0	10	14	< 2.15	> 5.41	PASS
		10^{-1}	0	0			

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