



# Abbott Analytical



Consulting Scientists to the Disinfectant Industry

## Test Report

**Product name:** Safe4 Instrument Disinfectant

**Batch or ref no:**

**Manufacturer or supplier:** Safe Solutions (Safe4) Ltd  
Wharton Green House, Bostock Road, Winsford, CW7 3BD

**Sample ref:** 18K/057                      **Date received:** 22 October 2018

**Date tested:** 24 October 2018              **Report date:** 29 May 2019

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**Analysis required:** EN 14204:2012, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)

**Storage conditions:** Room temperature in darkness

**Appearance of product (solution):** Dark green liquid

**Active substance(s) and their concentration(s):** Not disclosed

### Notes

The test results in this report relate only to the sample tested, as received from the client.

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Report re-issued with updated product name. Original report 18K.057VMm.SSL, dated 9 November 2018.

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## Experimental conditions

**Concentration(s) of product tested:** 1:100 v/v <sup>1</sup>

**Product diluent:** Sterile hard water (300 mg/l CaCO<sub>3</sub>)

**Test organism(s):** *Mycobacterium marinum* (NCIMB 1297) <sup>2</sup>

**Contact time(s):** 30 min ± 10 s

**Test temperature:** 10 °C ± 1 °C

**Test conditions:** High-level soiling

**Interfering substance:** 10.0 g/l bovine albumin +  
10.0 g/l yeast extract

**Method:** Dilution-neutralisation

**Neutralising solution:** 30 g/l Polysorbate 80 + 3 g/l Lecithin +  
1 g/l L-histidine + 1 g/l L-cysteine

**Incubation temperature:** 36 °C ± 1 °C

## Remarks and/or Deviations

- 1) Sample tested at a single concentration only, as requested by the client.
- 2) According to EN 14204:2012 (Clauses 5.4.1.6 and 5.5.2.7) all plates should be incubated for an initial period of 21 days, counted, incubated for a further 7 days and then recounted.

However, *Mycobacterium marinum* grows more quickly than the obligatory test organism, *Mycobacterium avium*. Therefore, for this test all plates were incubated for an initial period of 7 days, counted, incubated for a further 7 days and then recounted.

## Conclusion

When tested at a concentration of 1:100 this sample of Safe4 Instrument Disinfectant meets the requirements of EN 14204:2012 for mycobactericidal activity in 30 minutes at 10°C, under high-level soiling conditions, against the referenced strain of *Mycobacterium marinum*.

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Results: Mycobacterium marinum (NCIMB 1297)

**Validation and controls:**

Validation suspension ( $N_{v_o}$ )			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C) Product conc.: 1:100		
Vc1	67	$\kappa =$	Vc1	69	$\kappa =$	Vc1	62	$\kappa =$	Vc1	67	$\kappa =$
Vc2	64	65.5	Vc2	73	71	Vc2	60	61	Vc2	62	64.5
30 $\leq \kappa (N_{v_o}) \leq 160$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\kappa (A) \geq 0.5 \times \kappa (N_{v_o})$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\kappa (B) \geq 0.5 \times \kappa (N_{v_o})$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\kappa (C) \geq 0.5 \times \kappa (N_{v_o})$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

**Test suspension:  
(N and  $N_o$ )**

N	Vc1	Vc2	$\kappa_{wm} = 4.00 \times 10^8$ ; lg N = 8.60
$10^{-6}$	>330	>330	$N_o = N/10$ ; lg $N_o = 7.60$
$10^{-7}$	41	39	7.48 $\leq$ lg $N_o \leq$ 7.90 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Control of weighted mean counts			Quotient = N/A Between 5 and 15 ? <input type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Product test conc.	Contact time	Diln. step	Vc1	Vc2	lg $N_a =$ lg ( $\kappa_{wm} \times 10$ )	lg R (lg $N_o = 7.60$ )	Status
1:100	30 min	$10^0$	34	31	2.51	5.09	PASS
		$10^{-1}$	3	2			

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