



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Test Report

Product name: Safe4 Instrument Disinfectant

Batch or ref no:

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

Sample ref: 15E/223 **Date received:** 27 May 2015

Date tested: 15 June 2015 **Report date:** 29 May 2019

Report no: 15E.223VMb2.SSL **Page:** 1 of 3

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): Clear colourless liquid

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

Notes

The test results in this report relate only to the sample(s) tested. This test report may not be reproduced except in full, without written approval from Abbott Analytical.

Report re-issued with updated product name. Original report 15E.223VMb.SSL, dated 13 July 2015.

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Report no: 15E.223VMb2.SSL

Date: 29 May 2019

Page: 2 of 3

Experimental conditions

Concentration(s) of product tested: 1:40 v/v

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

Test organism(s): *Mycobacterium bovis* (NCTC 10772)

Contact time(s): 30 min ± 10 s

Test temperature: 10°C ± 1°C

Test conditions: High-level soiling

Interfering substance: 10g/l bovine albumin +
10g/l yeast extract

Method: Dilution-neutralisation

Neutralising solution: 30g/l 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 1:40, this sample of Safe4 Instrument Disinfectant passes the requirements of EN 14204:2012 for mycobactericidal activity in 30 minutes at 10°C under high-level soiling conditions against *Mycobacterium bovis* (NCTC 10772).

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Date: 29 May 2019

Page: 3 of 3

Results: Mycobacterium bovis (NCTC 10772)

Validation and controls:

Validation suspension (Nv _o)			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
Vc1	78	κ =	Vc1	60	κ =	Vc1	56	κ =	Vc1	58	κ =
Vc2	88	83	Vc2	62	61	Vc2	57	56.5	Vc2	69	63.5
30 ≤ κ (Nv _o) ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			κ (A) ≥ 0.5 x κ (Nv _o) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			κ (B) ≥ 0.5 x κ (Nv _o) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			κ (C) ≥ 0.5 x κ (Nv _o) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

Test suspension: (N and N_o)

N	Vc1	Vc2	κ _{wm} = 2.87 x 10 ⁸ ; lg N = 8.46
10 ⁻⁶	264	281	N _o = N/10 ; lg N _o = 7.46
10 ⁻⁷	36	51	7.48 ≤ lg N _o ≤ 7.90 ? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Control of weighted mean counts			Quotient = 6.26 Between 5 and 15 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Product test conc.	Contact time	Diln. step	Vc1	Vc2	lg Na = lg (κ _{wm} x 10)	lg R (lg N _o = 7.46)	Status
1:40	30 min	10 ⁰	144	240	3.28	4.18	PASS
		10 ⁻¹	17	21			

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