mgsLABORATORIES Microbiological Services and Consultancy						Doc No.	ENR-2020-092-02	UKAS TESTING 4393
Title	**Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)**							
Product	**Antibacterial Hand Gel FO 28-00004**	**MGS No**	**N/A**	**SO No**	**7975**			

a) **Identification of test laboratory:**	
Test laboratory	MGS Laboratories Ltd Unit 2, Merlin Park Airport Service Road Portsmouth Hampshire PO3 5FU
b) **Identification of the Customer:**	
Customer Name	Zidac Laboratories Ltd
Customer Address	Unit 5, Merlin Park Airport Service Road Portsmouth Hants PO3 5FU
c) **Identification of the sample:**	
Name of product	Antibacterial Hand Gel FO 28-00004
Batch number (and expiry date if available)	Not stated
Manufacturer (or supplier)	Zidac Laboratories Ltd
Date of delivery	14 JUN 20
Storage conditions	Room temperature and darkness
Product diluent recommended by the manufacturer for use	N/A
Active substance(s) and their concentration(s) (optional)	Not stated
Appearance of the product	Clear colourless gel
d) **Test method and its validation:**	
MGS procedure reference	WIN-1000.050-08
Method	Dilution neutralisation

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

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Neutraliser	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Details of validation of the neutraliser	Neutraliser validation performed according to 5.5.2 of EN 1276:2019
e) **Experimental conditions:**	
Period of analysis	14 JUN 20 – 16 JUN 20
Product diluent used during the test	N/A
Product test concentrations	Ready to use (RTU)
Appearance of product dilutions	Clear colourless gel
Contact time	1 minute ± 10s
Test temperature range	20 ±1°C
Interfering substance	0.3g/l Bovine albumin & 3.0g/l Bovine albumin
Stability of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C ± 2°C
Identification of the bacterial strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli K12* (Handwash products) NCTC 10538
f) **Results:**	
Test results	1) Controls and validation 2) Evaluation of bactericidal activity
g) **Conclusion:**	Based on EN 1276 (2019), the batch supplied of the product Antibacterial Hand Gel FO 28-00004, when tested RTU, possesses bactericidal activity in 1 minute at 20°C under clean and dirty conditions for the referenced strains of *P. aeruginosa, S. aureus, E. hirae* and *E. coli K12.*
h) **Deviations:**	Although the inoculum for *S. aureus* was 0.11logs higher than specified in EN 1276, the product passed the more stringent test. Therefore, this deviation is accepted.
i) Comments:	This report replaces ENR-2020-092-01. Product name amended.

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Product	**Antibacterial Hand Gel FO 28-00004**	**MGS No**	**N/A**	**SO No**	**7975**		

UKAS TESTING 4393

Re-issued by:	**Approved by:**
Name: Ruth Robinson	**Name:** Kim Morwood
Position: Customer Services Coordinator	**Position:** Technical Director
Date: 24Aug20	**Date:** 25 Aug 20
Locality: Hampshire, United Kingdom	**Locality: Hampshire, United Kingdom**

The MGS procedure WIN-1000.050 is a laboratory method based on the EN 1276 (2019) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- EN 1276 states an allowed tolerance of 36°C ±1°C or 37°C±1°C, MGS laboratories equipment is validated to ±2°C therefore MGS procedures state ±2°C. The tests are self-validating so any stress caused to the organism will be reflected in the validations.
- The incubation period may be extended due to business hours.
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism.

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Product batch number: Not stated
Dilution-neutralisation method — Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.7°C
Test organism: *P. aeruginosa* ATCC 15442
Incubation temperature: 36°C ± 2°C
Interfering substances: 0.3g/l Bovine albumin
Date of Test: 14 JUN 20
Person responsible: Omid Nazari — Signature: pp. [signature]
Diluent used for product test solutions: N/A
Appearance of product test solutions: Clear colourless gel

Validation and Controls

Clean conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	108	χ = 111	Vc1	85	χ = 89	Vc1	109	χ = 100	Vc1	119	χ = 121
Vc2	114		Vc2	92		Vc2	90		Vc2	122	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Dirty conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	108	χ = 111	Vc1	92	χ = 89	Vc1	109	χ = 100	Vc1	104	χ = 110
Vc2	114		Vc2	85		Vc2	90		Vc2	116	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	$\chi = 4.90 \times 10^8$; $lgN = 8.69$	7.17 ≤ lg N_0 ≤ 7.70?			
	10^{-6}	>330	>330	$N_0 = N/10$; $lgN_0 = 7.69$				
	10^{-7}	50	48		Yes	X	No	

Conc of the product	Conditions	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
RTU	Clean	<14	<14	<140	<2.15	>5.54	1 minute
	Dirty	<14	<14	<140	<2.15	>5.54	

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Product batch number: Not stated
Dilution-neutralisation method Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.7°C
Test organism: *E. coli K12* NCTC 10538
Incubation temperature: 36°C ± 2°C
Interfering substances: 0.3g/l Bovine albumin
Date of Test: 14 JUN 20
Person responsible: Omid Nazari Signature: pp. cmfl
Diluent used for product test solutions: N/A
Appearance of product test solutions: Clear colourless gel

Validation and Controls

Clean conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	114	χ = 111	Vc1	107	χ = 105	Vc1	110	χ = 101	Vc1	127	χ = 120
Vc2	108		Vc2	103		Vc2	92		Vc2	113	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Dirty conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	114	χ = 111	Vc1	118	χ = 111	Vc1	110	χ = 101	Vc1	95	χ = 96
Vc2	108		Vc2	103		Vc2	92		Vc2	97	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ = 4.50 x 10^8; lgN= 8.65 N_0 = N/10; lgN_0 = 7.65	7.17 ≤ lg N_0 ≤ 7.70?			
	10^{-6}	>330	>330		Yes	X	No	
	10^{-7}	34	56					

Conc of the product	**Conditions**	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	Clean	<14	<14	<140	<2.15	>5.50	1 minute
	Dirty	<14	<14	<140	<2.15	>5.50	

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Product batch number: Not stated
Dilution-neutralisation method — Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.7°C
Test organism: *S. aureus* ATCC 6538
Incubation temperature: 36°C ± 2°C
Interfering substances: 0.3g/l Bovine albumin
Date of Test: 14 JUN 20
Person responsible: Omid Nazari — Signature: pp. OmN
Diluent used for product test solutions: N/A
Appearance of product test solutions: Clear colourless gel

Validation and Controls

Clean conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	152	χ = 157	Vc1	149	χ = 151	Vc1	135	χ = 140	Vc1	133	χ = 143
Vc2	162		Vc2	153		Vc2	145		Vc2	153	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Dirty conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	152	χ = 157	Vc1	137	χ = 133	Vc1	135	χ = 140	Vc1	150	χ = 144
Vc2	162		Vc2	129		Vc2	145		Vc2	137	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	$\chi = 6.45 \times 10^8$; lgN= 8.81 N_0 = N/10; lgN_0 = 7.81	7.17 ≤ lg N_0 ≤ 7.70?			
	10^{-6}	>330	>330		Yes		No	X
	10^{-7}	67	62					

Conc of the product	**Conditions**	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	Clean	<14	<14	<140	<2.15	>5.66	1 minute
	Dirty	<14	<14	<140	<2.15	>5.66	

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Product batch number: Not stated
Dilution-neutralisation method — Pour plate [X] — Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.7°C
Test organism: *E. hirae* ATCC 10541
Incubation temperature: 36°C ± 2°C
Interfering substances: 0.3g/l Bovine albumin
Date of Test: 14 JUN 20
Person responsible: Omid Nazari — Signature: pp.
Diluent used for product test solutions: N/A
Appearance of product test solutions: Clear colourless gel

Validation and Controls

Clean conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	64	χ = 64	Vc1	74	χ = 71	Vc1	64	χ = 61	Vc1	66	χ = 60
Vc2	64		Vc2	67		Vc2	57		Vc2	53	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Dirty conditions

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)**		
									Prod conc:		RTU
Vc1	64	χ = 64	Vc1	76	χ = 76	Vc1	64	χ = 61	Vc1	52	χ = 65
Vc2	64		Vc2	75		Vc2	57		Vc2	78	
30 ≤ χ of Nv_0 ≤ 160?			χ of A is ≥ 0.5 x χ of Nv_0?			χ of B is ≥ 0.5 x χ of Nv_0?			χ of C is ≥ 0.5 x χ of Nv_0?		
Yes	X	No	Yes	X	No	Yes	X	No	Yes	X	No

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 2.85 x 10^8; lgN= 8.45 N_0 = N/10; lgN_0 = 7.45	7.17 ≤ lg N_0 ≤ 7.70?			
	10^{-6}	287	279					
	10^{-7}	35	27		Yes	X	No	

Conc of the product	**Conditions**	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	Clean	<14	<14	<140	<2.15	>5.30	1 minute
	Dirty	<14	<14	<140	<2.15	>5.30	

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Explanations:

Vc = count per plate (one plate or more)
χ = average of Vc1 and Vc2 (1. + 2. duplicate)
χ wm = weighed mean of χ
R = reduction ($lgR = lgN_0 - lgNa$)
Na = number of survivors in the test mixture
N = number of cells in the test suspension
N_0 = N/10
Nv = number of cells in the validation suspension
Nv_0 = Nv/10

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.

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