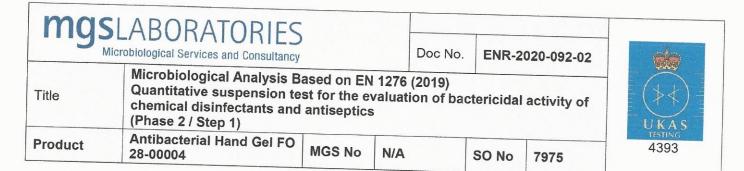
#### Microbiological Services and Consultancy Doc No. ENR-2020-092-02 Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of Title chemical disinfectants and antiseptics (Phase 2 / Step 1) Antibacterial Hand Gel FO **Product** 4393 MGS No N/A 28-00004 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
) Test method and its validation:	
MGS procedure reference	WIN-1000.050-08
lethod	Dilution neutralisation

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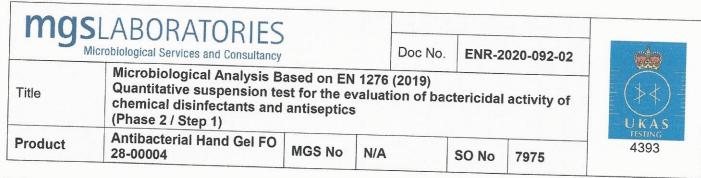
NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.



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:	201
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	-
dentification of the bacterial strains used	Pseudomonas aeruginosa ATCC 15442 Staphylococcus aureus ATCC 6538 Enterococcus hirae ATCC 10541 Escherichia coli K12 (Handwash products) NCTC 10538	
) Results:		
Fest results	Controls and validation     Evaluation of bactericidal activity	
y) Conclusion:	Based on EN 1276 (2019), the batch supplied of the product Antibacterial Hand Gel FO 28-00004, when tested RTU, possess bactericidal activity in 1 minute at 20°C under clean and dirty conditions for the referenced strains of <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>hirae</i> and <i>E. coli K12</i> .	
) Deviations:	Although the inoculum for <i>S. aureus</i> was 0.11logs higher than specified in EN 1276, the product passed the more stringent test. Therefore, this deviation is accepted.	
Comments:	This report replaces ENR-2020-092-01. Product name amended.	

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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.



Re-issued by:	Approved by:
Name: Ruth Robinson	Name: Kim Morwood
Position: Customer Services Coordinator	Position: Technical Director
Date: 24A2920	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.

Microbiological Services and Consultancy

Doc No.

ENR-2020-092-02

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) **Antibacterial Hand Gel FO** 

**Product** 28-00004

MGS No N/A

SO No

7975



Product batch number: Not stated

Dilution-neutralisation method

Pour plate

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. cm/

Diluent used for product test solutions: N/A

Appearance of product test solutions: Clear colourless gel

# Validation and Controls

#### Clean conditions

Valid		susp Nv <sub>0</sub> )	ension	Cond	Exper	imental Control (A)	Neu	tralise	r Control (B)			dation (C)
Vc1	1	80		Vc1	85	John (A)			1-7	Pro	d conc:	RTU
Vc2		14	X = 111			x = 89	Vc1	109	y = 100	Vc1	119	
			1000	Vc2	92	, ,	Vc2	90	$\chi = 100$	Vc2	122	$\chi = 121$
	≥ X 01	NV0 ≤	160?	χ of A	is $\geq 0$ .	5 x χ of Nv <sub>0</sub> ?	x of F	$3 \text{ is } \geq 0$	.5 x χ of Nv <sub>0</sub> ?			501
Yes	X	No		Yes	X	No	1	The state of the s			U IS ≥ 0.5	x χ of Nv <sub>0</sub> ?
1000000				. 00	^	110	Yes	X	No	Yes	X	Vo

**Dirty conditions** 

Valid		n susp Nv₀)	ension	Conc	Experi	mental Control (A)	Neu	tralise	er Control (B)			lidation (C)
Vc1		108		Vc1	92	John (A)	-		. ,	Pro	d conc:	RTU
Vc2		114	X = 111			X = 89	Vc1	109	400	Vc1	104	
				Vc2	85	1 20000	Vc2	90	$\chi = 100$	Vc2		x = 110
	≤ χ of	Nv <sub>0</sub> ≤	160?	χ of A	is ≥ 0.	5 x χ of Nv <sub>0</sub> ?			).5 x x of Nv <sub>0</sub> ?		116	1
Yes	X	No	2	Yes	X				Construction of the second	Хог	$\cup$ is $\geq 0.8$	5 x χ of Nv <sub>0</sub> ?
				165	^	No	Yes	X	No	Yes	X	No

Test suspension and test

est suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2	$\chi = 4.90 \times 10^8$ ; IgN= 8.69	
	10-6	>330		$N_0 = N/10$ ; $IgN_0 = 7.69$	$7.17 \le \lg N_0 \le 7.70$ ?
	10-7	50	48		Yes X No

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

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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.

NOTE 2: This report may not be reproduced except in full, without written approval of MGS Laboratories Ltd.

# **mqs**LABORATORIES

Microbiological Services and Consultancy

Doc No. ENR-2020-092-02

Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of Title chemical disinfectants and antiseptics (Phase 2 / Step 1) **Antibacterial Hand Gel FO Product** MGS No 28-00004 N/A

4393

Product batch number: Not stated

Dilution-neutralisation method Number of plates: 1 / ml

Pour plate

Spread plate

SO No

7975

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. cm/L

Diluent used for product test solutions: N/A

Appearance of product test solutions: Clear colourless gel

## Validation and Controls

### Clean conditions

Valid		suspens Iv <sub>0</sub> )	ion	Cond	Exper	imental Control (A)	Neu	tralise	r Control (B)			dation (C)
Vc1	1	14		Vc1		Control (A)	-		(-)	Pro	d conc:	RTU
Vc2		08 X =	111		107	$\chi = 105$	Vc1	110	V = 101	Vc1	127	
		Nv <sub>0</sub> ≤ 160	2	Vc2	103		Vc2	92	$\chi = 101$	Vc2	113	$\chi = 120$
A STATE OF THE STATE OF	- X 01		<u> </u>	X OT A	$s \ge 0$ .	5 x χ of Nv <sub>0</sub> ?	χ of I	$3 \text{ is } \ge 0$	$0.5 \times \chi \text{ of Nv}_0$ ?	x of	C is ≥ 0.5	x x of Nvo?
Yes	X	No		Yes	X	No	Yes	X	No	Yes		Vo.

**Dirty conditions** 

Valid		n sus <sub> </sub> (Nv <sub>0</sub> )	pension	Cone	Exper	imental Control (A)	Neu	tralise	r Control (B)			idation (C)
Vc1		114		Vc1			-		(-/	Prod	d conc:	RTU
Vc2			$\chi = 111$		118	X = 111	Vc1	110	101	Vc1	95	
		108		Vc2	103		Vc2	92	$\chi = 101$	Vc2	97	$\chi = 96$
30	≤ Χ ο	† Nv <sub>0</sub> ≤	≤ 160?	χ of A	is ≥ 0.	5 x χ of Nv <sub>0</sub> ?	y of I	3 is > 0	0.5 x χ of Nv <sub>0</sub> ?			
Yes	X	N	0	Yes	X	No				X OI (	J IS ≥ 0.5	x χ of Nvo?
				100	^	INO	Yes	X	No	Yes	X	No

Test suspension and test

Test suspension	N	Vc1	Vc2	$\chi = 4.50 \times 10^8$ ; IgN= 8.65	1		
(N and N <sub>0</sub> ):	10 <sup>-6</sup>	>330		$N_0 = N/10$ ; $IgN_0 = 7.65$	$7.17 \le \lg N_0 \le 7$		$N_0 \le 7.70$ ?
,	10-7	34	56		Van	· ·	I I
					Yes	Х	No

Conc of the product	Conditions	Vc1	Vc2	Na = χ x10	IgNa	IgR	Contact time
RTU	Clean	<14	<14	<140	<2.15	>5.50	
NIO .	Dirty	<14	<14	<140	<2.15	>5.50	1 minute

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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.

# **mqs**LABORATORIES

Microbiological Services and Consultancy

Doc No. ENR-2020-092-02

Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of Title chemical disinfectants and antiseptics

(Phase 2 / Step 1)

Antibacterial Hand Gel FO **Product** 28-00004

MGS No N/A

SO No

7975



Product batch number: Not stated

Dilution-neutralisation method Number of plates: 1 / ml

Pour plate

Spread plate

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. cm

Diluent used for product test solutions: N/A

Appearance of product test solutions: Clear colourless gel

# Validation and Controls

### Clean conditions

Valid		suspension		Exper	imental Control (A)	Neu	tralise	er Control (B)			idation (C)
Vc1	1	52	1/01		- ' '				Pro	d conc:	RTU
Vc2		$\chi = 15$	/	149	$\chi = 151$	Vc1	135		Vc1	133	
			Vc2	153	1.	Vc2	145	$\chi = 140$	Vc2	153	$\chi = 143$
	≥ X ot	$Nv_0 \le 160$ ?	χ of A	is $\geq 0$ .	5 x χ of Nv <sub>0</sub> ?	x of l	3 is ≥ (	).5 x x of Nv <sub>0</sub> ?			
Yes	X	No	Yes	X	No	Yes	SAN SERVICE STREET		1	U 15 ≥ U.5	x χ of Nv <sub>0</sub> ?
				/	110	res	X	No	Yes	X	No

**Dirty conditions** 

Valid		n sus (Nv <sub>0</sub> )	pension	Conc	Experi	mental Control (A)	Neu	tralise	r Control (B)			lidation (C)
Vc1		152		Vc1		John (A)	-		(- <i>i</i>	Pro	d conc:	RTU
Vc2		162	$\chi = 157$		137	$\chi = 133$	Vc1	135	V = 140	Vc1	150	
				Vc2	129		Vc2	145	$\chi = 140$	Vc2	137	$\chi = 144$
Section Control	≥ X 0.	f NV <sub>0</sub> s	≤ 160?	χ of A	is $\geq 0$ .	5 x χ of Nv <sub>0</sub> ?	χ of E	3 is ≥ 0	0.5 x x of Nvo?			5 x x of Nv <sub>0</sub> ?
Yes	X	N	0	Yes	X	No	Yes	V	Decision of the last of the la	1	100	
						110	168	_ ^	No	Yes	X	No

Test suspension and test

Test suspension	N	Vc1	Vc2	$\chi = 6.45 \times 10^8$ ; IgN= 8.81	1	<del></del>	
(N and N <sub>0</sub> ):	10-6	>330	>330	$N_0 = N/10$ ; $IgN_0 = 7.81$	7.17 ≤	$lg\ N_0 \le 7.7$	70?
	10 <sup>-7</sup>	67	62		Yes	No	V

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

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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.

# **mgs**LABORATORIES

Microbiological Services and Consultancy

Doc No. ENR-2020-092-02

SO No

7975

Microbiological Analysis Based on EN 1276 (2019) Quantitative suspension test for the evaluation of bactericidal activity of Title chemical disinfectants and antiseptics (Phase 2 / Step 1) **Antibacterial Hand Gel FO Product** 

4393

Product batch number: Not stated

28-00004

Dilution-neutralisation method Number of plates: 1 / ml

Pour plate X

MGS No

N/A

Spread plate

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. cm/

Diluent used for product test solutions: N/A

Appearance of product test solutions: Clear colourless gel

# Validation and Controls

## Clean conditions

Valid		sus <sub>l</sub>	pension	Conc	Experi	imental Control (A)	Neu	tralise	er Control (B)			dation (C)
Vc1	1	64				Control (A)	-			Proc	d conc:	RTU
	_		$\chi = 64$	Vc1	74	V = 71	Vc1	64		Vc1	66	
Vc2		64	1 222	Vc2	67	$\chi = 71$	Vc2	57	$\chi = 61$	Vc2		$\chi = 60$
	≤ χ of	Nv <sub>0</sub> ≤	160?	χ of A	is ≥ 0.	5 x χ of Nv <sub>0</sub> ?			).5 x χ of Nv <sub>0</sub> ?		53	x x of Nv <sub>0</sub> ?
Yes	X	N	0	Yes	X	No	Yes	Х	No	Yes		VO VO

Dirty conditions

Valid		sus Vv <sub>0</sub> )	pension	Conc	Experi	mental Control (A)	Neu	tralise	er Control (B)			lidation (C)
Vc1		64	T			Control (A)			(-)	Prod	d conc:	RTU
			$\chi = 64$	Vc1	76	$\chi = 76$	Vc1	64		Vc1	52	
Vc2		64		Vc2	75	X - 70	Vc2	57	$\chi = 61$	Vc2		$\chi = 65$
	$\leq \chi$ of	Nvo:	≤ 160?	χ of A	is ≥ 0.	5 x χ of Nv <sub>0</sub> ?			).5 x x of Nv <sub>0</sub> ?		78	5 x x of Nv <sub>0</sub> ?
Yes	X	N	0	Yes	X	No	Yes	Х	No	Yes	X X	No No

Test suspension and test

N	Vc1	Vc2	$x \text{ wm} = 2.85 \times 10^8 \cdot \text{ lgN} = 8.45$					
10-6	287	279	$N_0 = N/10$ ; $IgN_0 = 7.45$	$7.17 \le \lg N_0 \le 7.70$ ?				
10-7	35	27		Yes		No	Т	
		10-6 287	10-6 287 279	$\frac{10^{-6}}{287}$ $\frac{287}{279}$ $\frac{279}{N_0 = N/10}$ ; $\frac{10}{10}$ , $\frac{10}{10}$ , $\frac{10}{10}$ , $\frac{10}{10}$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	10 <sup>-6</sup> 287 279 $N_0 = N/10$ ; $IgN_0 = 7.45$ 7.17 $\leq Ig$	10 <sup>-6</sup> 287 279 $N_0 = N/10$ ; $IgN_0 = 7.45$ 7.17 $\leq Ig N_0 \leq 7$ .	

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

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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.

mas	LABORATORIES						
Microbiological Services and Consultancy			Doc No.		ENR-2020-092-02		
Title	Microbiological Analysis B Quantitative suspension te chemical disinfectants and (Phase 2 / Step 1)	st for the e antiseptics	valuation -	9) of bacte	ericidal	activity of	UKAS.
Product	Antibacterial Hand Gel FO 28-00004	MGS No	N/A	9	SO No	7975	4393

## **Explanations:**

Vc = count per plate (one plate or more)

X = average of Vc1 and Vc2 (1. + 2. duplicate)

 $\chi$  wm = weighed mean of  $\chi$ 

 $R = reduction (IgR = IgN_0 - IgNa)$ 

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.