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Test Report: EN 1276:2019

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional

areas – Test method and requirements (phase 2, step 1)

Identification of the test laboratory: Abbott Analytical Ltd

Unit 2, Hickmans Road, Birkenhead, CH41 1JH, United Kingdom

Identification of the client: Coventry Chemicals Ltd

Woodhams Road, Coventry, CV3 4FX, United Kingdom

Identification of the sample: 19J/037

Name of the product: Sanitiser Concentrate

Batch number/reference and expiry date (if available):

AQBK1 P32

Date of delivery: 06 September 2019

Storage conditions: Room temperature in darkness

Product diluent recommended by

the manufacturer for use:

Not disclosed

Active substance(s) and their

concentrations (s) (optional):

Not disclosed

Appearance of the product: Dark green liquid

Notes:

- 1) The test results in this report relate only to the sample(s) tested.
- 2) This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical Ltd.







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Dilution-neutralisation Neutraliser: 30.0 g/l Polysorbate 80 + 5.0 g/l Lecithin + 1.0 g/l L-histidine +

1.0 g/l L-cysteine (Neutraliser A) or

100.0 g/l Polysorbate 80 + 30.0 g/l Lecithin +

30.0 g/l Tryptone Soya Broth + 5.0 g/l Sodium thiosulphate +

1.0 g/l L-histidine (Neutraliser B)

Neutraliser validation: Validated in accordance with EN 1276:2019 (5.5.2)

Experimental conditions:

Test method and its validation:

Method:

Period of analysis: 17 September 2019 to 23 September 2019

Product test concentration(s): 1:60 v/v (1 part product to 59 parts water)

Diluent used for product test

solution(s):

Hard water

Contact time(s): $30 s \pm 5 s$

Test temperature(s): 20°C ± 1°C

Interfering substance: 0.3 g/l bovine albumin (clean conditions)

Temperature of incubation: 36°C ± 1°C

Identification of the bacterial Pseudomonas aeruginosa (NCIMB 10421)

strain(s) used: Escherichia coli (NCTC 10418)

> Staphylococcus aureus (NCTC 10788) Enterococcus hirae (NCIMB 8192)

Deviations: None

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 1276:2019 (5.4.2) or EN 1276:2019 (5.5.1.1).

Company number: 10031406







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Requirements:

The product shall demonstrate at least a 5 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 1276:2019, Sanitiser Concentrate possesses bactericidal activity when tested at a concentration of 1:60 (1 part product to 59 parts water) with a contact time of 30 seconds at 20°C under clean conditions against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Enterococcus hirae*.

Report prepared by:

Signed:

Name:

Position: General Manager

Tony Watson

Date: 27 September 2019

Approved by:

Signed:

Name: Gareth Bayliss

Position: Laboratory Manager

Date: 27 September 2019







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RST 002 (Issue 4)

Test organism: Pseudomonas aeruginosa (NCIMB 10421)

Date of test: 17 September 2019

Test temperature: $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Dilution-neutralisation method: Pour plate Number of plates: 1/ml

Neutraliser: A Test conditions: Clean conditions

Validation and controls:

Results: EN 1276:2019

Validation	n suspensio	n (Nv _o)	Experimental conditions			Neutralis	Neutraliser or filtration			Method validation (<i>C</i>)		
				control (A)			control (B)			Product conc.: 1:60		
Vc1	93	<u>₩</u> =	Vc1	89	<u>₩</u> =	Vc1	101	<u></u> =	Vc1	103	<u>n</u> =	
Vc2	94	93.5	Vc2	92	90.5	Vc2	94	97.5	Vc2	97	100	
$30 \le \overline{n}$ of	$30 \le \overline{\mu} \text{ of } Nv_0 \le 160 ?$ $\overline{\mu} \text{ of } A \ge 0.5 \times \overline{\mu} \text{ of } Nv_0 ?$		$\overline{\mu}$ of $B \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		ν _o ?	$\overline{\mu}$ of $C \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		v _o ?				
⊠ yes	□no		⊠ yes	□no		⊠ yes	□no		⊠ yes	□no		

Test suspension (N and N_o):

N	Vc1	Vc2	$\overline{\mu}$ wm = 4.80 x 10 ⁸ ;	lg N =	8.68
10 ⁻⁶	>330	>330	$N_0 = N/10$; $\lg N_0 =$	7.68	
10 ⁻⁷	47	49	$7.17 \le \lg N_0 \le 7.70$?	⊠ yes	□ no

Conc. of the product	Contact time	Vc1	Vc2	<i>Na</i> (l ~	lg R (lg N _o - lg Na)
1:60	30 s	0	0	<140	<2.15	>5.53







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RST 002 (Issue 4)

Test organism: Escherichia coli (NCTC 10418)

Date of test: 17 September 2019

Test temperature: $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Dilution-neutralisation method: Pour plate Number of plates: 1/ml

Neutraliser: A Test conditions: Clean conditions

Validation and controls:

Results: EN 1276:2019

Validatio	n suspensio	on (Nv _o)	Experime	ntal condit	tions	Neutralis	er or filtra	tion	Method v	Method validation (<i>C</i>)		
	1/-4			control (A)			control (B)			Product conc.: 1:60		
Vc1	107	<u></u> <u>n</u> =	Vc1	103	<u></u> =	Vc1	97	<u></u> =	Vc1	99	<u> </u>	
Vc2	103	105	Vc2	99	101	Vc2	101	99	Vc2	104	101.5	
$30 \le \overline{\varkappa} \text{ of } Nv_0 \le 160 ?$ $\overline{\varkappa} \text{ of } A \ge 0.5 \times \overline{\varkappa} \text{ o}$			$.5 \times \overline{\mu}$ of N	ν _o ?	$\overline{\mu}$ of $B \ge 0.5 \times \overline{\mu}$ of Nv_0 ?			$\overline{\varkappa}$ of $C \ge 0.5 \times \overline{\varkappa}$ of Nv_0 ?				
⊠ yes	□ no □ yes □ no □ yes □ no			⊠ yes	□no							

Test suspension (N and N_0):

Ν	Vc1	Vc2	$\overline{\mu}$ wm = 3.11 x 10 ⁸ ;	lg N =	8.49
10 ⁻⁶	307	313	$N_0 = N/10$; $\lg N_0 =$	7.49	
10 ⁻⁷	33	31	$7.17 \le \lg N_0 \le 7.70$?	⊠ yes	□no

Conc. of the	Contact	Vc1	Vc2	Na	_	lg R
product	time			(x x 10)		$(\lg N_0 - \lg Na)$
1:60	30 s	0	0	<140	<2.15	>5.34







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RST 002 (Issue 4)

Test organism: Staphylococcus aureus (NCTC 10788)

Date of test: 20 September 2019

Test temperature: $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Dilution-neutralisation method: Pour plate Number of plates: 1/ml

Neutraliser: B Test conditions: Clean conditions

Validation and controls:

Results: EN 1276:2019

Validatio	n suspensio	on (Nv _o)	Experimental conditions			Neutralis	Neutraliser or filtration			Method validation (C)		
				control (A)			control (B)			Product conc.: 1:60		
Vc1	143	<u></u> <u>n</u> =	Vc1	150	<u></u> =	Vc1	142	<u> </u>	Vc1	143	<u> </u>	
Vc2	137	140	Vc2	144	147	Vc2	147	144.5	Vc2	144	143.5	
$30 \le \overline{\mu}$ of $Nv_0 \le 160$?		$\overline{\mu}$ of $A \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		$\overline{\mu}$ of $B \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		$\overline{\mu}$ of $C \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		lvo?				
⊠ yes	□ no			⊠ yes	□no							

Test suspension (N and N_0):

Ν	Vc1	Vc2	$\overline{\mu} \text{ wm} = 4.80 \times 10^8 ;$	lg N =	8.68
10 ⁻⁶	>330	>330	$N_0 = N/10$; $\lg N_0 =$	7.68	
10 ⁻⁷	47	49	$7.17 \le \lg N_0 \le 7.70$?	⊠ yes	□no

Conc. of the	Contact	Vc1	Vc2	Na	lg Na	lg R
product	time			(π x 10)		(lg N _o - lg Na)
1:60	30 s	41	37	390	2.59	5.09







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RST 002 (Issue 4)

Test organism: Enterococcus hirae (NCIMB 8192)

Date of test: 17 September 2019

Test temperature: $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ Dilution-neutralisation method: Pour plate Number of plates: 1/ml

Neutraliser: A Test conditions: Clean conditions

Validation and controls:

Results: EN 1276:2019

Validation	n suspensio	on (Nv _o)	Experimental conditions			Neutralis	Neutraliser or filtration			Method validation (C)		
				control (A)			control (B)			Product conc.: 1:60		
Vc1	59	<u></u> =	Vc1	59	<u></u> =	Vc1	62	<u></u> =	Vc1	61	<u> </u>	
Vc2	62	60.5	Vc2	64	61.5	Vc2	63	62.5	Vc2	63	62	
$30 \le \overline{\varkappa}$ of $Nv_0 \le 160$? $\overline{\varkappa}$ of $A \ge 0.5 \times \overline{\varkappa}$ of Nv_0 ?		$\overline{\mu}$ of $B \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		ν _o ?	$\overline{\mu}$ of $C \ge 0.5 \times \overline{\mu}$ of Nv_0 ?		lvo?					
⊠ yes	□no		⊠ yes	□no		⊠ yes	□no		⊠ yes	□no		

Test suspension (N and N_0):

Ν	Vc1	Vc2	$\overline{\mu} \text{ wm} = 2.66 \times 10^8 ;$	lg N =	8.42
10 ⁻⁶	278	256	$N_0 = N/10$; $\lg N_0 =$	7.42	
10 ⁻⁷	26	25	$7.17 \le \lg N_0 \le 7.70$?	⊠ yes	□no

Conc. of the product	Contact time	Vc1	Vc2	<i>Na</i> (π x 10)	l ~	lg <i>R</i> (lg <i>N</i> _o - lg <i>Na</i>)
1:60	30 s	0	0	<140	<2.15	>5.27







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Explanations:

Vc count per ml (one plate or more)

 $\overline{\mu}$ average of Vc1 and Vc2 (1 + 2 duplicate)

 $\overline{\mu}$ wm weighted mean of $\overline{\mu}$

N number of cells per ml in the test suspension

 N_0 number of cells in the test mixture at the beginning of the contact time ($N_0 = N / 10$)

Na number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or

filtration)

R reduction ($\lg R = \lg N_0 - \lg Na$)

Nv number of cells per ml in the validation suspension

 Nv_0 number of cells in the validation mixtures at the beginning of the contact time ($Nv_0 = Nv / 10$)

A number of survivors per ml in the experimental conditions control mixture

B number of survivors per ml in the neutraliser or filtration control mixture

C number of survivors per ml in the method validation mixture

All test results have an associated uncertainty of measurement, details of which are available on request.