

**Report:** SSL.19F006.IMpTmMn-L2

**Issued:** 17 September 2019

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**Test Report:**

**EN 1650:2019**

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal 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:**

Safe Solutions (Safe4) Ltd  
Wharton Green, Bostock Road, Winsford, CW7 3BD, United Kingdom

**Identification of the sample:**

19F/006

Name of the product: PDSA Shampoo

Batch number/reference and expiry date (if available): 3671

Date of delivery: 07 June 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: Thick pink 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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**Test method and its validation:**

Method: 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)  
Neutraliser validation: Validated in accordance with EN 1650:2019 (5.5.2)

**Experimental conditions:**

Period of analysis: 10 September 2019 to 16 September 2019  
Product test concentration(s): Neat  
Diluent used for product test solution(s): N/A  
Contact time(s): 5 min ± 10 s  
Test temperature(s): 20°C ± 1°C  
Interfering substance: 0.3 g/l bovine albumin (clean conditions)  
Temperature of incubation: 30°C ± 1°C  
Identification of the fungal strain(s) used: *Malassezia pachydermatis* (NCPF 2667)  
*Trichophyton mentagrophytes* (CECT 20806)  
*Microsporium canis* (CECT 2797)

**Deviations:**

- 1) Additional serial dilutions of *Na* – down to 10<sup>-2</sup> – undertaken at client's request in order to show a greater than 3 lg reduction against each test organism.

**Remarks:**

- 1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 1650:2019 (5.4.2) or EN 1650:2019 (5.5.1.1).
- 2) Products can only be tested at a concentration of 80% or less as some dilution is always produced by adding the test organisms and interfering substance.

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**Requirements:**

The client has requested that the product demonstrates at least a 2 decimal log (lg) reduction against every test organism.

**Conclusion:**

PDSA Shampoo achieves a greater than 2 lg reduction when tested neat with a contact time of 5 minutes at 20°C under clean conditions against all of the referenced strains of *Malassezia pachydermatis*, *Trichophyton mentagrophytes* and *Microsporum canis*.

**Report prepared by:**

Signed:



Name:

Tony Watson

Position:

General Manager

Date:

16 September 2019

**Approved by:**

Signed:



Name:

Gareth Bayliss

Position:

Laboratory Manager

Date:

17 September 2019

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Results: EN 1650:2019

RST 006a (Issue 3)

Test organism:	<i>Malassezia pachydermatis</i>	(NCPF 3667)
Date of test:	10 September 2019	
Test temperature:	20°C ± 1°C	Incubation temperature: 30°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates: 1 / ml
Neutraliser:	A	Test conditions: Clean conditions

**Validation and controls:**

Validation suspension ( $N_{v_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: 5 min		
Vc1	33	$\bar{x}$ =	Vc1	34	$\bar{x}$ =	Vc1	30	$\bar{x}$ =	Vc1	29	$\bar{x}$ =
Vc2	31	32	Vc2	31	32.5	Vc2	27	28.5	Vc2	31	30
30 ≤ $\bar{x}$ of $N_{v_0}$ ≤ 160 ?			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 1.95 x 10 <sup>7</sup> ; $N_0 = N / 10$ ; 6.17 ≤ lg $N_0$ ≤ 6.70 ?
10 <sup>-5</sup>	>165	>165	lg $N$ = 7.29 lg $N_0$ = 6.29
10 <sup>-6</sup>	19	20	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x}$ x 10 or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
Neat	5 min	10 <sup>0</sup>	>165	>165	8.30 x 10 <sup>3</sup>	3.92	2.37
		10 <sup>-1</sup>	89	77			
		10 <sup>-2</sup>	8	7			

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Results: EN 1650:2019

RST 006a (Issue 3)

Test organism:	<i>Trichophyton mentagrophytes</i>	(CECT 20806)
Date of test:	10 September 2019	
Test temperature:	20°C ± 1°C	Incubation temperature: 30°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates: 1 / ml
Neutraliser:	A	Test conditions: Clean conditions

**Validation and controls:**

Validation suspension ( $N_{v_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: 5 min		
Vc1	41	$\bar{x} =$	Vc1	43	$\bar{x} =$	Vc1	42	$\bar{x} =$	Vc1	39	$\bar{x} =$
Vc2	44	42.5	Vc2	41	42	Vc2	37	39.5	Vc2	34	36.5
30 ≤ $\bar{x}$ of $N_{v_0}$ ≤ 160 ?			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 2.00 x 10 <sup>7</sup> ;	lg $N$ = 7.30
10 <sup>-5</sup>	>165	>165	$N_0 = N / 10$ ;	lg $N_0$ = 6.30
10 <sup>-6</sup>	17	23	6.17 ≤ lg $N_0$ ≤ 6.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x}$ x 10 or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	5 min	10 <sup>0</sup>	>165	>165	1.60 x 10 <sup>3</sup>	3.20	3.10
		10 <sup>-1</sup>	16	16			
		10 <sup>-2</sup>	1	3			

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Results: EN 1650:2019

RST 006a (Issue 3)

Test organism:	<i>Microsporium canis</i>	(CECT 2797)
Date of test:	10 September 2019	
Test temperature:	20°C ± 1°C	Incubation temperature: 30°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates: 1 / ml
Neutraliser:	A	Test conditions: Clean conditions

**Validation and controls:**

Validation suspension ( $N_{v_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: 5 min		
Vc1	32	$\bar{x} =$	Vc1	43	$\bar{x} =$	Vc1	34	$\bar{x} =$	Vc1	42	$\bar{x} =$
Vc2	41	36.5	Vc2	37	40	Vc2	36	35	Vc2	39	40.5
30 ≤ $\bar{x}$ of $N_{v_0}$ ≤ 160 ?			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{v_0}$ ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 1.60 x 10 <sup>7</sup> ; $N_0 = N / 10$ ; 6.17 ≤ lg $N_0$ ≤ 6.70 ?
10 <sup>-5</sup>	>165	>165	lg $N$ = 7.20 lg $N_0$ = 6.20
10 <sup>-6</sup>	15	17	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x}$ x 10 or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	5 min	10 <sup>0</sup>	>165	>165	4.00 x 10 <sup>3</sup>	3.60	2.60
		10 <sup>-1</sup>	43	37			
		10 <sup>-2</sup>	4	5			

**Explanations:**

$V_c$	count per ml (one plate or more)
$\bar{x}$	average of $V_{c1}$ and $V_{c2}$ (1 + 2 duplicate)
$\bar{x}_{wm}$	weighted mean of $\bar{x}$
$N$	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 ( $N_0 = N / 10$ )
$N_a$	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
$R$	reduction ( $\lg R = \lg N_0 - \lg N_a$ )
$N_v$	number of cells per ml in the validation suspension
$N_{v_0}$	number of cells in the validation mixtures at the beginning of the contact time ( $N_{v_0} = N_v / 10$ )
$A$	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