



EVS-EN 16615:2015
INTERFLO OÜ
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Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test)

TEST REPORT no 676

1.General information and material

Client:

Medisept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
Reg. 946001016
2021/04/27

Date of order:

2. Identification of sample

Name of the product:

CHUSTECZKI VELOX OXY ETA (CONCEPTION 10)

Batch number:

LOT: 06042021_126

Manufacturer:

Medisept Sp. Z.O.O.

Date of delivery:

2021/04/16

Storage conditions:

room temperature and darkness

Apperance of the product:

wipes soaked in 100% VELOX OXY ETA and stored in non-sealed original bin for 30 days

Active substance and concentration:

Ethanol (CAS: 64-17-5) – 72 g/100 ml; Propan-2-ol (CAS:67-63-0) – 7,2 g / 100 ml;

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Hydrogen peroxide (CAS: 7722-84-1) – 3 g/100 ml

3. Test conditions

Test period:	2021/04/27 – 2021/05/31
Date of tests:	2021/05/27
Product test concentrations:	100 %
Exposure time:	1 min
Test temperature:	19,5 ± 0,5°C
Temperature of incubation	36,5 ± 0,5°C – for bacteria; 29,5 ± 0,5°C – for yeast
Organic load:	3,0 g/l bovine albumine and 3 ml/l sheep erythrocytes for high-level soiling
Neutralizer:	Polysorbate 80, 30 g/l, Saponin, 30 g/l, Lecithin, 3 g/l, Sodium thiosulphate, 5 g/l
Test organisms:	Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 Pseudomonas aeruginosa ATCC 15442, Candida albicans ATCC 10231

4. Methods

Test method and its validation: dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 16615:2015, wet wipes with product CHUSTECZKI VELOX OXY ETA (CONCEPTION 10) (LOT: 06042021_126) for surface disinfection with concentration 100 % possesses bactericidal activity in carrier test in 1 min at 20 °C under dirty conditions for referenced strains Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Pseudomonas aeruginosa ATCC 15442. Product CHUSTECZKI VELOX OXY ETA (CONCEPTION 10) (LOT: 06042021_126) demonstrates at least a 5 lg reduction.

Wet wipes with product CHUSTECZKI VELOX OXY ETA (CONCEPTION 10) (LOT: 06042021_126) for surface disinfection with concentration 100 % possesses yeasticidal activity in carrier test in 1 min at 20 °C under dirty conditions for reference strain Candida albicans ATCC 10231. Product CHUSTECZKI VELOX OXY ETA (CONCEPTION 10) (LOT: 06042021_126) demonstrates at least a 4 lg reduction.

The conclusion is true only for the studied sample of the product CHUSTECZKI VELOX OXY ETA (CONCEPTION 10) (LOT: 06042021_126).

Total 10 pages

Annex on 8 pages

Tallinn, 2021/05/31

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Annex 1

 Table 1. **Validation and controls.**

Test organisms	Validation suspension Nvo			Neutralizer control B			Method validation C Concentration 80 %		
	Vc1	V c2	$\bar{X}$	Vc1	V c2	$\bar{X}$	Vc1	V c2	$\bar{X}$
Staphylococcus aureus ATCC 6538	80	95	88	64	60	62	76	80	78
Pseudomonas aeruginosa ATCC 15442	72	60	66	55	51	53	48	54	51
Enterococcus hirae ATCC 10541	54	48	51	39	43	41	50	41	46
Candida albicans ATCC 10231	35	47	41	34	37	36	40	43	42

Annex 2

 Table 2. **Test suspensions**

Test organisms	Dilution range	Vc1	Vc2	N and No
Staphylococcus aureus ATCC 6538	-7 -8	>200 24	200 16	$N = 2,0 \times 10^9$ $\lg N = 9,3$ $No = N / 20 \quad \lg No 8,0$
Pseudomonas aeruginosa ATCC 15442	-7 -8	>200 23	>100 15	$N = 1,9 \times 10^9$ $\lg N = 9,28$ $No = N / 20 \quad \lg No 7,98$
Enterococcus hirae ATCC 10541	-7 -8	>100 18	>100 12	$N = 1,5 \times 10^9$ $\lg N = 9,18$ $No = N / 20 \quad \lg No 7,88$
Candida albicans ATCC 10231	-6 -7	>100 14	>100 18	$N = 1,6 \times 10^8$ $\lg N = 8,2$ $No = N / 20 \quad \lg No 6,9$

Annex 3

 Table 3. **Drying controls Dct**

Test organisms	Dilution range	Vc1	Vc2	Dct
Staphylococcus aureus ATCC 6538	-5	135	150	1,45 x 10 ⁷ Dct lg 7,16
	-6	18	16	6,88 ≤ Dct ≤ 8,40
Pseudomonas aeruginosa ATCC 15442	-5	149	163	1,62 x 10 ⁷ Dct 7,21
	-6	19	26	6,88 ≤ Dct ≤ 8,40
Enterococcus hirae ATCC 10541	-5	152	168	1,6 x 10 ⁷ Dct 7,2
	-6	14	17	6,88 ≤ Dct ≤ 8,40
Candida albicans ATCC 10231	-4	162	150	1,55 x 10 ⁶ Dct 6,19
	-5	17	13	5,88 ≤ Dct ≤ 7,40

Annex 4

 Table 4. **Drying controls Dco**

Test organisms	Dilution range	Vc1	Vc2	Dco
Staphylococcus aureus ATCC 6538	-5	>100	164	1,68 x 10 ⁷ Dct lg 7,23
	-6	19	18	6,88 ≤ Dct ≤ 8,40
Pseudomonas aeruginosa ATCC 15442	-5	161	157	1,59 x 10 ⁷ Dct 7,2
	-6	14	17	6,88 ≤ Dct ≤ 8,40
Enterococcus hirae ATCC 10541	-5	>100	>100	1,6 x 10 ⁷ Dct 7,2
	-6	12	20	6,88 ≤ Dct ≤ 8,40
Candida albicans ATCC 10231	-4	172	155	1, 1,65 x 10 ⁶ Dct 6,22
	-5	19	16	5,88 ≤ Dct ≤ 7,40

Annex 5

 Table 5. **Test field T1 (reduction) Dirty condition**

Test organisms	Concentration of the product	Dilution range	Vc1	Vc2	Na	Ig Na	Ig R	Contact time
Staphylococcus aureus ATCC 6538	100 %	1	0	0	<14	<1,15	> 5,01	1 min
		-1	0	0				
Pseudomonas aeruginosa ATCC 15442	100 %	1	0	0	<14	<1,15	> 5,06	1 min
		-1	0	0				
Enterococcus hirae ATCC 10541	100 %	1	0	0	<14	<1,15	> 5,05	1 min
		-1	0	0				
Candida albicans ATCC 10231	100 %	1	0	0	<14	<1,15	> 4,04	1 min
		-1	0	0				

Annex 6

 Table 6. Test fields T2 to T4 (cfu / 25 cm²) Dirty conditions

Test organisms	Concentration of the product	Dilution range	Vc T2	Vc T3	Vc T4	V _{T2 to T4} $\bar{X} \times 5$ cfu / 25 cm ²	Contact time
Staphylococcus aureus ATCC 6538	100 %	1	0	0	0	<14 x 5 = <70	1 min
		-1	0	0	0		
Pseudomonas aeruginosa ATCC 15442	100 %	1	0	0	0	<14 x 5 = <70	1 min
		-1	0	0	0		
Enterococcus hirae ATCC 10541	100 %	1	0	0	0	<14 x 5 = <70	1 min
		-1	0	0	0		
Candida albicans ATCC 10231	100 %	1	0	0	0	<14 x 5 = <70	1 min
		-1	0	0	0		

Annex 7

 Table 7. Nw Test fields T2 to T 4 (cfu / 25 cm ²)

Test organisms	Concentration of the product	Dilution range	Vc T2	Vc T3	Vc T4	Nw V T2 to T4 $\bar{X} \times 5$ cfu / 25 cm ²	Contact time
Staphylococcus aureus ATCC 6538	0%	1	>300	>100	12	>712,12	1 min
		-1	41	15	2		
Pseudomonas aeruginosa ATCC 15442	0%	1	>300	>300	42	>1122,72	1 min
		-1	36	30	33		
Enterococcus hirae ATCC 10541	0%	1	>300	>100	46	>754,55	1 min
		-1	29	17	6		
Candida albicans ATCC 10231	0%	1	>300	>100	15	>747,00	1 min
		-1	31	14	33		

Annex 8

$$N = c / (n_1 + 0.1 n_2) \times 10^{-z}$$

$$N_a = (c \times 5) / (2.2 \times 10^z)$$

$$R = \lg R = \lg D_{ct} - \lg N_a$$

$$\bar{X} = (V_{t2} + V_{t3} + V_{t4}) \times 5 / 3$$

$\bar{X}$ = average of V_{c1} and V_{c2} (1. + 2. duplicate)

c is the sum of V_c -values taken into account

V_c = count per ml

z is the dilution factor corresponding to the lower dilution

N_w is the control with hard water and polysorbat 80

R is the reduction

cfu = colony forming unit(s) per millilitre