



EVS-EN 16615:2015
INTERFLO OÜ
LABORATORY
Supluse pst. 5-3, 11911, Tallinn,
Estonia
Tel.+372 58098890
e-mail: norbak@norbak.ee

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 710

1.General information and material

Client:

Medisept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
NIP: 9460010016

Date of order:

2022/03/03

2. Identification of sample

Name of the product:

VELOX OXY ETA

Batch number:

LOT: 220221 45

Manufacturer:

Medisept Sp. Z.O.O

Date of delivery:

2022/03/03

Storage conditions:

room temperature and darkness

Apperance of the product:

Colorless liquid

Recommended diluent:

the product is ready for use

Microbiologist
Ljudmila Shljapnikova
Biol. Ph.D.
Head of the Laboratory



Active substance and concentration:

Ethanol – 72 g; Propan-2-ol – 7.2 g; Hydrogen peroxid – 3 g

3. Test conditions

Test period:

2022/03/09 – 2022/03/14

Date of tests:

2022/03/09; 2022/03/10

Product test concentrations:

100 %

Product diluent used during the test

product is ready to use

Exposure time:

30 s.

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, wipes soaked by product MEDISEPT VELOX OXY ETA (LOT: 220221 45) for surface disinfection with concentration 100 % possesses bactericidal activity in carrier test in 30 s. at 20 °C under dirty conditions for reference strains Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541 and Pseudomonas aeruginosa ATCC 15442. Product VELOX OXY ETA (LOT: 220221 45) demonstrates at least a 5 lg reduction.

Wipes soaked by product VELOX OXY ETA (LOT: 220221 45) for surface disinfection with concentration 100 % possesses yeasticidal activity in carrier test in 30 s. at 20 °C under dirty conditions for reference strain Candida albicans ATCC 10231. Product VELOX OXY ETA (LOT: 220221 45) demonstrates at least a 4 lg reduction.

The conclusion is true only for the studied sample of the product VELOX OXY ETA (LOT: 220221 45).

Total 9 pages

Annex on 7 pages

Tallinn, 2022/03/14

Microbiologist

Ljudmila Shljapnikova

Biol. Ph.D.

Head of the Laboratory



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	55	60	58	48	50	49	55	51	53
Pseudomonas aeruginosa ATCC 15442	71	80	76	65	68	67	67	60	64
Enterococcus hirae ATCC 10541	85	96	91	76	70	73	99	84	92
Candida albicans ATCC 10231	49	38	44	35	37	36	41	42	42

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 2

Table 2. Test suspensions

Test organisms	Dilution range	Vc1	Vc2	N and No
Staphylococcus aureus ATCC 6538	-7 -8	177 15	190 19	$N = 1,82 \times 10^9$ $\lg N = 9,26$ $No = N / 20 \quad \lg No 7,96$
Pseudomonas aeruginosa ATCC 15442	-7 -8	>200 17	>200 23	$N = 2,0 \times 10^9$ $\lg N = 9,3$ $No = N / 20 \quad \lg No 8,0$
Enterococcus hirae ATCC 10541	-7 -8	>200 34	>200 22	$N = 2,8 \times 10^9$ $\lg N = 9,45$ $No = N / 20 \quad \lg No 8,15$
Candida albicans ATCC 10231	-6 -7	>300 33	>300 27	$N = 3,0 \times 10^8$ $\lg N = 8,48$ $No = N / 20 \quad \lg No 7,18$

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 3

 Table 3. **Drying controls Dct = Dco**

Test organisms	Dilution range	Vc1	Vc2	Dct
Staphylococcus aureus ATCC 6538	-5	122	100	110,45 x 10 ⁷ Dct lg 7,04
	-6	11	10	6,88 ≤ Dct ≤ 8,40
Pseudomonas aeruginosa ATCC 15442	-5	103	90	95,0 x 10 ⁵ Dct 6,98
	-6	7	9	6,88 ≤ Dct ≤ 8,40
Enterococcus hirae ATCC 10541	-5	87	97	90,45 x 10 ⁵ Dct 6,96
	-6	6	9	6,88 ≤ Dct ≤ 8,40
Candida albicans ATCC 10231	-4	78	93	85,91 x 10 ⁴ Dct 5,93
	-5	9	9	5,88 ≤ Dct ≤ 7,40

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 4

 Table 4. **Test field T1 (reduction)**

Test organisms	Concentration of the product	Dilution range	Vc1	Vc2	Na	lg Na	lg R	Contact time
Staphylococcus aureus ATCC 6538	100%	1	0	0	<14	<1,15	>5,89	30 s.
		-1	0	0				
Pseudomonas aeruginosa ATCC 15442	100%	1	0	0	<14	<1,15	>5,83	30 s.
		-1	0	0				
Enterococcus hirae ATCC 10541	100%	1	0	0	<14	<1,15	>5,81	30 s.
		-1	0	0				
Candida albicans ATCC 10231	100%	1	0	0	<14	<1,15	>4,78	30 s.
		-1	0	0				

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 5

 Table 5. Test fields T2 to T4 (cfu / 25 cm²)

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	0/0	0/0	<14 x 5 = <70	30 s.
		-1	0/0	0/0	0/0		
Pseudomonas aeruginosa ATCC 15442	100%	1	0/0	0/0	0/0	<14 x 5 = <70	30 s.
		-1	0/0	0/0	0/0		
Enterococcus hirae ATCC 10541	100%	1	0/0	0/0	0/0	<14 x 5 = <70	30 s.
		-1	0/0	0/0	0/0		
Candida albicans ATCC 10231	100%	1	0/0	0/0	0/0	<14 x 5 = <70	30 s.
		-1	0/0	0/0	0/0		

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 6

 Table 9. 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	59	12	>1048	30 s.
		-1	>300	17	4		
Pseudomonas aeruginosa ATCC 15442	0%	1	>300	40	3	>988	30 s.
		-1	>300	9	0		
Enterococcus hirae ATCC 10541	0%	1	>300	>50	32	>1065	30 s.
		-1	>300	18	3		
Candida albicans ATCC 10231	0%	1	>200	>100	22	>547	30 s.
		-1	21	14	4		

Microbiologist
 Ljudmila Shljapnikova
 Biol. Ph.D.
 Head of the Laboratory



Annex 7

$$N = c / (n1 + 0.1 n2) \times 10^{-z}$$

$$Na = (c \times 5) / (2,2 \times 10^z)$$

$$R = \lg R = \lg Dct - \lg Na$$

$$\bar{X} = (Vt2 + Vt3 + Vt4) \times 5 / 3$$

$\bar{X}$ = average of Vc1 and Vc2 (1. + 2. duplicate)

c is the sum of Vc-values taken into account

Vc = count per ml

z is the dilution factor corresponding to the lower dilution

Nw is the control with hard water and polysorbat 80

R is the reduction

cfu = colony forming unit(s) per millilitre

Microbiologist
Ljudmila Shljapnikova
Biol. Ph.D.
Head of the Laboratory

