EAK
EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L236

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

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 ± 0,5ºC
Temperature of incubation	36,5 ± 0,5ºC – for bacteria; 29,5 ± 0,5ºC – 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 ºC 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 ºC 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

EESTI VABARIIK
OÜ INTERFLO
Reg.kood 11586747

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

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 x 10^9 lg N= 9,26 No = N / 20 lg No 7,96
Pseudomonas aeruginosa ATCC 15442	-7 -8	>200 17	>200 23	N= 2,0 x 10^9 lg N= 9,3 No = N / 20 lgNo 8,0
Enterococcus hirae ATCC 10541	-7 -8	>200 34	>200 22	N= 2,8 x 10^9 lg N= 9,45 No = N / 20 lgNo 8,15
Candida albicans ATCC 10231	-6 -7	>300 33	>300 27	N = 3,0 x 10^8 lg N= 8,48 No = N / 20 lgNo 7,18

Annex 3

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

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

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

EESTI VABARIIK
OÜ INTERFLO
Reg.kood 11586747

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				

Annex 5

Table 5. **Test fields T2 to T4 (cfu / 25 cm ²)**

Test organisms	**Concentration of the product**	**Dilution range**	**Vc T2**	**Vc T3**	**Vc T4**	**$V_{T2\ to\ T4}$ $\bar{X}$ x 5 cfu / 25 см 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		

Annex 6

Table 9. **Nw Test fields T2 toT 4 (cfu / 25 cm ²)**

Test organisms	**Concentration of the product**	**Dilution range**	**Vc T2**	**Vc T3**	**Vc T4**	**Nw V T2 to T4 $\bar{X}$ x 5 cfu / 25 см 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		

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