



EVS-EN 16615:2015
OÜ BALTIACHEMI
LABORATORY
Tel +372 6214 694
e-mail: info@baltiacemi.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 (phase 2, step 2)**

TEST REPORT no 423a

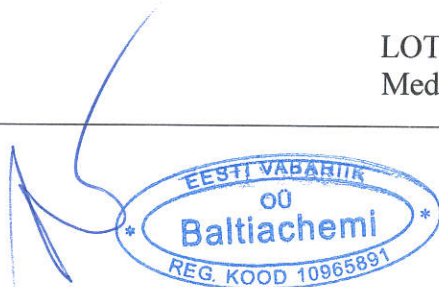
1. General information and material

Client: Medi-Sept Sp. z.o.o., Konopnica 159 c, 21-030 Motycz, Poland
Date of order: 2018/12/20

2. Identification of sample

Name of the product: VELOX SPRAY
Batch number: LOT:180822_3
Manufacturer: Medi-Sept Sp. z.o.o.

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



Date of delivery: 2019/01/11
Storage conditions: room temperature and darkness
Apperance of the product: clear liquid
Recommended diluent: product is ready to use
Active substance: Etanol, 63.7 %; Propan-2-ol, 6,3 %

3. Test conditions

Test period: 2019/01/11 – 2019/01/19
Date of tests: 2019/01/11; 2019/01/15
Product test concentrations: 100 %
Exposure time: 30 s.
Test temperature: $19,5 \pm 0,5^{\circ}\text{C}$
Organic load: for clean condition is bovine albumine, 0,3g/l
for dirty conditions are bovine albumine, 3,0 g/l and sheep erythrocytes, 3 ml/l
Neutralizer: Polysorbate 80, 30 g/l; Lecithin, 3 g/l; Saponin, 30 g/l
Temperature of incubation $36,5^{\circ}\text{C} \pm 0,5^{\circ}\text{C}$ for bacteria and $29,5^{\circ}\text{C} \pm 0,5^{\circ}\text{C}$ for yeast
Test organisms: Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442,
Enterococcus hirae ATCC 10541, Candida albicans ATCC 10231

4. Methods

2.1. Test method and its validation: dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 16615:2015, product VELOX SPRAY (LOT:180822_3) with concentration 100 % in 30 s. possesses bactericidal activity on non-porous surfaces with mechanical action employing wipes at 20 °C under clean and dirty conditions for referenced strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541. The product VELOX SPRAY (LOT:180822_3) demonstrates at least a 5 lg reduction. The VELOX SPRAY (LOT:180822_3) possesses high yeasticidal activity (4 lg reduction) under conditions: concentration 100 % in 30 s. on non-porous surfaces with mechanical action employing wipes at 20 °C under clean and dirty conditions in relation to Candida albicans ATCC 10231.

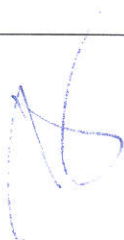
Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory



Total 14 pages
Annex on 11 pages

Maardu, 2019/01/19

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



Annex 1

VALIDATION AND CONTROLS

Test organisms	Validation suspension N _{vo}			Neutralizer control B			Method validation C		
	V _{c 1}	V _{c 2}	\bar{X}	V _{c 1}	V _{c 2}	\bar{X}	V _{c 1}	V _{c 2}	\bar{X}
Staphylococcus aureus ATCC 6538	71	79	75	59	65	62	59	69	64
Pseudomonas aeruginosa ATCC 15442	52	58	55	40	54	47	43	39	41
Enterococcus hirae ATCC 10541	91	107	99	70	82	76	69	84	73
Candida albicans ATCC 10231	76	64	70	62	50	56	51	53	52

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




Annex 2

TEST SUSPENSION

Test organisms	Dilution step	Vc 1	Vc 2	N
Staphylococcus aureus ATCC 6538	10^{-7}	155	160	$N = 1,5 \times 10^9 = \lg N 9,18$ $No = N/20, \lg No = 7,88$ $7,88 \leq \lg No \leq 8,40$
	10^{-} <input type="checkbox"/>	14	16	
Pseudomonas aeruginosa ATCC 15442	10^{-7}	>300	>300	$N = 3,4 \times 10^9 = \lg N 9,53$ $No = N/20, \lg No = 8,23$ $7,88 \leq \lg No \leq 8,40$
	10^{-} <input type="checkbox"/>	38	30	
Enterococcus hirae ATCC 10541	10^{-7}	174	186	$N = 1,8 \times 10^9 = \lg N 9,26$ $No = N/20, \lg No = 7,95$ $7,88 \leq \lg No \leq 8,40$
	10^{-} <input type="checkbox"/>	16	20	
Candida albicans ATCC 10231	10^{-6}	>200	>200	$N = 2,6 \times 10^8 = \lg N 8,42$ $No = N/20, \lg No = 7,11$ $6,88 \leq \lg No \leq 7,40$
	10^{-7}	23	29	

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




Annex 3

DRYING CONTROL (Dco)

Test organisms	Dilution step	Vc 1	Vc 2	N
Staphylococcus aureus ATCC 6538	10^{-5}	>200	>200	N = $2,4 \times 10^7 = \lg N 7,38$ $6,88 \leq \lg Dco \leq 8,40$
	10^{-6}	20	28	
Pseudomonas aeruginosa ATCC 15442	10^{-5}	>300	>300	N = $7,5 \times 10^7 = \lg N 7,88$ $6,88 \leq \lg Dco \leq 8,40$
	10^{-6}	69	81	
Enterococcus hirae ATCC 10541	10^{-5}	300	300	N = $2,75 \times 10^7 = \lg N 7,43$ $6,88 \leq \lg Dco \leq 8,40$
	10^{-6}	26	29	
Candida albicans ATCC 10231	10^{-4}	80	82	N = $8,1 \times 10^5 = \lg N 5,91$ $5,88 \leq \lg Dco \leq 7,40$
	10^{-5}	7	8	

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




Annex 4

DRYING CONTROL (Dct)

Test organisms	Dilution step	Vc 1	Vc 2	N
Staphylococcus aureus ATCC 6538	10 ⁻⁵ 10 ⁻⁶	>200 19	>200 25	N = 2,2 x 10 ⁷ = lgN 7,34 6,88 ≤ lg Dct ≤ 8,40
Pseudomonas aeruginosa ATCC 15442	10 ⁻⁵ 10 ⁻⁶	>300 88	>300 74	N = 8,1 x 10 ⁷ = lgN 7,9 6,88 ≤ lg Dct ≤ 8,40
Enterococcus hirae ATCC 10541	10 ⁻⁵ 10 ⁻⁶	296 27	284 33	N = 2,91 x 10 ⁷ = lgN 7,46 6,88 ≤ lg Dct ≤ 8,40
Candida albicans ATCC 10231	10 ⁻⁴ 10 ⁻⁵	75 8	79 9	N = 7,7 x 10 ⁵ = lgN 5,89 5,88 ≤ lg Dct ≤ 7,40

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



Annex 5

TEST FIELD I

Test organisms	Dilution step	Vc1	Vc2	Na	Ig Na	Ig R	Contact time	Conditions
Staphylococcus aureus ATCC 6538	10 ⁰	36	44	40	1,6	5,74	30 s.	Clean
		162	178	170	2,23	5,11	30 s.	Dirty
Pseudomonas aeruginosa ATCC 15442	10 ⁰	17	23	20	1,3	6,6	30 s.	Clean
		20	36	28	1,45	6,45	30 s.	Dirty
Enterococcus hirae ATCC 10541	10 ⁰	27	17	22	1,34	6,12	30 s.	Clean
		38	24	31	1,49	5,97	30 s.	Dirty
Candida albicans ATCC 10231	10 ⁰	0	0	1	<1	>4,89	30 s.	Clean
		0	0	1	<1	>4,89	30 s.	Dirty

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



Annex 6

 TEST FIELDS 2 to 4 (cfu/25 cm²)

Test organisms	Dilution step	Vc T2	Vc T3	Vc T4	V T2 to 4 C x 5 Cfu/25 cm ²	Contact time	Conditions
Staphylococcus aureus ATCC 6538	10 ⁰	0	0	0	1 x 5 = 5	30 s.	Clean
		0	0	0	1 x 5 = 5	30 s.	Dirty
Pseudomonas aeruginosa ATCC 15442	10 ⁰	0	0	0	1 x 5 = 5	30 s.	Clean
		0	0	0	1 x 5 = 5	30 s.	Dirty
Enterococcus hirae ATCC 10541	10 ⁰	0	0	0	1 x 5 = 5	30 s.	Clean
		0	0	0	1 x 5 = 5	30 s.	Dirty
Candida albicans ATCC 10231	10 ⁰	0	0	0	1 x 5 = 5	30 s.	Clean
		0	0	0	1 x 5 = 5	30 s.	Dirty

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



Annex 7

 1. Nw TEST FIELDS 2 to 4 (cfu/25 cm²) Staphylococcus aureus

Test organisms	Dilution step	Vc T2	Vc T3	Vc T4	VT2 to 4 C x 5	Contact time
Staphylococcus aureus ATCC 6538	10 ⁰	85	73	32	316,5	30 s.
	10 ⁻¹	9	9	5		

Annex 8

 2. Nw TEST FIELDS 2 to 4 (cfu/25 cm²) *Pseudomonas aeruginosa*

Test organisms	Dilution step	Vc T2	Vc T3	Vc T4	VT2 to 4 C x 5	Contact time
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁰	150	89	27	443,5	30 s.
	10 ⁻¹	17	11	3		

Annex 9

3. Nw TEST FIELDS 2 to 4 (cfu/25 cm²) *Enterococcus hirae*

Test organisms	Dilution step	Vc T2	Vc T3	Vc T4	V T2 to 4 C x 5	Contact time
<i>Enterococcus hirae</i> ATCC 10541	10 ⁰	135	91	22	413,5	30 s.
	10 ⁻¹	15	10	3		

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

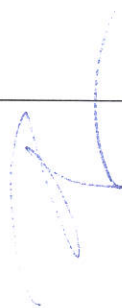


Annex 10

4. Nw TEST FIELDS 2 to 4 (cfu/25 cm²) Candida albicans

Test organisms	Dilution step	Vc T2	Vc T3	Vc T4	V T2 to 4 C x 5	Contact time
Candida albicans ATCC 10231	10 ⁰	35	46	28	181,5	30 s.
	10 ⁻¹	5	7	4		

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



Annex 11

$$N = c / (n1 + 0.1 n2) \times 10^{-7}$$

$$D_{co}, D_{ct} = c / (n1 + 0.1 n2) \times 10^{-5}$$

$$N_v = c / n$$

$$N_{vo} = N_v / 10$$

$$N_{aT1} = \frac{V_{c1} + V_{c2}}{2}$$

$$N_a, N_w T 2 \text{ to } 4 = c \times 5 / n \text{ (for test fields 2 to 4, cfu/25 cm}^2\text{)}$$

$$B, C = c / n$$

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

N – is the number of cfu (colony forming unit) for 1 ml test suspension

V_{c1}, V_{c2} - is the is number of cfu for 1 ml sample

c – is the sum of V_c-values taken into account

n – is the number of V_c-values taken into account

N_w – water control

R – reduction

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

