



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

TEST REPORT no 711

1.General information and material

Client:

Medisept Sp. z o.o., Konopnica 159 c, 21-030 Motycz, Poland
NIP. 946001016

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 to use

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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 test:

2022/03/09

Product test concentrations:

100 %

Product diluent used during the test

product is ready to use

Exposure time:

30 s., 60 s.

Test temperature:

19,5 ± 0,5°C

Temperature of incubation

29,5 ± 0,5°C

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:

Aspergillus brasiliensis ATCC 16404 – additional test organism

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 VELOX OXY ETA (LOT: 220221 45) for surface disinfection with concentration 100 % possesses fungicidal activity in carrier test in 30 and 60 sec. at 20 °C under dirty conditions for additional strain Aspergillus brasiliensis ATCC 16404. 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

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Annex 1

Table 1. **Validation and controls.**

Test organism	Validation suspension Nvo			Neutralizer control B			Method validation C Concentration 80 %		
	Vc1	V c2	$\bar{X}$	Vc1	V c2	$\bar{X}$	Vc1	V c2	$\bar{X}$
Aspergillus brasiliensis ATCC 16404	40	37	39	35	34	35	38	43	41

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Annex 2

Table 2. **Test suspension**

Test organism	Dilution range	Vc1	Vc2	N and No
Aspergillus brasiliensis ATCC 16404	-7	146	150	$N = 1,5 \times 10^8$ $\lg N = 8,18$ $No = N / 20 \quad \lg No 6,88$
	-8	16	18	

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Annex 3

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

Test organism	Dilution range	Vc1	Vc2	Dct
Aspergillus brasiliensis ATCC 16404	-3	>165	>165	18x 10 ⁴
	-4	19	17	Dct lg 5,26 <i>6,88 ≤ Dct ≤ 8,40</i>

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Annex 4

Table 4. Test field T1 (reduction)

Test organism	Concentration of the product	Dilution range	Vc1	Vc2	Na	lg Na	lg R	Contact time
Aspergillus brasiliensis ATCC 16404	100%	1	0	0	<14	<1,15	> 4,11	30 s.
		-1	0	0				
		1	0	0	<14	<1,15	> 4,11	60 s.
		-1	0	0				

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Annex 5

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

Test organism	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
Aspergillus brasiliensis ATCC 16404	100%	1	0/0	0/0	0/0	<14 x 5 = <70	30 s.
		-1	0/0	0/0	0/0		
		1	0/0	0/0	0/0	<14 x 5 = <70	60 s.
		-1	0/0	0/0	0/0		

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Annex 6

 Table 9. Nw Test fields T2 to T 4 (cfu / 25 cm ²)

Test organism	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
Aspergillus brasiliensis ATCC 16404	0%	1	51	40	9	179	30 s.
		-1	7	9	2		

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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

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