EN ISO/IEC 17025
L236

EVS-EN 14563:2009
INTERFLO OÜ
LABORATORY
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Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants in the medical area (phase 2, step 2)

TEST REPORT no 784

1. Client: ZHIVAS LTD
14 Assen Jordanov Blvd. 1592, Sofia, Bulgaria

Date of order: 2023/02/27

2. Identification of sample

Name of the product: **OXISEPT**
Batch number: 173_01.2023
Manufacturer: ZHIVAS LTD
Date of delivery: 2023/02/24

Microbiologist
Ljudmila Shljapnikova
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Storage conditions:	Room temperature, darkness
Apperance of the product:	White powder
Recommended diluent:	Water
Active substance and concentration	Sodium percarbonate – 30 - 50 %; TAED – 15 - 25 %

3. Test conditions

Test period:	2023/03/01 – 2023/03/21
Date of test:	2023/03/01
Product test concentrations:	0,75 %, 1,0 %, 1,5 %
Exposure time:	15 min
Test temperature:	19,5 ± 0,5ºC
Temperature of incubation	36,5 ± 0,5ºC
Organic load:	0,3 g/l bovine albumine for low-level soiling
Neutralizer:	Polysorbate 80, 30 g/l, Lecithin, 3 g/l, Sodium thiosulphate, 5 g/l
Test organisms:	Mycobacterium terrae ATCC 15755, Mycobacterium avium ATCC 15769

4. Method dilution neutralisation

5. Results see annex

6. Conclusion

In accordance with EVS-EN 14563:2009, the product OXISEPT (173_01.2023) with concentration 0,75 % possesses mycobactericidal and tuberculocidal activity in carrier tests in 15 min at 20 ºC under clean condition for referenced strains Mycobacterium terrae ATCC 15755 and Mycobacterium avium ATCC 15769. The product OXISEPT (173_01.2023) demonstrates at least than 4 logarithms of reduction.
*The conclusion is true only for the studied sample of the product OXISEPT (*173_01.2023*).*

Total 8 pages
Annex on 6 pages

Maardu, 2023/03/21

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Annex 1

VALIDATION AND CONTROLS

Test organism	**Validation suspension Nvo -1**			**Experimental conditions control A**			**Neutralizer control B**			**Method validation C** Concentration 1,5 %		
	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$	Vc1	Vc2	$\bar{X}$
Mycobacterium terrae ATCC 15755	39	47	43	42	40	41	35	38	37	37	44	41
Mycobacterium avium ATCC 15769	70	67	69	65	69	67	58	60	59	72	64	68
	$30 \leq \bar{X}$ of Nvo ≤ 160			*$\bar{X}$ of A is $\geq 0.5\bar{X}$ of Nvo*			*$\bar{X}$ of A is $\geq 0.5\bar{X}$ of Nvo*			*$\bar{X}$ of A is $\geq 0.5\bar{X}$ of Nvo*		

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Annex 2

TEST SUSPENSIONS

Test organisms	**Dilution range**	**Vc1**	**Vc2**	**N**
Mycobacterium terrae ATCC 15755	-7 -8	>300 56	>300 44	N= 5,0 x 10 9 = lg 9,7 *9,17≤lg N≥ 9,70*
Mycobacterium avium ATCC 15769	-7 -8	>300 40	>300 54	N= 4,7 x 10 9 = lg 9,67 *9,17≤lg N≥ 9,70*

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Annex 3

Water control Nw

Test organisms	N	Vc1	Vc2	Nw
Mycobacterium terrae ATCC 15755	-5 -6	80 10	92 13	Nw = 88,63x 10 6 = **lg 7,95** 6,15 ≤ lg Nw ≤ (lgN-1,3) 8,38
Mycobacterium avium ATCC 15769	-5 -6	65 8	78 9	Nw = 72,73x10 6 = **lg 7,86** 6,15 ≤ lg Nw ≤ (lgN-1,3) 8,32

Annex 4

TEST 1

Test organism	**Dilution range**	Vc1	Vc2	**Na x 10**	**lg Na**	**lg R**	**Concentration**	**Contact time**
Mycobacterium terrae ATCC 15755	1	0	0	<140	<2,15	**>5**,8	0,75 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>5**,8	1,0 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>5**,8	1,5 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 5

TEST 2

Test organism	**Dilution range**	Vc1	Vc2	**Na x 10**	**lg Na**	**lg R**	**Concentration**	**Contact time**
Mycobacterium avium ATCC 15769	1	0	0	<140	<2,15	**>5,71**	0,75 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>5,71**	1,0 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	0	0	<140	<2,15	**>5,71**	1,5 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 6

$N = c / (n1 + 0{,}1\ n2) \times 10^{-8}$

$Na, Nw = c \times 10 / n$

$R = \lg Nw - \lg Na$

N – is the number of colonies for 1 ml test suspension
Vc1, Vc2 - is the is number of colonies for 1 ml sample
n – is the number of Vc-values taken into account
R – reduction

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