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S.C. UNILAB srl
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EXAMINATION REPORT
№ 924/23.07.2012

а. Product identification

Product name:	**OXISEPT**
Batch number:	38
Valid until:	03.2013
Active substances and concentrates:	Sodium perborate 50 % taed 25 %
Manufacturer:	SC BORERO COMSERV LTD (SC BORERO COMSERV SRL) 1 Carpenului Str., Brasov
Storage conditions:	Areas protected from direct sunlight
Diluter recommended by manufacturer:	-
Number of Analysis Order /date:	119/16.05.2012
Date of receipt of product:	17.05.2012

б. Testing method

Testing method:	Dilution-neutralization
Neutralizer:	L_cysteine 1.5 %

в. Experimental conditions

Testing period:	30.05.2012 – 13.07.2012
Diluter of the product used during testing:	Hard water
Product concentrates:	2 % (required dilution) 1 %, 3 % (dilution selected by the laboratory)
External form of product:	Green powder
Contact time:	t = 10 min ± 10 c, 15 min ± 10 c

Temperature of testing:	20 °C ± 1 °C
Interfering substances:	Beef albumin (0.3 g/l)
Temperature of incubation:	37 °C ± 1 °C
Tested strains:	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
Method:	SR EN 14348:2005 „Chemical antiseptics and disinfectants. Quantity testing of suspension for evaluation of the micro bactericide action of the chemical disinfectants for medical usage, including disinfectants of tools. Methods of testing and requirements " (phase 2, stage 1)" (PSL-MIC-05)

Analyst:
Dumitru Tatiana
Signature: *illegible*

Head of laboratory:
Biologist Gianina Croc
Signature: *illegible*

Stamp: S.C. UNILAB Srl

The present examination report is valid only in its original (photocopying is prohibited). Contains 6 pages.

Examination report № **924/23.07.2012**

EXAMINATION RESULTS

I. *Mycobacterium avium*

Bacterial suspension (N and N_0)	N	Vc_1	Vc_2	$N = 31 \times 10^8 = 1g\ N = 9.49$ $N_0 = 1g\ 8.49$ $8.17 \leq N_0 \leq 8.70$ X Yes No
	10^{-7}	320	298	
	10^{-8}	31	25	

Suspension to validate (Nv_0)	Vc_1	Vc_2	M	$30 \leq$ Average $Nv_0 \leq 160$ X Yes No
	123	152	137.5	

II. *Mycobacterium terrae*

Bacterial suspension (N и N_0)	N	Vc_1	Vc_2	$N = 317 \times 10^7 = 1g\ N = 9.50$ $N_0 = 1g\ 8.50$ $8.17 \leq N_0 \leq 8.70$ X Yes No
	10^{-7}	299	334	
	10^{-8}	30	34	

[redacted]

Suspension to validate (Nv_0)	Vc_1	Vc_2	M	
	100	83	91.5	30 ≤ Average Nv_0 ≤ 160 X Yes No

Examination report № 924/23.07.2012

1. Contact time: 10 min
   Dilution: 2 %
   Dilution selected by the laboratory: 1 %, 3 %
   Interfering substances: beef albumin (0.3 g/l)
   Temperature: 20 °C
   Mycobacterium avium ATTC 15769

Testing of experimental conditions (A)			**Testing of neutralizer (B)**			**Validation of method (C)**		
Vc_1	88	M = 90.5	Vc_1	69	M = 73	Vc_1	61	M = 66.5
Vc_2	93		Vc_2	77		Vc_2	72	
Average A ≥ 0,5 x Average Nv_0 X Yes No			Average B ≥ 0,5 x Average Nv_0 X Yes No			Average C ≥ 0,5 x Average Nv_0 X Yes No		

Product concentration (%)	**Dilution**	**Vc_1**	**Vc_2**	**LgN_a**	**Reduction (1gR)**
1.00 %	10^0	>300	>300	6.05	2.44
	10^{-1}	>300	>300		
	10^{-2}	>300	>300		
	10^{-3}	123	100		
2.00 %	10^0	>300	>300	4.30	**4.19**
	10^{-1}	213	196		
	10^{-2}	25	15		
	10^{-3}	< 14	< 14		
3.00 %	10^0	>300	>300	4.03	4.46
	10^{-1}	116	100		
	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		

2. Requested contact time: 10 min
   Dilution: 2 %
   Dilution selected by the laboratory: 1 %, 3 %
   Interfering substances: beef albumin (0.3 g/l)
   Temperature: 20 °C
   Mycobacterium terrae ATTC 15755

[redacted]

Testing of experimental conditions (A)			Testing of neutralizer (B)			Validation of method (C)		
Vc_1	74	M = 82.5	Vc_1	59	M = 65	Vc_1	50	M = 58
Vc_2	88		Vc_2	71		Vc_2	66	
Average A ≥ 0,5 x Average Nv_0 X Yes No			Average B ≥ 0,5 x Average Nv_0 X Yes No			Average C ≥ 0,5 x Average Nv_0 X Yes No		

Product concentration (%)	Dilution	Vc_1	Vc_2	LgN_a	Reduction (1gR)
1.00 %	10^0	>300	>300	5.55	2.95
	10^{-1}	>300	>300		
	10^{-2}	316	329		
	10^{-3}	33	38		
2.00 %	10^0	>300	>300	4.26	**4.24**
	10^{-1}	199	169		
	10^{-2}	21	15		
	10^{-3}	< 14	< 14		
3.00 %	10^0	>300	>300	3.94	4.56
	10^{-1}	98	78		
	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		

3. Contact time: 15 min
   Dilution: 2 %
   Dilution selected by the laboratory: 1 %, 3 %
   Interfering substances: beef albumin (0.3 g/l)
   Temperature: 20 °C
   Mycobacterium avium ATTC 15769

Testing of experimental conditions (A)			Validation of method (C)		
Vc_1	70	M = 76	Vc_1	75	M = 70
Vc_2	82		Vc_2	65	
Average A ≥ 0,5 x Average Nv_0 X Yes No			Average C ≥ 0,5 x Average Nv_0 X Yes No		

Product concentration (%)	Dilution	Vc_1	Vc_2	LgN_a	Reduction (1gR)
1.00 %	10^0	>300	>300	5.78	2.71
	10^{-1}	>300	>300		
	10^{-2}	>300	>300		
	10^{-3}	67	53		
2.00 %	10^0	>300	>300	3.61	**4.88**
	10^{-1}	43	39		

[redacted]

	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		
3.00 %	10^{0}	210	189		
	10^{-1}	17	16	3.22	5.27
	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		

2. Contact time: 15 min
   Dilution: 2 %
   Dilution selected by the laboratory: 1 %, 3 %
   Interfering substances: beef albumin (0.3 g/l)
   Temperature: 20 °C
   Mycobacterium terrae ATTC 15755

Testing of experimental conditions (A)			**Validation of method (C)**		
Vc_1	105	M = 101.5	Vc_1	75	M = 81
Vc_2	98		Vc_2	87	
Average A ≥ 0,5 x Average Nv_0 X Yes No			Average C ≥ 0,5 x Average Nv_0 X Yes No		

Product concentration (%)	**Dilution**	**Vc_1**	**Vc_2**	**LgN_a**	**Reduction (1gR)**
1.00 %	10^{0}	>300	>300		
	10^{-1}	>300	>300	5.31	3.19
	10^{-2}	244	251		
	10^{-3}	23	18		
2.00 %	10^{0}	310	277		
	10^{-1}	28	30	3.46	**5.04**
	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		
3.00 %	10^{0}	182	166		
	10^{-1}	15	< 14	3.24	5.25
	10^{-2}	< 14	< 14		
	10^{-3}	< 14	< 14		

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Note:
V_c – quantity of colonies, listed on the sign
N – quantity of UFC/ml of the bacterial suspension for testing
N_v – quantity UFC/ml of the bacterial suspension for validation
N_a – quantity UFC/ml in the tested mixture
R – decrease of quantity of living cells

[redacted]

INTERPRETATION:

Examination results are located in the tables.

In correspondence with SR EN 14348:2005 the tested product **OXISEPT,** batch 38, diluted 2 %, at 10 min and respectively 15 min, at 20 °C in clean conditions (beef albumin (0.3 g/l)) using the method of dilution-neutralization has decreased the quantity of living cells of the *Mycobacterium avium and Mycobacterium terrae* reference strains, proving a reduction of minimum 1g 4.

CONCLUSIONS:

In correspondence with SR EN 14348:2005, batch 38 of product **OXISEPT** – diluted 2 %, represents **mycobactericidal action*** at 10 min and 15 min, at 20 °C under clean conditions (beef albumin (0.3 g/l)) regarding the *Mycobacterium avium and Mycobacterium terrae* reference strains.

- Mycobactericide action – ability of the product to inhibit the growth of microbacteria under certain conditions.

Note: Examination was performed observing the active European standards.
The present bulletin was issued in 2 (two) copies.

Analyst:
Bch. Dumitru Tatiana
Signature: *illegible*

Head of laboratory:
Biologist Gianina Croc
Signature: *illegible*

Stamp: S.C. UNILAB Srl

Date: 02.02.2009

End

I, the undersigned Bojidar Dimitrov Draganov, certify hereby that this is a full, true and correct translation from Bulgarian into English language of the attached document. The translation consists of 6 pages.
Translated by:
Bojidar Dimitrov Draganov

[redacted]

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INCERCARE
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SR EN ISO/CEI 17025:2005
CERTIFICAT DE ACREDITARE
nr. LI 859/2010

RAPORT DE INCERCARE
Nr. 924 / 23.07.2012

a. Identificarea produsului

Numele produsului:	**OXISEPT**
Numar lot:	38
Data expirare	03.2013
Substante active si concentratii	perborat de sodiu 50% taed 25%
Producator:	**SC BORERO COMSERV SRL** Str. Carpenului, Nr. 1, Brasov
Conditii de depozitare:	zone ferite de razele solare
Diluant recomandat de producator:	-
Numar comanda analiza/data:	119 / 16.05.2012
Data primirii produsului:	17.05.2012

b. Metoda de testare

Metoda de testare	diluție-neutralizare
Neutralizantul:	l cysteina 1.5%

c. Conditii experimentale

Perioada de testare:	30.05.2012-13.07.2012
Diluantul produsului utilizat in cursul testarii:	apa dura
Concentratii ale produsului:	2 % (dilutie solicitata) 1%, 3 % (dilutii aleasa de laborator)
Aspectul produsului :	pulbere de culoare verzui
Timp de contact:	t = 10 min ± 10 s; t = 15 min ± 10 s
Temperatura de testare	20° C ± 1° C
Substante interferente	albumina bovina (0.3 g/l)
Temperatura de incubare:	37°C ± 1° C
Tulpini test	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
Metoda	SR EN 14348:2005 "Antiseptice si dezinfectante chimice. Testarea cantitativa a suspensiei pentru evaluarea activitatii micobactericide a dezinfectantelor chimice de uz medical, inclusiv a dezinfectantelor pentru instrumentar. Metode de testare si cerinte (faza 2, etapa 1) " (PSL-MIC-05)

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REZULTATELE TESTARII

I. Mycobacterium avium

Suspensia bacteriana (N si N_o)	N	Vc_1	Vc_2	$N = 31 \times 10^8 = lgN=9.49$ $N_o = lg\ 8.49$ $8.17 \leq N_o \leq 8.70$ X Da Nu
	10^{-7}	320	298	
	10^{-8}	31	25	

Suspensia de validare (N_{vo})	Vc_1	Vc_2	M	$30 \leq$ Media $N_{vo} \leq 160$ X Da Nu
	123	152	137.5	

II. Mycobacterium terrae

Suspensia bacteriana (N si N_o)	N	Vc_1	Vc_2	$N = 317 \times 10^7 = lgN=9.50$ $N_o = lg\ 8.50$ $8.17 \leq N_o \leq 8.70$ X Da Nu
	10^{-7}	299	334	
	10^{-8}	30	34	

Suspensia de validare (N_{vo})	Vc_1	Vc_2	M	$30 \leq$ Media $N_{vo} \leq 160$ X Da Nu
	100	83	91.5	

1. Timp de contact: 10 min.
   Dilutie: 2%
   Dilutii alese de laborator: 1%, 3%
   Substanta de interferenta:albumina bovina (0.3 g/l)
   Temperatura: 20°C
   Mycobacterium avium ATTC 15769

Controlul conditiilor experimentale (A)			Controlul neutralizantului (B)			Validarea metodei (C)		
V_{c1}	88	M = 90.5	V_{c1}	69	M = 73	V_{c1}	61	M = 66.5
V_{c2}	93		V_{c2}	77		V_{c2}	72	
Media A ≥ 0.5 x Media N_{vo} X Da Nu			Media B ≥ 0,5 x Media N_{vo} X Da Nu			Media C ≥ 0,5 x Media N_{vo} X Da Nu		

Concentratia produsului (%)	Dilutia	V_{c1}	V_{c2}	Lg N_a	Reductia (lg R)
1.00%	10^0	>300	>300	6.05	2.44
	10^{-1}	>300	>300		
	10^{-2}	>300	>300		
	10^{-3}	123	100		
2.00%	10^0	>300	>300	4.30	**4.19**
	10^{-1}	213	196		
	10^{-2}	25	15		
	10^{-3}	<14	<14		
3.00%	10^0	>300	>300	4.03	4.46
	10^{-1}	116	100		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		

[redacted]

2. Timp de contact solicitat : 10 min.
Dilutie: 2%
Dilutii alese de laborator: 1%, 3%
Substanta de interferenta:albumina bovina (0.3 g/l)
Temperatura: 20°C
Mycobacterium terrae ATCC 15755

Controlul conditiilor experimentale (A)			**Controlul neutralizantului (B)**			**Validarea metodei (C)**		
V_{c1}	74	M = 82.5	V_{c1}	59	M = 65	V_{c1}	50	M = 58
V_{c2}	88		V_{c2}	71		V_{c2}	66	
Media A ≥ 0.5 x Media N_{vo}			Media B ≥ 0,5 x Media N_{vo}			Media C ≥ 0.5 x Media N_{vo}		
X Da Nu			X Da Nu			X Da Nu		

Concentratia produsului (%)	**Dilutia**	V_{c1}	V_{c2}	Lg N_a	**Reductia (lg R)**
1.00%	10^{0}	>300	>300	5.55	2.95
	10^{-1}	>300	>300		
	10^{-2}	316	329		
	10^{-3}	33	38		
2.00%	10^{0}	>300	>300	4.26	**4.24**
	10^{-1}	199	169		
	10^{-2}	21	15		
	10^{-3}	<14	<14		
3.00%	10^{0}	>300	>300	3.94	4.56
	10^{-1}	98	78		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		

3. Timp de contact: 15 min.
Dilutie: 2%
Dilutii alese de laborator: 1%, 3%
Substanta de interferenta:albumina bovina (0.3 g/l)
Temperatura: 20°C
Mycobacterium avium ATTC 15769

Controlul conditiilor experimentale (A)			**Validarea metodei (C)**		
V_{c1}	70	M = 76	V_{c1}	75	M = 70
V_{c2}	82		V_{c2}	65	
Media A ≥ 0,5 x Media N_{vo} X Da Nu			Media C ≥ 0,5 x Media N_{vo} X Da Nu		

Concentratia produsului (%)	**Dilutia**	V_{c1}	V_{c2}	Lg N_a	**Reductia (lg R)**
1.00%	10^{0}	>300	>300	5.78	2.71
	10^{-1}	>300	>300		
	10^{-2}	>300	>300		
	10^{-3}	67	53		
2.00%	10^{0}	>300	>300	3.61	**4.88**
	10^{-1}	43	39		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		
3.00%	10^{0}	210	189	3.22	5.27
	10^{-1}	17	16		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		

[redacted]

2. Timp de contact solicitat : 15 min.
Dilutie: 2%
Dilutii alese de laborator: 1%, 3%
Substanta de interferenta:albumina bovina (0.3 g/l)
Temperatura: 20°C
Mycobacterium terrae ATCC 15755

Controlul conditiilor experimentale (A)			**Validarea metodei (C)**		
V_{c1}	105	M = 101.5	V_{c1}	75	M = 81
V_{c2}	98		V_{c2}	87	
Media A ≥ 0.5 x Media N_{vo} X Da Nu			Media C ≥ 0,5 x Media N_{vo} X Da Nu		

Concentratia produsului (%)	**Dilutia**	V_{c1}	V_{c2}	Lg N_a	**Reductia (lg R)**
1.00%	10^{0}	>300	>300	5.31	3.19
	10^{-1}	>300	>300		
	10^{-2}	244	251		
	10^{-3}	23	18		
2.00%	10^{0}	310	277	3.46	**5.04**
	10^{-1}	28	30		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		
3.00%	10^{0}	182	166	3.24	5.25
	10^{-1}	15	<14		
	10^{-2}	<14	<14		
	10^{-3}	<14	<14		

Nota:
V_c – numarul de colonii numarate pe placuta
N – numarul UFC/ml ale suspensiei bacteriene de testare
N_v – numar UFC/ml ale suspensiei bacteriene de validare
N_a – nuamrul UFC/ml in amestecul de testare
R – reducere a numarului de celule viabile

INTERPRETARE:

Rezultatele testului se regasesc in tabele.

Conform standardului european SR EN 14348:2005, produsul **OXISEPT** testat, lot. 38 , diluat 2% , in 10 min si respectiv 15 min, la 20°C, in conditii de curatenie (albumina bovina (0.3 g/l)) , prin metoda dilutie-neutralizare a scazut numarul de celule viabile ale tulpinilor de referinta *Mycobacterium avium* si *Mycobacterium terrae*, dovedind o reductie de cel putin lg 4 .

CONCLUZII:

Conform SR EN 14348:2005, lotul 38 al produsului **OXISEPT** – diluat 2% , prezinta o **activitate micobactericida*** , in 10 min si 15 min, la 20°C, in conditii de curatenie (albumina bovina (0.3 g/l)) fata de tulpinile de referinta *Mycobacterium avium* si *Mycobacterium terrae*.

* activitate micobactericida – capabilitatea produsului de a inhiba cresterea micobacteriilor in conditiile definite

Obs Analizele au fost efectuate respectand standardele europene in vigoare.
Prezentul buletin s-a emis in 2 (doua) exemplare

Analist,

[redacted]atiana

Sfarsit

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