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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2018.

Copy No.: 1
Issue No.: 1

Test report No.: S19/2022 - 2

**DETERMINATION OF SURGICAL HAND DISINFECTION
(EN 12791:2016+A1:2017)
OF THE PRODUCT
F3320**

Sample ID: S19/2022
Sample name: F3320
Client: SODEL, 190 rue René Barthélemy, Lisieux, France
Manufacturer: SODEL, 190 rue René Barthélemy, Lisieux, France
Sampling point: SODEL, 190 rue René Barthélemy, Lisieux, France

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Incoming date:
27.1.2022

Delivery date:
26.10.2022

The test results relate only to the samples stated in the test report. The test report may be reproduced only as a whole, in parts only upon written permission of the laboratory. In case that the laboratory is not responsible for sampling, the results concern the samples as they have been received. The laboratory does not take any guarantee for the identity of the samples not taken by the lab personnel. The client is responsible for the information provided about the samples.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID:	S19/2022	Sampling date:	26.1.2022
Sample name:	F3320	Sample delivered:	27.1.2022
Sampled:	Client	Testing date:	23.6. - 5.7.2022
Sampling point:	SODEL	Delivered amount:	4x250 ml
Client:	SODEL	Page:	2

Subject of testing:

Surgical handwash - immediate effect

Identification of the sample:

Name of the product:	F3320
Batch number (Lot):	RDO224E17
Date of manufacture:	25/01/2022
Expiry date:	01/2024
Manufacturer:	SODEL, 190 rue René Barthélemy, Lisieux, France
Incoming date:	27.1.2022
Storage conditions:	room temperature, dark area
Active ingredients:	CAS: 18472-51-0 Chlorhexidine gluconate 4.0%

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-19-00 (EN 12791:2016+A1:2017)

Effect:	immediate effect
Period of analysis:	23.06.2022 - 05.07.2022
Test temperature:	20°C ± 1°C
Test method:	dilution neutralization method
Appearance of the product:	pink gel
Test concentration:	100%
The volume of the product:	2 x 3 ml
The application time:	2 x 2,5 min
Procedure:	handwash
Rinsing tap water:	10 s
The soap:	soft soap from linseed oil
Reference item:	CAS 71-23-8 1-propanol p.a., 60% (V/V) batch number: K52972497115, expiry date: 31.12.2025
The volume of the reference propan-1-ol used per person:	2 x 3 ml, according to reference surgical hand disinfection procedure, the total application volume is 6 ml
The application time:	2 x 1.5 min, according to reference surgical hand disinfection procedure, the total application time is 3 min
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Surgical hand disinfection procedure	with product: handwash procedure, immediate effect
Requirements:	The mean reduction for immediate effect of a product shall at least be not inferior to that achieved by a specified reference product (60% volume concentration of propan-1-ol). To demonstrate additionally a "sustained effect", the mean reduction for the 3 h effect of a product shall be superior to that achieved by the reference product.

Test procedure:

1. Determination of the presence of microorganisms in the product
2. Determination of the prevalue - number of cfu sampled immediately before treatment from the hand
3. Determination of the postvalue - number of cfu sampled after treatment from the hand
4. Expression and interpretation of results - reduction factor - ratio of prevalue and postvalue, generally expressed by decimal logarithms

The standard:

EN 12791:2016+A1:2017 Chemical disinfectants and antiseptics – Surgical hand disinfection - Test method and requirements (phase 2/step 2), November 2017

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S19/2022
 Sample name: **F3320**
 Sampled: Client
 Sampling point: SODEL
 Client: SODEL

Sampling date: 26.1.2022
 Sample delivered: 27.1.2022
 Testing date: 23.6. - 5.7.2022
 Delivered amount: 4x250 ml
 Page: 3

The number of CFU in the tested product: 0 CFU/ml

Testing the efficacy of chemical disinfectant **F3320** on *Pseudomonas aeruginosa* ATCC 15442

Test suspensions

N	V1	V2	IgN	IgNo
10 ⁻⁶	228	228		
10 ⁻⁷	31	16	8,36	7,36
$\Phi = 2,29 \times 10^8$			$8,17 \leq \text{IgN} \leq 8,7$	$7,17 \leq \text{IgNo} \leq 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid.(C), conditions: 80 %, 5 min, distilled water, 20°C	
V _{c1}	56	V _{c1}	56
V _{c2}	58	V _{c2}	52
30 ≤ 57 ≤ 160		54 ≥ 0,5 N _{vo}	

Testing the efficacy of chemical disinfectant **F3320** on *Staphylococcus aureus* ATCC 6538

Test suspensions

N	V1	V2	IgN	IgNo
10 ⁻⁶	251	245		
10 ⁻⁷	24	27	8,4	7,4
$\Phi = 2,49 \times 10^8$			$8,17 \leq \text{IgN} \leq 8,7$	$7,17 \leq \text{IgNo} \leq 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid.(C), conditions: 80 %, 5 min, distilled water, 20°C	
V _{c1}	45	V _{c1}	39
V _{c2}	70	V _{c2}	64
30 ≤ 57,5 ≤ 160		51,5 ≥ 0,5 N _{vo}	

Testing the efficacy of chemical disinfectant **F3320** on *Enterococcus hirae* ATCC 10541

Test suspensions

N	V1	V2	IgN	IgNo
10 ⁻⁶	268	250		
10 ⁻⁷	28	23	8,41	7,41
$\Phi = 2,59 \times 10^8$			$8,17 \leq \text{IgN} \leq 8,7$	$7,17 \leq \text{IgNo} \leq 7,7$

Verification of methodology

Validation of suspension (N _{vo})		Method valid.(C), conditions: 80 %, 5 min, distilled water, 20°C	
V _{c1}	50	V _{c1}	70
V _{c2}	73	V _{c2}	49
30 ≤ 61,5 ≤ 160		59,5 ≥ 0,5 N _{vo}	

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID:	S19/2022	Sampling date:	26.1.2022
Sample name:	F3320	Sample delivered:	27.1.2022
Sampled:	Client	Testing date:	23.6. - 5.7.2022
Sampling point:	SODEL	Delivered amount:	4x250 ml
Client:	SODEL	Page:	4

Testing the efficacy of chemical disinfectant **F3320** on *Escherichia coli* K 12 NCTC 10538

Test suspensions

N	V1	V2	lgN	lgNo
10 ⁻⁶	239	243		
10 ⁻⁷	27	22	8,38	7,38
$\Phi = 2,41 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

Validation of suspension (N _{v0})		Method valid.(C), conditions: 80 %, 5 min, distilled water, 20°C	
V _{c1}	43	V _{c1}	54
V _{c2}	71	V _{c2}	59
$30 \leq 57 \leq 160$		$56,5 \geq 0,5 N_{v0}$	

Testing the efficacy of chemical disinfectant **F3320** on *Candida albicans* ATCC 10231

Test suspensions

N	V1	V2	lgN	lgNo
10 ⁻⁵	249	250		
10 ⁻⁶	24	25	7,4	6,4
$\Phi = 2,49 \times 10^7$			$7,17 \leq \lg N \leq 7,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

Validation of suspension (N _{v0})		Method valid.(C), conditions: 80 %, 5 min, distilled water, 20°C	
V _{c1}	50	V _{c1}	40
V _{c2}	73	V _{c2}	68
$30 \leq 61,5 \leq 160$		$54 \geq 0,5 N_{v0}$	

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_{v0} = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, C = the number of surviving bacteria per ml in control tests

Acceptance criteria for test results:

Only if the results of the test procedure fulfil the following requirements, they shall be accepted for further evaluation, otherwise the test shall be repeated:

- A complete set of results from at least 23, but maximum 28 volunteers shall be available. All complete sets of results shall be used for further evaluation.
- The overall means of the lg prevalues for RP and PP shall be both at least 3,50.
- The absolute difference of mean differences between lg reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2,00
- All quotients of weighted mean counts between 5 and 15.

Performed by: Mgr. Alena Holíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID:	S19/2022	Sampling date:	26.1.2022
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Client:	SODEL	Page:	5

Conclusion:

The acceptance criteria for the test results were met.

From table in EN 12791:2016+A1:2017 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for $n = 24$ and a one sided 0,025 level of significance, the critical value of 81 is found. Hence $c = 81 + 1 = 82$. The pairwise differences are sorted in descending order. **The 82nd value is -1,08.** Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is -1,08, which is less than the agreed inferiority margin of 0,75. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

The tested product:	F3320
Batch number:	RDO224E17
Standard:	EN 12791:2016+A1:2017
Test method:	dilution neutralization method
Effect:	immediate effect
Procedure:	handwash

Conditions:

Application time:	2 x 2,5 min
Volume of the product:	2 x 3 ml
Concentration:	100%

The tested product is suitable to be used as surgical hand disinfection.

Approved by: Ing. Barbora Stoklásková, Leader of Study

Hodonín, 26.10.2022



Propan-1-ol batch No.: K52972497115, expiry date 31.12.25 60%, 2 x 3 ml, 2 x 1,5 min, immediate effect, hand disinfection procedure

No	Volunteer		Number of CFU per plate from dilution 10 [*]								
	Sequence	Hand (left or right)	Prevalues			Immediate postvalues					
			-1	-2	-3	0	-1	-2			
1	RP → PP	l	>330	>330	55	>330	45	<14	<14	<14	
2	RP → PP	l	>330	81	<14	>330	38	<14	<14	<14	
3	RP → PP	l	>330	301	30	>330	>330	>330	43	<14	
4	RP → PP	l	>330	160	19	52	<14	<14	<14	<14	
5	RP → PP	l	>330	>330	56	>330	52	<14	<14	<14	
6	RP → PP	l	>330	>330	38	280	30	<14	<14	<14	
7	RP → PP	r	>330	>330	37	145	21	<14	<14	<14	
8	RP → PP	r	>330	>330	77	>330	>330	>330	93	<14	
9	RP → PP	r	>330	>330	43	>330	>330	>330	38	<14	
10	RP → PP	r	>330	>330	90	>330	>330	>330	98	<14	
11	RP → PP	r	>330	>330	60	>330	167	>330	20	<14	
12	RP → PP	r	>330	>330	64	>330	>330	>330	36	<14	
13	PP → RP	l	>330	>330	93	>330	38	<14	<14	<14	
14	PP → RP	l	>330	134	20	121	<14	<14	<14	<14	
15	PP → RP	l	>330	180	16	>330	49	<14	<14	<14	
16	PP → RP	l	>330	>330	40	>330	277	>330	30	<14	
17	PP → RP	l	>330	>330	72	>330	110	>330	>330	>330	
18	PP → RP	l	>330	188	23	>330	47	<14	<14	<14	
19	PP → RP	r	>330	>330	66	>330	56	<14	<14	<14	
20	PP → RP	r	>330	>330	51	>330	104	>330	>330	>330	
21	PP → RP	r	>330	296	28	>330	164	>330	16	<14	
22	PP → RP	r	>330	>330	102	>330	>330	>330	85	<14	
23	PP → RP	r	>330	96	<14	>330	183	>330	20	<14	
24	PP → RP	r	>330	>330	41	>330	>330	>330	37	<14	

Period of analysis: 23.6.2022 - 5.7.2022

23.6.-24.6.2022, 4.7.-5.7.2022

Prepared by: Mgr. Alena Holíková

Product F3320, sample S19/2022 100%, 2 x 3 ml, 2 x 2,5 min, immediate effect, handwash, 10 s rinse

No	Volunteer		Number of CFU per plate from dilution 10 ³						
	Sequence	Hand (left or right)	Prevalues			Immediate postvalues			
			-1	-2	-3	0	-1	-2	
1	RP → PP	r	116	<14	<14	<14	<14	<14	<14
2	RP → PP	r	>330	228	26	<14	<14	<14	<14
3	RP → PP	r	>330	41	<14	<14	<14	<14	<14
4	RP → PP	r	>330	>330	72	109	<14	<14	<14
5	RP → PP	r	>330	92	<14	<14	<14	<14	<14
6	RP → PP	r	>330	>330	116	>330	53	<14	<14
7	RP → PP	l	>330	>330	85	<14	<14	<14	<14
8	RP → PP	l	>330	>330	116	80	<14	<14	<14
9	RP → PP	l	>330	>330	124	>330	77	<14	<14
10	RP → PP	l	>330	>330	135	>330	56	<14	<14
11	RP → PP	l	>330	>330	126	<14	<14	<14	<14
12	RP → PP	l	>330	156	17	<14	<14	<14	<14
13	PP → RP	r	>330	192	17	<14	<14	<14	<14
14	PP → RP	r	>330	284	29	<14	<14	<14	<14
15	PP → RP	r	>330	>330	69	137	18	<14	<14
16	PP → RP	r	>330	>330	90	>330	>330	43	<14
17	PP → RP	r	>330	224	23	<14	<14	<14	<14
18	PP → RP	r	>330	>330	124	<14	<14	<14	<14
19	PP → RP	l	>330	>330	105	40	<14	<14	<14
20	PP → RP	l	>330	>330	124	101	<14	<14	<14
21	PP → RP	l	>330	>330	129	20	<14	<14	<14
22	PP → RP	l	>330	>330	108	82	<14	<14	<14
23	PP → RP	l	>330	264	27	<14	<14	<14	<14
24	PP → RP	l	>330	115	<14	<14	<14	<14	<14

Period of analysis: 23.6.2022 - 5.7.2022

23.6.-24.6.2022, 4.7.-5.7.2022

Prepared by: Mgr. Alena Holiková

Volunteer	Chronological Sequence	Reference hand disinfection procedure RP						Reference handwash procedure with product PP						Difference RP - PP
		N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	N prevalues	N postvalues	lg prevalues	lg postvalues	lg R			
1	RP	5,50E+04	4,50E+02	4,74	2,65	2,09	1,16E+03	1,40E+01	3,06	1,15	1,91	0,18		
2	RP	8,10E+03	3,80E+02	3,91	2,58	1,33	2,31E+04	1,40E+01	4,36	1,15	3,21	-1,88		
3	RP	3,00E+04	4,30E+03	4,48	3,63	0,85	4,10E+03	1,40E+01	3,61	1,15	2,46	-1,61		
4	RP	1,63E+04	5,20E+01	4,21	1,72	2,49	7,20E+04	1,09E+02	4,86	2,04	2,82	-0,33		
5	RP	5,60E+04	5,20E+02	4,75	2,72	2,03	9,20E+03	1,40E+01	3,96	1,15	2,81	-0,78		
6	RP	3,80E+04	2,82E+02	4,58	2,45	2,13	1,16E+05	5,30E+02	5,06	2,72	2,34	-0,21		
7	RP	3,70E+04	1,51E+02	4,57	2,18	2,39	8,50E+04	1,40E+01	4,93	1,15	3,78	-1,39		
8	RP	7,70E+04	9,30E+03	4,89	3,97	0,92	1,16E+05	8,00E+01	5,06	1,90	3,16	-2,24		
9	RP	4,30E+04	3,80E+03	4,63	3,58	1,05	1,24E+05	7,70E+02	5,09	2,89	2,20	-1,15		
10	RP	9,00E+04	9,80E+03	4,95	3,99	0,96	1,35E+05	5,60E+02	5,13	2,75	2,38	-1,42		
11	RP	6,00E+04	1,70E+03	4,78	3,23	1,55	1,26E+05	1,40E+01	5,10	1,15	3,95	-2,40		
12	RP	6,40E+04	3,60E+03	4,81	3,56	1,25	1,57E+04	1,40E+01	4,20	1,15	3,05	-1,80		
13	PP	9,30E+04	3,80E+02	4,97	2,58	2,39	1,90E+04	1,40E+01	4,28	1,15	3,13	-0,74		
14	PP	1,40E+04	1,21E+02	4,15	2,08	2,07	2,85E+04	1,40E+01	4,45	1,15	3,30	-1,23		
15	PP	1,78E+04	4,90E+02	4,25	2,69	1,56	6,90E+04	1,42E+02	4,84	2,15	2,69	-1,13		
16	PP	4,00E+04	2,80E+03	4,60	3,45	1,15	9,00E+04	4,30E+03	4,95	3,63	1,32	-0,17		
17	PP	7,20E+04	1,10E+03	4,86	3,04	1,82	2,25E+04	1,40E+01	4,35	1,15	3,20	-1,38		
18	PP	1,92E+04	4,70E+02	4,28	2,67	1,61	1,24E+05	1,40E+01	5,09	1,15	3,94	-2,33		
19	PP	6,60E+04	5,60E+02	4,82	2,75	2,07	1,05E+05	4,00E+01	5,02	1,60	3,42	-1,35		
20	PP	5,10E+04	1,04E+03	4,71	3,02	1,69	1,24E+05	1,00E+02	5,09	2,00	3,09	-1,40		
21	PP	2,95E+04	1,64E+03	4,47	3,21	1,26	1,29E+05	2,00E+01	5,11	1,30	3,81	-2,55		
22	PP	1,02E+05	8,50E+03	5,01	3,93	1,08	1,08E+05	8,20E+01	5,03	1,91	3,12	-2,04		
23	PP	9,60E+03	1,85E+03	3,98	3,27	0,71	2,65E+04	1,40E+01	4,42	1,15	3,27	-2,56		
24	PP	4,10E+04	3,70E+03	4,61	3,57	1,04	1,15E+04	1,40E+01	4,06	1,15	2,91	-1,87		
Ø	Overall	4,71E+04	2,37E+03	4,58	3,02	1,56	7,02E+04	2,88E+02	4,63	1,66	2,97			
s		2,71E+04	2,95E+03	0,31	0,62	0,54	4,98E+04	8,78E+02	0,56	0,72	0,64			
n				24	24	24			24	24	24			
Ø	RP → PP			4,61	3,02	1,59			4,54	1,69	2,84	-1,25		
s				0,30	0,74	0,61			0,69	0,73	0,62			
n				12	12	12			12	12	12			
Ø	PP → RP			4,56	3,02	1,54			4,73	1,62	3,10	-1,56		
s				0,34	0,50	0,50			0,38	0,74	0,66			
n				12	12	12			12	12	12			

