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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.

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Issue No.: 1

Test report No.: S19/2022 - 3

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:	14.7. - 26.7.2022
Sampling point:	SODEL	Delivered amount:	4x250 ml
Client:	SODEL	Page:	2

Subject of testing:
Surgical handwash - 3 h 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:	3 h effect
Period of analysis:	14.07.2022 - 26.07.2022
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, 3h effect
Requirements:	The mean reduction for 3-hour 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:	<ol style="list-style-type: none">1. Determination of the presence of microorganisms in the product2. Determination of the prevalue - number of cfu sampled immediately before treatment from the hand3. Determination of the postvalue - number of cfu sampled after treatment from the hand after wearing surgical gloves for 3 h following disinfection4. 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: 14.7. - 26.7.2022
 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	lgN	lgNo
10 ⁻⁶	228	228		
10 ⁻⁷	31	16	8,36	7,36
$\Phi = 2,29 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

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

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

Test suspensions

N	V1	V2	lgN	lgNo
10 ⁻⁶	251	245		
10 ⁻⁷	24	27	8,4	7,4
$\Phi = 2,49 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

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

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

Test suspensions

N	V1	V2	lgN	lgNo
10 ⁻⁶	268	250		
10 ⁻⁷	28	23	8,41	7,41
$\Phi = 2,59 \times 10^8$			$8,17 \leq \lg N \leq 8,7$	$7,17 \leq \lg N_0 \leq 7,7$

Verification of methodology

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

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: 14.7. - 26.7.2022
Delivered amount: 4x250 ml
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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 ≤ 57 ≤ 160		56,5 ≥ 0,5 N _{v0}	

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

Test suspensions

N	V1	V2	lgN	lgNo
10 ⁻⁶	249	250		
10 ⁻⁷	24	25	8,4	7,4
$\Phi = 2,49 \times 10^8$			$7,17 \leq \lg N \leq 7,7$	$7,17 \leq \lg N_0 \leq 7,7$

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 ≤ 61,5 ≤ 160		54 ≥ 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
Sample name:	F3320	Sample delivered:	27.1.2022
Sampled:	Client	Testing date:	14.7. - 26.7.2022
Sampling point:	SODEL	Delivered amount:	4x250 ml
Client:	SODEL	Page:	5

Conclusion:

The acceptance criteria for the test results were met.

For 3 h effect - 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 -0,31**. Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is -0,31, which is less than the agreed inferiority margin of 0,85. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is non-inferior to RP.

For "sustained effect"-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 $P = 0,01$ level of significance, the critical value of 69 is found. Hence $c = 69 + 1 = 70$. The pairwise differences are sorted in descending order. **The 70th value is -0,23**. Hence the Hodges-Lehmann upper one sided 97,5% confidence limit for the difference in lg Rs between RP and PP is -0,23, which is less than the agreed inferiority margin of 0,85. 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: 3 h 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



Ing. Jana Štítná, Head of Laboratory
č. 1273

Propan-1-ol batch No.: K52972497115, expiry date 31.12.25 60%, 2 x 3 ml, 2 x 1,5 min, 3 h effect, gloves, 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	38	>330	>330	>330	55
2	RP → PP	l	>330	200	22	>330	>330	49	<14
3	RP → PP	l	>330	>330	136	>330	>330	>330	38
4	RP → PP	l	>330	228	21	>330	>330	>330	92
5	RP → PP	l	>330	300	27	>330	>330	184	21
6	RP → PP	l	>330	>330	105	>330	>330	>330	63
7	RP → PP	r	>330	188	25	>330	>330	>330	102
8	RP → PP	r	>330	>330	52	>330	>330	264	32
9	RP → PP	r	>330	>330	75	>330	>330	>330	38
10	RP → PP	r	212	26	<14	40	<14	<14	<14
11	RP → PP	r	>330	>330	75	>330	>330	>330	103
12	RP → PP	r	>330	>330	63	>330	>330	>330	113
13	PP → RP	l	>330	>330	56	>330	>330	>330	58
14	PP → RP	l	>330	164	20	41	<14	<14	<14
15	PP → RP	l	>330	>330	90	>330	>330	>330	82
16	PP → RP	l	>330	300	25	>330	>330	>330	53
17	PP → RP	l	>330	>330	50	>330	>330	142	15
18	PP → RP	l	>330	>330	124	>330	>330	>330	72
19	PP → RP	r	>330	145	14	>330	>330	>330	48
20	PP → RP	r	>330	>330	40	>330	>330	>330	48
21	PP → RP	r	>330	>330	102	>330	>330	>330	98
22	PP → RP	r	>330	>330	68	101	<14	<14	<14
23	PP → RP	r	>330	>330	91	>330	>330	>330	88
24	PP → RP	r	>330	>330	53	>330	>330	>330	70

Period of analysis: 14.7.2022 - 26.7.2022

14.7.-15.7.2022, 25.7.-26.7.2022

Prepared by: Mgr. Alena Holíková

Product F3320, sample S19/2022 100%, 2 x 3 ml, 2 x 2,5 min, 3 h effect, gloves, handwash

No	Volunteer		Number of CFU per plate from dilution 10 ⁴								
	Sequence	Hand (left or right)	Prevalues			Immediate postvalues					
			-1	-2	-3	0	-1	-2			
1	RP → PP	r	>330	119	<14	20	<14	>330	>330	<14	<14
2	RP → PP	r	>330	153	14	>330	>330	>330	>330	60	<14
3	RP → PP	r	>330	264	31	>330	>330	130	17	<14	<14
4	RP → PP	r	>330	286	30	>330	110	<14	<14	<14	<14
5	RP → PP	r	>330	75	<14	201	20	<14	<14	<14	<14
6	RP → PP	r	>330	224	36	>330	>330	88	<14	<14	<14
7	RP → PP	l	>330	>330	130	>330	>330	>330	48	<14	<14
8	RP → PP	l	>330	>330	101	>330	>330	>330	126	<14	<14
9	RP → PP	l	>330	>330	110	>330	80	<14	<14	<14	<14
10	RP → PP	l	>330	>330	39	>330	40	<14	<14	<14	<14
11	RP → PP	l	>330	>330	128	>330	>330	>330	69	<14	<14
12	RP → PP	l	>330	>330	51	>330	>330	304	35	<14	<14
13	PP → RP	r	>330	124	<14	101	<14	<14	<14	<14	<14
14	PP → RP	r	>330	272	25	>330	>330	224	30	<14	<14
15	PP → RP	r	>330	192	19	>330	>330	117	<14	<14	<14
16	PP → RP	r	>330	272	26	>330	198	23	<14	<14	<14
17	PP → RP	r	>330	>330	66	>330	20	<14	<14	<14	<14
18	PP → RP	r	>330	254	25	>330	>330	127	<14	<14	<14
19	PP → RP	l	>330	>330	131	>330	>330	204	21	<14	<14
20	PP → RP	l	>330	>330	57	>330	>330	>330	106	<14	<14
21	PP → RP	l	>330	>330	106	>330	21	<14	<14	<14	<14
22	PP → RP	l	>330	>330	69	>330	14	<14	<14	<14	<14
23	PP → RP	l	>330	>330	130	>330	38	<14	<14	<14	<14
24	PP → RP	l	>330	>330	40	>330	>330	99	<14	<14	<14

Period of analysis: 14.7.2022 - 26.7.2022

14.7.-15.7.2022, 25.7.-26.7.2022

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	3,80E+04	5,50E+03	4,58	3,74	0,84	1,19E+04	2,00E+01	4,08	1,30	2,78	-1,94		
2	RP	2,02E+04	4,90E+02	4,31	2,69	1,62	1,52E+04	6,00E+03	4,18	3,78	0,40	1,22		
3	RP	1,36E+05	3,80E+03	5,13	3,58	1,55	2,68E+04	1,34E+03	4,43	3,13	1,30	0,25		
4	RP	2,26E+04	9,20E+03	4,35	3,96	0,39	2,87E+04	1,10E+02	4,46	2,04	2,42	-2,03		
5	RP	2,97E+04	1,86E+03	4,47	3,27	1,20	7,50E+03	2,01E+02	3,88	2,30	1,58	-0,38		
6	RP	1,05E+05	6,30E+03	5,02	3,80	1,22	2,36E+04	8,80E+02	4,37	2,94	1,43	-0,21		
7	RP	1,94E+04	1,02E+04	4,29	4,01	0,28	1,30E+05	4,80E+03	5,11	3,68	1,43	-1,15		
8	RP	5,20E+04	2,69E+03	4,72	3,43	1,29	1,01E+05	1,26E+04	5,00	4,10	0,90	0,38		
9	RP	7,50E+04	3,80E+03	4,88	3,58	1,30	1,10E+05	8,00E+01	5,04	1,90	3,14	-1,84		
10	RP	2,16E+03	4,00E+01	3,33	1,60	1,73	3,90E+04	4,00E+01	4,59	1,60	2,99	-1,26		
11	RP	7,50E+04	1,03E+04	4,88	4,01	0,87	1,28E+05	6,90E+03	5,11	3,84	1,27	-0,40		
12	RP	6,30E+04	1,13E+04	4,80	4,05	0,75	5,10E+04	3,08E+03	4,71	3,49	1,22	-0,47		
13	PP	5,60E+04	5,80E+03	4,75	3,76	0,99	1,24E+04	1,01E+02	4,09	2,00	2,09	-1,10		
14	PP	1,67E+04	4,10E+01	4,22	1,61	2,61	2,70E+04	2,31E+03	4,43	3,36	1,07	1,54		
15	PP	9,00E+04	8,20E+03	4,95	3,91	1,04	1,92E+04	1,17E+03	4,28	3,07	1,21	-0,17		
16	PP	2,95E+04	5,30E+03	4,47	3,72	0,75	2,71E+04	2,01E+02	4,43	2,30	2,13	-1,38		
17	PP	5,00E+04	1,43E+03	4,70	3,16	1,54	6,60E+04	2,00E+01	4,82	1,30	3,52	-1,98		
18	PP	1,24E+05	7,20E+03	5,09	3,86	1,23	2,54E+04	1,27E+03	4,40	3,10	1,30	-0,07		
19	PP	1,45E+04	4,80E+03	4,16	3,68	0,48	1,31E+05	2,05E+03	5,12	3,31	1,81	-1,33		
20	PP	4,00E+04	4,80E+03	4,60	3,68	0,92	5,70E+04	1,06E+04	4,76	4,03	0,73	0,19		
21	PP	1,02E+05	9,80E+03	5,01	3,99	1,02	1,06E+05	2,10E+01	5,03	1,32	3,71	-2,69		
22	PP	6,80E+04	1,01E+02	4,83	2,00	2,83	6,90E+04	1,40E+01	4,84	1,15	3,69	-0,86		
23	PP	9,10E+04	8,80E+03	4,96	3,94	1,02	1,30E+05	3,80E+01	5,11	1,58	3,53	-2,51		
24	PP	5,30E+04	7,00E+03	4,72	3,85	0,87	4,00E+04	9,90E+02	4,60	3,00	1,60	-0,73		
∅	Overall	5,72E+04	5,36E+03	4,63	3,45	1,18	5,76E+04	2,28E+03	4,62	2,65	1,97			
s		3,66E+04	3,57E+03	0,40	0,74	0,60	4,40E+04	3,48E+03	0,38	0,97	1,01			
n				24	24	24			24	24	24			
∅	RP → PP			4,56	3,48	1,09			4,58	2,84	1,74	-0,65		
s				0,48	0,71	0,47			0,42	0,97	0,88			
n				12	12	12			12	12	12			
∅	PP → RP			4,71	3,43	1,27			4,66	2,46	2,20	-0,93		
s				0,30	0,79	0,72			0,34	0,97	1,12			
n				12	12	12			12	12	12			

