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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 - 1

DETERMINATION OF HYGIENIC HANDWASH (EN 1499:2013) 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

Incoming date:
27.1.2022

Delivery date:
26.10.2022

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:	by client	Testing date:	13.6. - 14.6.2022
Sampling point:	SODEL	Delivered amount:	4x250 ml
Client:	SODEL	Page:	2

Subject of testing:
Hygienic handwash

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:	SOP-M-19-00 (ČSN EN 1499:2013)
Period of analysis:	13. 6. 2022 - 14.6.2022
Test temperature:	20°C ± 1°C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Appearance of the product:	pink gel
The test concentration:	100%
The volume of the product:	3 ml
The application time:	30 s
The time for final rinsing:	10 s according to EN 1499:2013
Reference item:	soft soap from linseed oil 200 g/l
The volume of the reference item:	5 ml / person
The application time:	1 min
Test organism:	*Escherichia coli K 12* NCTC 10538
Treatment procedure:	hygienic handwash disinfection in accordance with the standard handwash procedure also include the instructions to keep hands wet with the product for a given time

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the suspension of the test organisms
3. Determination of the number of viable cells with test organisms
4. Prevalue - number of cfu sampled after the contamination with test organisms
5. Postvalue - number of cfu sampled after the treatment with the disinfectant
6. Reduction factor - ratio of prevalues and postvalues, generally expressed by decimal logarithms
7. Expression (Wilcoxon'smatched-pairs signed-ranks test)

The standard:
EN 1499:2013 Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2) April 2013

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

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

Test suspensions:

Dilutions	V1	V2	lgN	Weighted mean (ø)		
10^{-6}	284	310				
10^{-7}	31	26	8,47			
		$\Phi = 2{,}96 \times 10^8$	$8{,}17 \leq \lg N \leq 8{,}7$	for N	$5 \leq ø \leq 15$	10,42

Verification of methodology

Validation of suspension N_{V0}		Validation of suspension N_{Vb}		Neutralizer toxicity control (B)	
Vc1	80	Vc1	76	Vc1	74
Vc2	84	Vc2	80	Vc2	66
$30 \leq 82 \leq 160$		$30 \leq 78 \leq 160$		$70 \geq 0{,}0005\ \Phi_{NVB}$	
$30 \leq \Phi_{Nvo} \leq 160$		$30 < \Phi_{NVB}(N_{VB}/1000) < 160$		$\Phi_B \geq 0{,}0005\ \Phi_{NVB}$	

Method validation (C)

Testing conditions	Vc1	Vc2	ø C
80 %, 30 s, distilled water, 20°C	60	72	$66 \geq 0{,}5$ Nvo

Note: Vc = value is the number of cfu per ml, Φ = average Vc1 a Vc2 (1. + 2. duplicate Vc values), N = the number of cfu/ml of the bacterial test suspension, Nvo (C), Nvb (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture B, C at the beginning of the contact time = 0, B, C, = the number of surviving bacteria per ml in control tests (B - neutralizer toxicity validation, C - method validation)

Prepared by: Mgr. Alena Holíková, Lab Technician

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) A complete set of results from at least 12 volunteers shall be available. All complete sets of results shall be used for further evaluation.

b) The overall means of the lg prevalues for RP and PP shall be both at least 5,00.

c) 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.

d) All quotients of weighted mean counts between 5 and 15.

e) Basic limits
- N is between $1{,}5 \times 10^8$ and $5{,}0 \times 10^8$ ($8{,}17 \leq \lg N \leq 8{,}70$)
- N_V is between $3{,}0 \times 10^2$ and $1{,}6 \times 10^3$
- N_{Vo} is between 30 and 160 ($3{,}0 \times 10^1$ a $1{,}6 \times 10^2$)
- N_{VB} is between $3{,}0 \times 10^4$ and $1{,}6 \times 10^5$
- B is equal to or greater than 0,0005 x N_{VB} (half of one thousandth)
- C is equal to or greater than 0,5 x N_{Vo}

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Conclusion:

The acceptance criteria for the test results were met.
From table (see Table F.1 in EN 1499) of critical values for Wilcoxon´s matched-pairs signed-ranks test the entry for n = 14 and 0,01 level of significante, the critical value of 15 is found. If calculated smaller sum of ranks (here 0) ≤ 15, then PP is significantly more effective than RP.

The tested product	**F3320**
Batch number:	RDO224E17
Standard:	EN 1499:2013
Procedure:	handwash
Conditions:	
Application time:	30 s
Volume of the product:	3 ml
Concentration:	100%

The tested product is seemed suitable to be used as hygienic handwash.

Approved by: Ing. Barbora Stoklásková, Leader of Study

Hodonín, 26.10.2022

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Ing. Jana Šitrová, Head of Laboratory

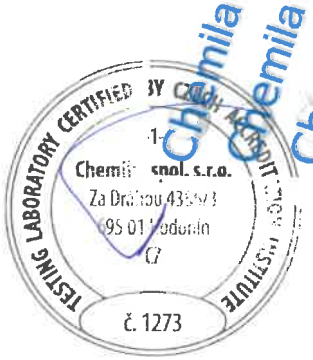
Volunteer	Hand	Soft soap from linseed oil 200 g/l			100%, 5 ml, 1 min, handwash			Product F3320, sample S19/2022			100%, 3 ml, 30 s, handwash		
	left or right	-3	-4	-5	0	-1	-2	-3	-4	-5	0	-1	-2
1	l	>330	114	<14	>330	>330	102	>330	126	15	>330	28	<14
	r	>330	94	<14	>330	>330	108	>330	106	<14	>330	45	<14
2	l	>330	284	32	>330	>330	104	>330	140	20	>330	88	<14
	r	>330	224	24	>330	>330	101	>330	264	28	>330	32	<14
3	l	>330	40	<14	>330	>330	53	>330	52	<14	157	16	<14
	r	>330	38	<14	>330	>330	52	>330	43	<14	121	14	<14
4	l	>330	141	<14	>330	>330	97	>330	>330	57	<14	<14	<14
	r	>330	127	<14	>330	>330	92	>330	>330	41	<14	<14	<14
5	l	>330	173	19	>330	>330	63	>330	>330	53	<14	<14	<14
	r	>330	119	<14	>330	>330	71	>330	>330	45	<14	<14	<14
6	l	>330	130	<14	>330	>330	51	>330	>330	50	<14	<14	<14
	r	>330	114	<14	>330	>330	67	>330	>330	33	<14	<14	<14
7	l	>330	95	<14	>330	>330	74	>330	>330	45	<14	<14	<14
	r	>330	114	<14	>330	>330	84	>330	>330	45	<14	<14	<14
8	l	>330	268	30	>330	288	39	>330	199	28	139	19	<14
	r	>330	164	22	>330	192	20	>330	168	21	128	16	<14
9	l	104	<14	<14	>330	>330	92	143	14	<14	>330	>330	43
	r	83	<14	<14	>330	>330	140	221	23	<14	>330	>330	56
10	l	>330	84	<14	>330	>330	122	>330	61	<14	>330	>330	50
	r	>330	94	<14	>330	>330	131	>330	48	<14	>330	>330	42
11	l	228	24	<14	>330	175	17	>330	>330	33	>330	>330	70
	r	231	26	<14	>330	182	22	>330	>330	43	>330	>330	66
12	l	>330	>330	47	>330	>330	101	>330	>330	34	62	<14	<14
	r	>330	>330	59	>330	>330	107	>330	>330	42	58	<14	<14
13	l	280	15	<14	>330	196	20	>330	279	27	>330	52	<14
	r	295	30	<14	>330	202	27	>330	284	33	>330	66	<14
14	l	>330	>330	46	>330	>330	122	>330	>330	51	<14	<14	<14
	r	>330	>330	80	>330	>330	134	>330	>330	67	<14	<14	<14

Volunteer	Chronological Sequence	Reference hand disinfection procedure RP					Reference handwash procedure with product PP					Difference RP - PP	Rank of difference
		N prevalues	N postvalues	lg prevalues	lg postvalues	lg R	N prevalues	N postvalues	lg prevalues	lg postvalues	lg R		
1	RP	1,04E+06	1,05E+04	6,02	4,02	2,00	1,18E+06	3,65E+02	6,07	2,56	3,51	-1,51	-6
2	RP	2,56E+06	1,03E+04	6,41	4,01	2,40	2,05E+06	6,00E+02	6,31	2,78	3,53	-1,13	-4
3	RP	3,90E+05	5,25E+03	5,59	3,72	1,87	4,75E+05	1,40E+02	5,68	2,15	3,53	-1,66	-8
4	RP	1,34E+06	9,45E+03	6,13	3,98	2,15	4,90E+06	1,40E+01	6,69	1,15	5,54	-3,39	-14
5	RP	1,48E+06	6,70E+03	6,17	3,83	2,34	4,90E+06	1,40E+01	6,69	1,15	5,54	-3,20	-12
6	RP	1,22E+06	5,90E+03	6,09	3,77	2,32	4,15E+06	1,40E+01	6,62	1,15	5,47	-3,15	-11
7	RP	1,05E+06	7,90E+03	6,02	3,90	2,12	4,50E+06	1,40E+01	6,65	1,15	5,50	-3,38	-13
8	RP	2,20E+06	2,45E+03	6,34	3,39	2,95	1,89E+06	1,37E+02	6,28	2,14	4,14	-1,19	-5
9	RP	9,35E+04	1,16E+04	4,97	4,06	0,91	1,82E+05	4,95E+03	5,26	3,69	1,57	-0,66	-3
10	RP	8,90E+05	1,27E+04	5,95	4,10	1,85	5,45E+05	4,60E+03	5,74	3,66	2,08	-0,23	-1
11	RP	2,31E+05	1,80E+03	5,36	3,26	2,10	3,80E+06	6,80E+03	6,58	3,83	2,75	-0,65	-2
12	RP	5,30E+06	1,04E+04	6,72	4,02	2,70	3,80E+06	6,00E+01	6,58	1,78	4,80	-2,10	-9
13	PP	2,82E+05	2,02E+03	5,45	3,31	2,14	2,83E+06	5,90E+02	6,45	2,77	3,68	-1,54	-7
14	PP	6,30E+06	1,28E+04	6,80	4,11	2,69	5,90E+06	1,40E+01	6,77	1,15	5,62	-2,93	-10
Ø	Overall	1,74E+06	7,83E+03	6,00	3,82	2,18	2,94E+06	1,31E+03	6,31	2,22	4,09		
s		1,87E+06	3,87E+03	0,51	0,30	0,49	1,89E+06	2,30E+03	0,46	1,02	1,37		
n				14	14	14			14	14	14		
Ø	RP → PP			6,06	3,89	2,17			6,39	1,72	4,66	-2,49	
s				0,25	0,12	0,19			0,39	0,74	1,06		
n				7	7	7			7	7	7		
Ø	PP → RP			5,94	3,75	2,19			6,24	2,72	3,52	-1,33	
s				0,71	0,41	0,69			0,54	1,06	1,47		
n				7	7	7			7	7	7		
Sum of (-) ranks													-105
Sum of (+) ranks													0

log R = decimal log reduction; RP→PP sequence: first RP, second PP; PP→RP sequence: first PP, second RP; Ø = mean; s = standard deviation; n = number of values (volunteer)

Difference of mean Rs (RP→PP): 2,17 - 4,66 = -2,49; Difference of mean Rs (PP→RP): 2,19 - 3,52 = -1,33; Absolute difference of differences: |-2,49 - (-1,33)| = 1,16

From table (see F.1 in EN 1499:2013) of ritical values for Wilcoxon's matched-pairs signed-ranks test the entry for n = 14 and 0,01 level of significance, the critical value of 15 is found. If calculated smaller sum of ranks (here 0) ≤ 15, then PP is significantly more effective than RP.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