

REPORT OF ANALYSIS No. 24585/21/CGDA

Copy of the report no. 225323/20/CGDA

Client DAN DRYER A/S ALSIKEVEJ 8 8920 RANDERS NV		Sample description <i>(according to declaration of Client)</i> Hånddesinfektion Gel 70 % Production date: 14-05-2020 Sample without any visible damages	
Sample received:	2020-05-22	Order of 2020-05-14 The samples were delivered by Client	
Analysis completed:	2020-06-22		
Report dated:	2021-01-18		
Test	Method	Unit	Result
* Chemical disinfectants and antiseptics Hygienic handrub - Test method and requirements (phase 2, step 2) ¹⁾	PN-EN 1500:2013		The preparation has bactericidal effect against transient microorganisms used in the hygienic procedure of hand disinfection- a single rubbing of 3ml of the preparation for 30 seconds.

¹⁾ The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

The results relate to the analysed samples only. Unless otherwise specified given expanded measurement uncertainty was estimated for the coverage factor $k=2$ at 95% confidence level. Sampling uncertainty has not been taken into consideration. Unless otherwise specified when conformity is stated J.S. Hamilton Poland Sp. z o.o. applies the simple acceptance decision rule in accordance with ILAC-G8:09/2019. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on www.hamilton.com.pl

* Test method accredited; # Test performed by external provider

Page 1 / 1

Form PO-10/02a of 20.01.2020

J.S. HAMILTON POLAND Sp. z o.o.
TESTING LABORATORY

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 24585/21/CGDA

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	Hånddesinfektion Gel 70 % Data produkcji: 14-05-2020
The active substance	Ethanol (CAS No. 64-17-5; 63 % (w/w) 529,2 g/L) Propan-2-ol (CAS No. 67-63-0; 7 % (w/w) 58,8 g/L)
B) TEST METHOD :	
Method	EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)
Neutralizer	Polysorbate 80 30 g/l, saponine 30g/l, histidine 1g/l, cysteine 1g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	3ml of the preparation for 30s
Incubation temperature	36±1 °C
Test-organism	<i>E. coli</i> K12 NCTC 10538

Date: 18.01.2021

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Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDRUB

PRODUCT: Standard 2-propanol 60% (V/V)

 TEST ORGANISM: *E. coli* K12 NCTC 10538

 NUMBER IN CONTAMINATION FLUID: $3,0 \times 10^8$ cfu/g

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues				log z	
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$	log y		
1	l	138	15		85	6	0		4,26	
	r	145	12	6,15	73	7	0	1,89		
2	l	161	18		64	5	0		4,45	
	r	157	13	6,20	51	4	0	1,75		
3	l	216	22		28	3	0		4,69	
	r	185	17	6,30	61	4	0	1,61		
4	l	199	20		34	4	0		4,71	
	r	245	21	6,34	52	6	0	1,63		
5	l	155	16		48	5	0		4,48	
	r	174	18	6,22	62	7	0	1,74		
6	l	165	14		71	8	0		4,44	
	r	184	13	6,23	55	4	0	1,79		
7	l	141	12		37	4	0		4,54	
	r	156	18	6,17	48	5	0	1,63		
8	l	236	26		25	3	0		4,92	
	r	241	21	6,38	33	3	0	1,46		
9	l	233	25		19	2	0		5,00	
	r	284	23	6,41	35	3	0	1,41		
10	l	214	22		45	5	0		4,63	
	r	235	18	6,35	62	3	0	1,71		
11	l	192	20		72	8	0		4,45	
	r	201	21	6,29	69	6	0	1,85		
12	l	155	16		85	8	0		4,38	
	r	181	22	6,23	61	5	0	1,85		
13	l	132	14		53	4	0		4,45	
	r	128	12	6,11	42	3	0	1,66		
14	l	122	11		77	8	0		4,26	
	r	159	19	6,15	75	8	0	1,88		
15	l	146	12		63	5	0		4,57	
	r	161	21	6,19	28	3	0	1,62		
16	l	170	22		33	3	0		4,86	
	r	178	23	6,25	18	2	0	1,39		
17	l	185	19		24	2	0		5,00	
	r	200	15	6,28	16	1	0	1,28		
18	l	203	21		86	6	0		4,38	
	r	172	14	6,27	72	5	0	1,88		
19	l	126	15		45	5	0		4,41	
	r	138	14	6,12	59	5	0	1,71		
20	l	141	13		66	6	0		4,49	
	r	150	18	6,17	35	3	0	1,68		
Xavg				6,24				1,67	4,57	
s				0,09				0,18	0,23	

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x avg - overall average of log x, log y, log z

Date: 18.01.2021

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Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P

 TEST ORGANISM: *E. coli* K12 NCTC 10538

 NUMBER IN CONTAMINATION FLUID: $3,0 \times 10^8$ cfu/g

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues				log y	log z
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$	log y		
1	l	188	21	6,18	45	6	0	1,74	4,44	
	r	122	13		69	4	0			
2	l	154	16	6,09	72	10	0	1,76	4,34	
	r	102	8		45	3	0			
3	l	191	22	6,21	28	4	0	1,48	4,73	
	r	135	14		33	2	0			
4	l	184	19	6,28	38	5	0	1,59	4,69	
	r	196	21		41	1	0			
5	l	102	11	6,04	45	6	0	1,73	4,31	
	r	116	12		62	5	0			
6	l	150	16	6,22	68	8	0	1,85	4,37	
	r	182	19		75	6	0			
7	l	250	25	6,26	92	10	1	2,00	4,27	
	r	136	12		105	11	1			
8	l	141	15	6,23	47	3	0	1,69	4,54	
	r	198	21		51	6	0			
9	l	180	19	6,25	36	4	0	1,63	4,62	
	r	175	16		47	8	0			
10	l	128	13	6,20	51	6	0	1,56	4,64	
	r	191	20		25	3	0			
11	l	147	15	6,17	36	4	0	1,71	4,46	
	r	150	13		72	7	0			
12	l	169	17	6,23	49	5	0	1,70	4,53	
	r	172	15		52	4	0			
13	l	148	13	6,19	63	5	0	1,70	4,49	
	r	165	12		41	3	0			
14	l	136	16	6,15	55	6	0	1,59	4,56	
	r	145	13		27	3	0			
15	l	165	17	6,22	38	4	0	1,61	4,62	
	r	171	15		42	5	0			
16	l	169	18	6,25	56	6	0	1,77	4,48	
	r	188	19		62	7	0			
17	l	175	21	6,25	72	8	0	1,79	4,46	
	r	183	15		54	4	0			
18	l	196	22	6,24	81	9	0	1,95	4,29	
	r	154	13		96	10	0			
19	l	135	17	6,16	47	5	0	1,51	4,65	
	r	148	15		21	3	0			
20	l	163	15	6,22	23	3	0	1,41	4,81	
	r	172	14		28	3	0			
X_{avg}				6,20				1,69	4,51	
s				0,06				0,15	0,15	

log x-logarithm of the average value of the initial left and right hand

log y-logarithm of the average value of the final left and right hand

log z-logarithm reduction

x avg - overall average of log x, log y, log z

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Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R 2-propanol 60% (V/V)			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,15	1,89	4,26	6,18	1,74	4,44
2	R-P	6,20	1,75	4,45	6,09	1,76	4,34
3	R-P	6,30	1,61	4,69	6,21	1,48	4,73
4	R-P	6,34	1,63	4,71	6,28	1,59	4,69
5	R-P	6,22	1,74	4,48	6,04	1,73	4,31
6	P-R	6,23	1,79	4,44	6,22	1,85	4,37
7	P-R	6,17	1,63	4,54	6,26	2,00	4,27
8	P-R	6,38	1,46	4,92	6,23	1,69	4,54
9	P-R	6,41	1,41	5,00	6,25	1,63	4,62
10	P-R	6,35	1,71	4,63	6,20	1,56	4,64
11	R-P	6,29	1,85	4,45	6,17	1,71	4,46
12	R-P	6,23	1,85	4,38	6,23	1,70	4,53
13	R-P	6,11	1,66	4,45	6,19	1,70	4,49
14	R-P	6,15	1,88	4,26	6,15	1,59	4,56
15	R-P	6,19	1,62	4,57	6,22	1,61	4,62
16	P-R	6,25	1,39	4,86	6,25	1,77	4,48
17	P-R	6,28	1,28	5,00	6,25	1,79	4,46
18	P-R	6,27	1,88	4,38	6,24	1,95	4,29
19	P-R	6,12	1,71	4,41	6,16	1,51	4,65
20	P-R	6,17	1,68	4,49	6,22	1,41	4,81
X ₂₀		6,24	1,67	4,57	6,20	1,69	4,51
X10(R-P)		6,22	1,75	4,47	6,18	1,66	4,52
X10 (P-R)		6,26	1,59	4,67	6,23	1,72	4,51

Criteria:

$$R_s (R-P) = 4,47 - 4,52 = - 0,05$$

$$R_s (P-R) = 4,67 - 4,51 = 0,16$$

$$Abs = - 0,05 - 0,16 = - 0,21 < 2$$

$$\log x(R) = 6,24 > 5$$

$$\log x(P) = 6,20 > 5$$

$$\log z (P), \log z (R) > 3$$

Validation conditions of neutralizer and methods have been satisfied

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Table 4. COMPUTATION OF INDIVIDUAL DIFFERENCES OF lg R-P

volunteer	log RF		difference	difference	Range +/-
	R	P	R-P	high to low	
1	4,26	4,44	-0,18	0,54	1
2	4,45	4,34	0,11	0,39	2
3	4,69	4,73	-0,04	0,38	3
4	4,71	4,69	0,02	0,38	4
5	4,48	4,31	0,16	0,28	5
6	4,44	4,37	0,07	0,16	6
7	4,54	4,27	0,28	0,11	7
8	4,92	4,54	0,38	0,09	8
9	5,00	4,62	0,38	0,07	9
10	4,63	4,64	0,00	0,02	10
11	4,45	4,46	-0,01	0,00	11
12	4,38	4,53	-0,15	-0,01	-12
13	4,45	4,49	-0,04	-0,04	-13
14	4,26	4,56	-0,30	-0,04	-14
15	4,57	4,62	-0,05	-0,05	-15
16	4,86	4,48	0,39	-0,15	-16
17	5,00	4,46	0,54	-0,18	-17
18	4,38	4,29	0,09	-0,24	-18
19	4,41	4,65	-0,24	-0,30	-19
20	4,49	4,81	-0,32	-0,32	-20
sum range (+): 66					
sum range (-): 144					

Table 5. SORTING OF INDIVIDUAL DIFFERENCES AND COMPUTATION FOR HODGES-LEHMANN 97,5% UPPER CONFIDENCE LIMITS FOR THE DIFFERENCE IN lg BETWEEN R-P

	0,54	0,39	0,38	0,38	0,28	0,16	0,11	0,09	0,07
1	0,54	0,54							
2	0,39	0,47	0,39						
3	0,38	0,46	0,39	0,38					
4	0,38	0,46	0,39	0,38	0,38				
5	0,28	0,41	0,34	0,33	0,33	0,28			
6	0,16	0,35	0,28	0,27	0,27	0,22	0,16		
7	0,11	0,33	0,25	0,25	0,25	0,20	0,14	-0,11	
8	0,09	0,32	0,24	0,24	0,24	0,19	0,13	-0,10	-0,09
9	0,07	0,31	0,23	0,23	0,23	0,18	0,12	-0,09	-0,08
10	0,02	0,28	0,21	0,20	0,20	0,15	0,09	-0,07	-0,06
11	0,00	0,27	0,20	0,19	0,19	0,14	0,08	-0,06	-0,05
12	-0,01	0,27	0,19	0,19	0,19	0,14	0,08	-0,05	-0,04
13	-0,04	0,25	0,18	0,17	0,17	0,12	0,06	-0,04	
14	-0,04	0,25	0,18	0,17	0,17	0,12	0,06		
15	-0,05	0,25	0,17	0,17	0,17	0,12			
16	-0,15	0,20	0,12	0,12	0,12				
17	-0,18	0,18	0,11	0,10					
18	-0,24	0,15	0,08						
19	-0,30	0,12							
20	-0,32								

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Table 6. WILCOXON'S T-MATCHED PAIRS SIGNED-RANKS TEST:
CRITICAL VALUES LESS WITH RANG SUM (+) OR (-) AT DIFFERENT LEVELS OF SIGNIFICANCE

n	one-sided level of significance		
	0,05	0,025	0,01
18	47	40	32
19	53	46	27
20	60	52	43
21	68	59	49
22	75	66	56

For the designated level of significance 0,025 for n=20 the value read from the table 6 is 52.

Hence $c = 52 + 1 = 53$.

For the distribution of 53 Table 5 assigns a value of 0,20 which is less than the agreed inferiority margin of 0,6.

Therefore, the hypothesis of inferiority of PP compared to the reference RP is rejected.

The test preparation (PP) is non-inferior to RP.

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