

Analysis Report

**REPORT NUMBER:
928841.4**



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Encl.: 6
Init.: ENB/HSA

Assignor: x
x
x
x

Item: Analysis of the product DesiLux intended for hygienic handrub according DS/EN 1500:2013

Sampling: The assignor

Period: Samples received: 10 August 2020
Test performed: 14 September – 17 September 2020

Storage: The test material will be destroyed after 3 months, unless otherwise agreed in writing.

Remark: The account of the method(s) used only concerns the analysed sample(s).

Terms: This test was conducted in accordance with international requirements (ISO/IEC 17025:2017) and in accordance with the General Terms and Conditions of Danish Technological Institute. The test results solely apply to the tested item(s) or to the sub-sample(s) selected for analysis. This analysis report may be quoted in extract only if Danish Technological Institute has granted its written consent.

Date/place: 28 September 2020
Danish Technological Institute, Aarhus
Laboratory for Chemistry and Microbiology

Signature: Digitally signed by Ebbe Norskov Bak
Date: 2020.09.28 09:45:18 +02'00'
Ebbe Norskov Bak
Specialist

Introduction

The efficacy of the product DesiLux intended for handrub was tested according to DS/EN 1500:2013.

When tested in accordance with the test method under the required test conditions, the product must demonstrate a log reduction in viable counts that is not inferior to the effect of the reference product, 60% propan-2-ol.

Hands of 18-22 volunteers are artificially contaminated with the test organism. The number of test organisms released from their fingertips into sampling fluids is assessed before and after hygienic hand rubbing.

To compensate for extraneous influences the result is compared with the reduction obtained with a reference handrub, which is performed with the same volunteers on the same day.

Validation tests were performed to check the effect of the experimental conditions and the effect of the neutralizing liquid.

Experimental conditions

Test organisms:	<i>Escherichia coli</i> K12 NCTC 10538, DSM 11250
Contact time:	30±5 sec.
Amount of product:	1x 2.7±0.2 mL (mean±std.dev)
Application of product:	The product was dosed using the foam dispenser provided with the product by the assignor
Reference:	Propan-2-ol (60% w/w), CAS No.: 67-63-0
Contact time for reference:	2x (30±5) sec.
Volume of reference:	2x3 mL
No. of volunteers:	19
Test temperature:	Room temperature (20 - 25°C)
Incubation of bacteria:	37±1°C for 48±2 hours
Growth media for bacteria:	Tryptone soya agar (TSA) and Tryptone soya selective agar (TSSA)
Neutralizer:	Tryptic soya broth 30 g/L
Diluted soap:	Linseed oil 50 g/L Potassium hydroxide 9.5 g/L Ethanol 7.0 g/L Dissolved in warm distilled water
Diluent for the product:	The product was a ready-to-use product

Product

Name: Desi Lux

Active substance: Didecyldimethylammonium Chloride

Storage: (DDAC) Room temperature

Appearance of the product: Clear liquid

Results

Average Log reduction	
Product	Reference
4.76	4.44

Table 1: Results of the efficacy when a product is tested according to requirements of hygienic handrub products using a contact time of 30 sec.

The Hodges-Lehmann upper one-sided 97.5% confidence limit for log-reductions differences between the reference and the product is 0.06. As this is lower than the accepted inferiority margin of 0.6, the hypothesis that the product under test is inferior to the reference is rejected.

See enclosure 1-6 for detailed results and statistical calculations.

Conclusion

The product fulfils the requirements according to DS/EN 1500: 2013.

Analysis method

Reference method: DS/EN 1500:2013. Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2, step 2).

Enclosure 1

Controls						
	log(FF)	Vc1	Vc2	Værdi	Kontrol Check	
N	6	232	236	2.40E+08	1.5E8 ≤ N ≤ 5.0E8	OK
	7	29	31			
Nv	1	57	52	545	300 ≤ Nv ≤ 1600	OK
Nv _B	3	49	46	4.75E+04	3.0E4 ≤ Nv ≤ 1.6E5	OK
Kontrol B	0	58	53	55.5	B ≥ 0.5E-3 * Nv _B	OK
Kontrol C	0	34	42	38	C ≥ 0.5Nv0	OK

Control for test suspension and method validation

Enclosure 2

CFU counts and calculated log-reductions for the reference product

Test person	Hand	Pre-value					Post-value					log-values		
		DF10 ³	DF10 ⁴	DF10 ⁵	log (cfu)	WMC	DF10 ⁰	DF10 ¹	DF10 ²	log (cfu)	WMC	Pre-val.	Post-val.	Re-duc.
#1	Right	<u>269</u>	<u>30</u>	7	6.43	9.0	<u>6</u>	0	0	1.78	-	6.41	1.89	4.52
	Left	<u>236</u>	<u>36</u>	3	6.39	6.6	<u>10</u>	1	0	2.00	-			
#2	Right	>330	<u>56</u>	9	6.75	-	<u>7</u>	1	0	1.85	-	6.86	1.42	5.44
	Left	>330	<u>94</u>	9	6.97	-	<u>1</u>	1	0	1.00	-			
#3	Right	<u>144</u>	<u>17</u>	2	6.17	8.5	<u>270</u>	<u>32</u>	9	3.44	8.4	6.38	3.36	3.03
	Left	>330	<u>40</u>	4	6.60	-	<u>190</u>	<u>18</u>	1	3.28	10.6			
#4	Right	<u>195</u>	<u>30</u>	0	6.31	6.5	<u>33</u>	4	0	2.52	-	6.27	2.26	4.01
	Left	<u>153</u>	<u>30</u>	0	6.22	5.1	<u>10</u>	0	0	2.00	-			
#5	Right	>330	<u>101</u>	<u>19</u>	7.04	5.3	<u>27</u>	2	0	2.43	-	7.10	2.50	4.60
	Left	>330	<u>145</u>	<u>17</u>	7.17	8.5	<u>37</u>	4	0	2.57	-			
#7	Right	>330	<u>287</u>	<u>32</u>	7.46	9.0	<u>110</u>	10	1	3.04	-	7.50	2.94	4.55
	Left	>330	>330	<u>34</u>	7.53	-	<u>70</u>	11	1	2.85	-			
#8	Right	>330	>330	<u>50</u>	7.70	-	<u>26</u>	0	0	2.41	-	7.65	2.46	5.18
	Left	>330	>330	<u>39</u>	7.59	-	<u>32</u>	4	2	2.51	-			
#9	Right	>330	<u>134</u>	10	7.13	-	<u>4</u>	0	0	1.60	-	7.12	1.78	5.34
	Left	>330	<u>126</u>	<u>16</u>	7.11	7.9	<u>9</u>	0	1	1.95	-			
#11	Right	>330	>330	<u>50</u>	7.70	-	<u>17</u>	4	0	2.23	-	7.69	2.29	5.40
	Left	>330	>330	<u>47</u>	7.67	-	<u>22</u>	0	0	2.34	-			
#12	Right	>330	<u>233</u>	<u>31</u>	7.38	7.5	<u>11</u>	1	0	2.04	-	7.48	2.49	4.99
	Left	>330	>330	<u>38</u>	7.58	-	<u>86</u>	8	2	2.93	-			
#13	Right	>330	<u>223</u>	<u>23</u>	7.35	9.7	>330	<u>66</u>	3	3.82	-	7.35	3.96	3.39
	Left	>330	<u>228</u>	<u>16</u>	7.35	14.3	>330	<u>125</u>	<u>14</u>	4.10	8.9			
#14	Right	>330	>330	<u>51</u>	7.71	-	<u>74</u>	11	2	2.87	-	7.75	3.09	4.66
	Left	>330	>330	<u>62</u>	7.79	-	<u>208</u>	<u>15</u>	1	3.31	13.9			
#15	Right	<u>164</u>	11	2	6.21	-	<u>311</u>	<u>36</u>	4	3.50	8.6	6.47	3.74	2.73
	Left	>330	<u>53</u>	5	6.72	-	>330	<u>92</u>	<u>15</u>	3.99	6.1			
#16	Right	>330	<u>130</u>	<u>17</u>	7.13	7.6	<u>134</u>	<u>26</u>	0	3.16	5.2	7.40	2.91	4.49
	Left	>330	>330	<u>47</u>	7.67	-	<u>46</u>	7	0	2.66	-			
#17	Right	>330	>330	<u>79</u>	7.90	-	<u>82</u>	13	0	2.91	-	7.82	2.90	4.92
	Left	>330	>330	<u>56</u>	7.75	-	<u>77</u>	2	2	2.89	-			
#18	Right	>330	<u>111</u>	<u>19</u>	7.07	5.8	>330	<u>94</u>	12	3.97	-	6.83	3.29	3.54
	Left	>330	<u>39</u>	6	6.59	-	<u>40</u>	2	0	2.60	-			
#19	Right	>330	<u>87</u>	8	6.94	-	<u>52</u>	6	2	2.72	-	6.96	2.88	4.07
	Left	>330	<u>94</u>	5	6.97	-	<u>112</u>	11	0	3.05	-			
#20	Right	>330	>330	<u>61</u>	7.79	-	<u>39</u>	3	0	2.59	-	7.72	2.72	5.00
	Left	>330	>330	<u>45</u>	7.65	-	<u>72</u>	15	0	2.86	-			
#21	Right	>330	<u>88</u>	5	6.94	-	<u>176</u>	<u>14</u>	2	3.24	12.6	6.86	3.17	3.70
	Left	>330	<u>60</u>	5	6.78	-	<u>124</u>	13	1	3.09	-			

The number of cfu per plate for pre- and post-values. Counts used for calculations are underlined.

DF: Dilution Factor. WMC: Weighted Mean Count.

Enclosure 3

CFU counts and calculated log-reductions for the product under test

Test person	Hand	Pre-value					Post-value					log-values		
		DF10 ³	DF10 ⁴	DF10 ⁵	log (cfu)	WMC	DF10 ⁰	DF10 ¹	DF10 ²	log (cfu)	WMC	Pre-val.	Post-val.	Re-duc.
#1	Right	>330	<u>91</u>	12	6.96	-	<u>1</u>	0	0	1.00	-	6.98	1.60	5.38
	Left	>330	<u>95</u>	<u>15</u>	7.00	6.3	<u>16</u>	0	1	2.20	-			
#2	Right	>330	<u>121</u>	<u>15</u>	7.09	8.1	<u>7</u>	3	0	1.85	-	7.22	1.81	5.41
	Left	>330	<u>225</u>	<u>24</u>	7.35	9.4	<u>6</u>	0	0	1.78	-			
#3	Right	<u>179</u>	<u>24</u>	1	6.27	7.5	<u>24</u>	3	0	2.38	-	6.26	2.11	4.15
	Left	<u>176</u>	<u>20</u>	0	6.25	8.8	<u>7</u>	2	0	1.85	-			
#4	Right	<u>185</u>	<u>30</u>	0	6.29	6.2	<u>12</u>	0	0	2.08	-	6.28	1.69	4.59
	Left	<u>184</u>	<u>21</u>	3	6.27	8.8	<u>2</u>	0	1	1.30	-			
#5	Right	>330	<u>138</u>	<u>17</u>	7.15	8.1	<u>1</u>	1	0	1.00	-	7.14	1.63	5.51
	Left	>330	<u>125</u>	<u>22</u>	7.13	5.7	<u>18</u>	4	0	2.26	-			
#7	Right	>330	>330	<u>41</u>	7.61	-	<u>1</u>	0	0	1.00	-	7.55	1.24	6.32
	Left	>330	<u>311</u>	<u>33</u>	7.50	9.4	<u>3</u>	0	0	1.48	-			
#8	Right	>330	>330	<u>41</u>	7.61	-	<u>1</u>	0	0	1.00	-	7.59	1.30	6.29
	Left	>330	>330	<u>37</u>	7.57	-	<u>4</u>	1	0	1.60	-			
#9	Right	>330	<u>44</u>	4	6.64	-	<u>1</u>	0	0	1.00	-	6.64	1.00	5.64
	Left	>330	<u>43</u>	7	6.63	-	<u>1</u>	0	0	1.00	-			
#11	Right	>330	>330	<u>50</u>	7.70	-	<u>10</u>	0	0	2.00	-	7.83	2.00	5.83
	Left	>330	>330	<u>91</u>	7.96	-	<u>10</u>	1	0	2.00	-			
#12	Right	>330	<u>244</u>	<u>30</u>	7.40	8.1	<u>26</u>	2	0	2.41	-	7.55	3.09	4.46
	Left	>330	>330	<u>50</u>	7.70	-	>330	<u>57</u>	12	3.76	-			
#13	Right	>330	>330	<u>48</u>	7.68	-	>330	<u>129</u>	<u>19</u>	4.13	6.8	7.77	4.02	3.75
	Left	>330	>330	<u>72</u>	7.86	-	>330	<u>83</u>	8	3.92	-			
#14	Right	>330	>330	<u>59</u>	7.77	-	>330	>330	<u>79</u>	4.90	-	7.76	4.92	2.83
	Left	>330	>330	<u>55</u>	7.74	-	>330	>330	<u>88</u>	4.94	-			
#15	Right	>330	<u>48</u>	7	6.68	-	<u>59</u>	7	0	2.77	-	6.75	2.27	4.48
	Left	>330	<u>67</u>	6	6.83	-	<u>6</u>	0	0	1.78	-			
#16	Right	>330	<u>55</u>	4	6.74	-	<u>35</u>	5	0	2.54	-	6.99	2.56	4.42
	Left	>330	<u>159</u>	<u>29</u>	7.23	5.5	<u>38</u>	5	0	2.58	-			
#17	Right	>330	<u>212</u>	<u>33</u>	7.35	6.4	>330	<u>79</u>	7	3.90	-	7.47	3.16	4.31
	Left	>330	>330	<u>39</u>	7.59	-	<u>26</u>	1	0	2.41	-			
#18	Right	>330	>330	<u>42</u>	7.62	-	>330	>330	<u>73</u>	4.86	-	7.59	4.73	2.86
	Left	>330	>330	<u>36</u>	7.56	-	>330	>330	<u>40</u>	4.60	-			
#19	Right	>330	<u>83</u>	5	6.92	-	<u>152</u>	<u>14</u>	2	3.18	10.9	6.93	2.82	4.11
	Left	>330	<u>86</u>	7	6.93	-	<u>29</u>	2	0	2.46	-			
#20	Right	>330	>330	<u>91</u>	7.96	-	<u>76</u>	5	0	2.88	-	7.91	2.61	5.30
	Left	>330	>330	<u>74</u>	7.87	-	<u>22</u>	0	0	2.34	-			
#21	Right	>330	<u>59</u>	9	6.77	-	<u>108</u>	11	0	3.03	-	6.74	2.89	3.84
	Left	>330	<u>51</u>	2	6.71	-	<u>57</u>	1	4	2.76	-			

The number of cfu per plate for pre- and post-values. Counts used for calculations are underlined.

DF: Dilution Factor. WMC: Weighted Mean Count.

Enclosure 4

Log-differences and sequence of product tests

Test person	Sequence	Reference			Product			Log-difference RP - PP
		Pre-val.	Post-val.	Reduction	Pre-val.	Post-val.	Reduction	
#1	RP > PP	6.41	1.89	4.52	6.98	1.60	5.38	-0.85
#2	RP > PP	6.86	1.42	5.44	7.22	1.81	5.41	0.03
#3	RP > PP	6.38	3.36	3.03	6.26	2.11	4.15	-1.12
#4	RP > PP	6.27	2.26	4.01	6.28	1.69	4.59	-0.58
#5	PP > RP	7.10	2.50	4.60	7.14	1.63	5.51	-0.91
#7	PP > RP	7.50	2.94	4.55	7.55	1.24	6.32	-1.76
#8	PP > RP	7.65	2.46	5.18	7.59	1.30	6.29	-1.10
#9	PP > RP	7.12	1.78	5.34	6.64	1.00	5.64	-0.30
#11	PP > RP	7.69	2.29	5.40	7.83	2.00	5.83	-0.43
#12	RP > PP	7.48	2.49	4.99	7.55	3.09	4.46	0.53
#13	RP > PP	7.35	3.96	3.39	7.77	4.02	3.75	-0.36
#14	RP > PP	7.75	3.09	4.66	7.76	4.92	2.83	1.83
#15	RP > PP	6.47	3.74	2.73	6.75	2.27	4.48	-1.75
#16	PP > RP	7.40	2.91	4.49	6.99	2.56	4.42	0.06
#17	PP > RP	7.82	2.90	4.92	7.47	3.16	4.31	0.61
#18	PP > RP	6.83	3.29	3.54	7.59	4.73	2.86	0.69
#19	PP > RP	6.96	2.88	4.07	6.93	2.82	4.11	-0.03
#20	RP > PP	7.72	2.72	5.00	7.91	2.61	5.30	-0.31
#21	RP > PP	6.86	3.17	3.70	6.74	2.89	3.84	-0.15
Average		7.15	2.72	4.44	7.23	2.48	4.76	
Average for RP > PP				4.15			4.42	
Average for PP > RP				4.68			5.03	

Enclosure 5

Check of acceptance criteria

Parameter	Acceptance criteria	Value	Evaluation
Number of volunteers	min. 18	19	OK
Average of pre-values for RP	min 5.00	7.14	OK
Average of pre-values for PP	min 5.00	7.21	OK
Number of tests with log-R for RP <3	max 3	1	OK
Difference in log-reduction for RP > PP		-0.27	
Difference in log-reduction for PP > RP		-0.35	
Absolute difference between mean differences	<2.00	0.08	OK

Enclosure 6

Calculation of Hodges-Lehmann upper one-sided 97.5% confidence limit

Mean pairwise difference (RP - PP)

	1.83	0.69	0.61	0.53	0.06	0.03	-0.03	-0.15	-0.30	-0.31
1.83	1.83									
0.69	1.26	0.69								
0.61	1.22	0.65	0.61							
0.53	1.18	0.61	0.57	0.53						
0.06	0.94	0.37	0.34	0.30	0.06					
0.03	0.93	0.36	0.32	0.28	0.04	0.03				
-0.03	0.90	0.33	0.29	0.25	0.01	0.00	-0.03			
-0.15	0.84	0.27	0.23	0.19	-0.04	-0.06	-0.09	-0.15		
-0.30	0.76	0.19	0.16	0.12	-0.12	-0.14	-0.17	-0.22	-0.30	
-0.31	0.76	0.19	0.15	0.11	-0.12	-0.14	-0.17	-0.23	-0.30	-0.31
-0.36	0.73	0.16	0.13	0.09	-0.15	-0.17	-0.20	-0.25		
-0.43	0.70	0.13	0.09	0.05	-0.18	-0.20	-0.23	-0.29		
-0.58	0.62	0.05	0.01	-0.03	-0.26	-0.28				
-0.85	0.49	-0.08	-0.12	-0.16						
-0.91	0.46	-0.11	-0.15	-0.19						
-1.10	0.36	-0.21	-0.25	-0.29						
-1.12	0.35	-0.22	-0.26	-0.29						
-1.75	0.04									
-1.76	0.03									

The mean pairwise differences larger than the median (-0.31) is shown in the above matrix. Wilcoxon's matched-pairs signed-ranks test for a one-sided test with 0.025 significance-level and 19 result pairs are 46 (table E.5 in EN 1500).

The Hodges-Lehmann upper one-sided 97.5% confidence limit for log-reductions differences between RP and PP is calculated as the 47th (46+1) highest value of the mean pairwise difference which is 0.06.

The accepted inferiority margin according to EN1500 is 0.6

As the Hodges-Lehmann upper one-sided 97.5% confidence limit for log-reductions differences between RP and PP is lower than the accepted inferiority margin, the hypothesis that the product under test is inferior to the reference is rejected.