

Saebefabriken A/S
Aarhusvej 5

DK- 4800 Nyköbing

2011-12-23

Händedes Gel
Hygienic Handrub

EXPERTISE

After testing the disinfectant **Händedes Gel** in accordance to prEN 1500 (status: 2002) I hereby issue the following evaluation of the test results from the test report of 2011-12-23 (SN 12874):

The product **Händedes Gel** is suitable for the hygienic hand disinfection according to prEN 1500.

Application recommendation for Hygienic Handrub

according to the "Requirements Specification for the Admission of Chemical Disinfection Processes" of the disinfection commission of the VAH.

Händedes Gel

5 ml Händedes Gel
rubbed on the hands during 60 seconds.

Prof. Dr. med. H.-P. Werner

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Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-715.98.13

 **AKS** Akkreditierung: AKS-PL-21301
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Staatliche Akkreditierungsstelle Hannover

2011-12-23
Prof. We/ku

Händedes Gel Hygienic handrub according to prEN 1500 (2002)

TESTREPORT

Identification of the test laboratory:	SN 12874.1
Test product:	Händedes Gel
Batch no.:	-
Manufacturer:	Saebefabriken A/S
Date of order:	2012-06-15
Date of delivery:	2012-11-16
Product diluent recommended by the manufacturer for use:	concentrated
Appearance:	colorless, slightly cloudy liquid
Odour:	alcoholic
Storage conditions:	those of the manufacturer
Active substance(s) per 100 g:	not indicated
pH-value (DIN EN 19266):	100%: 10.0

SN 12874 prEN 1500 page 1 of 7

Testing of Hygienic handrub according to prEN 1500 (2002)

Test strain: Escherichia coli NCTC 10538

Cfu in the test suspension: 8.74 lg/ml

Date of test: 2011-12-20

Reference procedure:

2 x 3 ml 60 % (v/v) propan-2-ol rubbed on the hands during 60 seconds.

Test procedure:

5 ml of Händedes Gel rubbed onto the hands during 60 seconds.

Reference handrub: 60% propan-2-ol - original list of results

Subject	Hand left right	pre values			post values		
		10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁰	10 ⁻¹	10 ⁻²
1	left	nc	<u>192</u>	<u>20</u>	<u>8</u>	0	0
	right	nc	<u>112</u>	12	<u>4</u>	0	0
2	left	nc	<u>114</u>	11	<u>226</u>	<u>23</u>	3
	right	nc	<u>173</u>	<u>18</u>	<u>180</u>	<u>19</u>	2
3	left	nc	nc	<u>108</u>	<u>1</u>	0	0
	right	nc	nc	<u>90</u>	<u>4</u>	0	0
4	left	nc	nc	<u>75</u>	<u>9</u>	1	0
	right	nc	nc	<u>98</u>	<u>24</u>	2	0
5	left	nc	<u>226</u>	<u>24</u>	<u>28</u>	3	0
	right	nc	<u>261</u>	<u>27</u>	<u>17</u>	2	0
6	left	nc	nc	<u>39</u>	<u>4</u>	0	0
	right	nc	<u>156</u>	<u>17</u>	<u>6</u>	0	0
7	left	nc	nc	<u>67</u>	<u>13</u>	1	0
	right	nc	nc	<u>57</u>	<u>33</u>	3	0
8	left	nc	nc	<u>59</u>	<u>9</u>	1	0
	right	nc	<u>238</u>	<u>24</u>	<u>2</u>	0	0
9	left	nc	nc	<u>120</u>	<u>5</u>	0	0
	right	nc	nc	<u>132</u>	<u>1</u>	0	0
10	left	nc	<u>205</u>	<u>21</u>	<u>3</u>	0	0
	right	nc	<u>281</u>	<u>29</u>	<u>13</u>	1	0
11	left	nc	nc	<u>42</u>	<u>40</u>	4	0
	right	nc	nc	<u>56</u>	<u>159</u>	<u>15</u>	2
12	left	nc	<u>224</u>	<u>23</u>	<u>5</u>	0	0
	right	nc	<u>137</u>	14	<u>1</u>	0	0
13	left	nc	<u>127</u>	14	<u>10</u>	1	0
	right	nc	<u>97</u>	11	<u>17</u>	2	0
14	left	nc	nc	<u>33</u>	<u>3</u>	0	0
	right	nc	nc	<u>65</u>	<u>61</u>	6	0
15	left	nc	nc	<u>64</u>	<u>12</u>	1	0
	right	nc	nc	<u>59</u>	<u>1</u>	0	0

nc = not countable

— = count used for further computation

Hygienic handrub with the test product – Händedes Gel - original list of results

Subject	Hand left right	pre values			post values		
		10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁰	10 ⁻¹	10 ⁻²
1	left	nc	<u>283</u>	<u>29</u>	<u>28</u>	3	0
	right	nc	<u>251</u>	<u>25</u>	<u>5</u>	0	0
2	left	nc	nc	<u>46</u>	<u>150</u>	<u>15</u>	0
	right	nc	<u>193</u>	<u>20</u>	<u>184</u>	<u>19</u>	1
3	left	nc	nc	<u>44</u>	<u>27</u>	2	0
	right	nc	nc	<u>56</u>	<u>34</u>	3	0
4	left	nc	nc	<u>41</u>	<u>3</u>	0	0
	right	nc	<u>210</u>	<u>21</u>	<u>3</u>	0	0
5	left	nc	<u>289</u>	<u>29</u>	<u>27</u>	2	0
	right	nc	<u>170</u>	<u>18</u>	<u>1</u>	0	0
6	left	nc	nc	<u>46</u>	<u>5</u>	0	0
	right	nc	nc	<u>64</u>	<u>175</u>	<u>18</u>	1
7	left	nc	<u>166</u>	<u>17</u>	<u>7</u>	1	0
	right	nc	<u>100</u>	11	<u>10</u>	1	0
8	left	nc	<u>274</u>	<u>28</u>	<u>1</u>	0	0
	right	nc	<u>94</u>	9	<u>1</u>	0	0
9	left	nc	nc	<u>106</u>	<u>1</u>	0	0
	right	nc	nc	<u>81</u>	<u>2</u>	0	0
10	left	nc	nc	<u>57</u>	<u>4</u>	0	0
	right	nc	nc	<u>51</u>	<u>1</u>	0	0
11	left	nc	nc	<u>75</u>	<u>87</u>	8	0
	right	nc	nc	<u>47</u>	<u>33</u>	4	0
12	left	nc	<u>124</u>	12	<u>2</u>	0	0
	right	nc	<u>136</u>	14	<u>3</u>	0	0
13	left	nc	<u>239</u>	<u>24</u>	<u>2</u>	0	0
	right	nc	<u>240</u>	<u>25</u>	<u>10</u>	1	0
14	left	nc	nc	<u>52</u>	<u>4</u>	0	0
	right	nc	<u>219</u>	<u>23</u>	<u>41</u>	4	0
15	left	nc	nc	<u>85</u>	<u>6</u>	1	0
	right	nc	nc	<u>68</u>	<u>8</u>	1	0

nc = not countable

— = count used for further computation

List of the results (values of left and right hands) and lg-reduction factors of reference handrub and handrub with the test product (Händedes Gel)

Subject	reference product			Händedes Gel		
	Nr.	lg x	lg y	lg z	lg x	lg y
1	6.17	0.75	5.42	6.43	1.08	5.35
2	6.15	2.31	3.84	6.48	2.23	4.25
3	6.99	0.30	6.69	6.70	1.48	5.22
4	6.94	1.17	5.77	6.47	0.48	5.99
5	6.39	1.34	5.05	6.35	0.72	5.63
6	6.40	0.69	5.71	6.74	1.47	5.27
7	6.80	1.32	5.48	6.11	0.93	5.18
8	6.58	0.63	5.95	6.21	0.00	6.21
9	7.10	0.35	6.75	6.97	0.15	6.82
10	6.38	0.80	5.58	6.74	0.30	6.44
11	6.69	1.90	4.79	6.78	1.73	5.05
12	6.25	0.35	5.90	6.11	0.39	5.72
13	6.05	1.12	4.93	6.38	0.65	5.73
14	6.67	1.14	5.53	6.53	1.11	5.42
15	6.79	0.54	6.25	6.88	0.84	6.04
\bar{x}	6.56	0.98	5.58	6.53	0.90	5.62
s	0.33	0.58	0.74	0.27	0.62	0.63
N	15	15	15	15	14	15

lg x lg pre value
 lg y lg post value
 lg z lg reduction factor
 \bar{x} mean of lg x, lg y and lg z
 s standard deviation
 N count of subjects in each column

**Statistical comparison of values as obtained with reference handrub
and handrub with test product**
(Optional sign - rank test according to WILCOXON)

Subject No.	lg RF of R	difference		rank of difference	
		P	R-P	without OS	with OS
1	5.42	5.35	0.07	1,5	1,5
2	3.84	4.25	-0.41	10	-10
3	6.69	5.22	1.47	15	15
4	5.77	5.99	-0.22	6	-6
5	5.05	5.63	-0.58	12	-12
6	5.71	5.27	0.44	11	11
7	5.48	5.18	0.30	9	9
8	5.95	6.21	-0.26	7,5	-7,5
9	6.75	6.82	-0.07	1,5	-1,5
10	5.58	6.44	-0.86	14	-14
11	4.79	5.05	-0.26	7,5	-7,5
12	5.90	5.72	0.18	4	4
13	4.93	5.73	-0.80	13	-13
14	5.53	5.42	0.11	3	3
15	6.25	6.04	0.21	5	5

RF reduction factor
R reference
P test product
VZ / OS optional sign

rank sum (+) : 48,5

rank sum (-) : 71,5

Subject	significance niveau
(number of pairs unequal 0)	0.1
15	36

Conclusion: The test procedure with Händedes Gel according to prEN 1500 (2002) resulted in a lower mean reduction factor of 5.62 lg than the reference procedure. The difference is statistically not significant.

Händedes Gel is suitable for the hygienic hand rub under the following conditions:

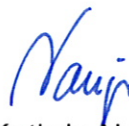
5 ml of Händedes Gel rub onto the hands during 60 seconds.

Archive: The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.

Information: The test results are valid for the named test subject only. Reproduction of any part of this report requires the written permission of HygCen GmbH.



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