

INGEKOMEN - 1 FEB. 2010

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Die Akkreditierung gilt für die in der Urkunde
aufgeführten Verfahren.



Bad Bocklet, 26 January 2010

Technical Report

Sample: TC WW Enriched Foam Instant Hand Sanitizer

L+S-No.: 12911859

Order: Hygienic hand disinfection according to EN 1500

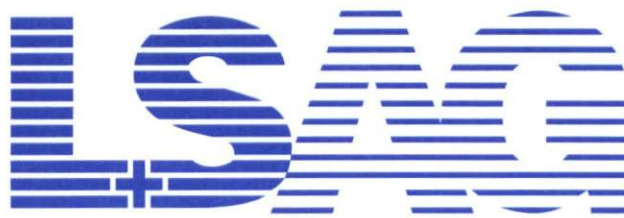
The test results apply solely to the designated sample.
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- Test Report on TC WW Enriched Foam Instant Hand Sanitizer (Hygienic hand disinfection according to EN 1500) -

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Vorstand:	Aufsichtsrat: Werner Wohnhas (Vors.)	HypoVereinsbank Bad Kissingen:	IBAN: DE10 7932 0075 0002 0110 00
Dr. Lothar Bomblies	Dr. Rüdiger Leimbeck	Konto-Nr. 2 011 000 (BLZ 793 200 75)	BIC: HYVEDEMM451 · ATLAS-Zoll-Nr.: 5 18 44 60
Dr. Frank Böttcher	Prof. Dr. Bernd Sonnenschein	Deutsche Bank Würzburg:	Handelsregister HRB 2726 (Amtsgericht Schweinfurt)
	Ärztl. Leiter: PD Dr. med. A. Schwarzkopf	Konto-Nr. 8 401 325 (BLZ 790 700 16)	USt.-Id.-Nr.: DE 814360374



Material and Method

Hygienic hand disinfection according to EN 1500

1. Identification of the testing laboratory

Labor L+S AG
Mangelsfeld 4

D - 97708 Bad Bocklet

2. Identification of the sample

Name of the product:

TC WW Enriched Foam Instant Hand Sanitizer,
Batch: BE09/46/LAB0011

Date of delivery:

17 December 2009

Appearance of the product:

colourless, slightly viscous, clear

pH-value (100%):

5.5

Storage conditions:

room temperature

3. Hygienic hand disinfection according to EN 1500

Period of testing:

14 January - 18 January 2010

Instruction for use:

Within the reference hand disinfection (R) 2 x 3 ml 60% Propan-2-ol were rubbed in for 1 minute (2 x 30 seconds) immediately after determination of pre-values.

Within the hygienic hand disinfection with the product (P) 2 x 3 ml of the undiluted product were rubbed in for 1 minute (2 x 30 seconds) immediately after determination of pre-values.

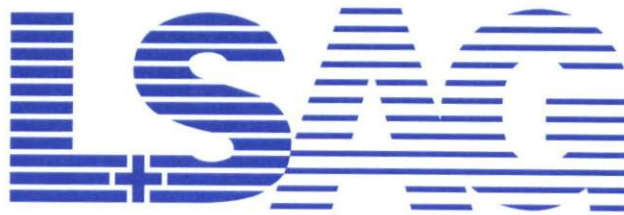
Finally the hands were washed-up for 5 seconds under flowing water and the post-values were determined.

Inactivation combination:

3.0 % Tween 80, 3.0 % saponine, 0.1 % histidin,
0.1 % cystein in casein-soybean-broth

Conditions of incubation:

48 hours, 37°C ± 1°C



Validation of test procedure:

Complete results of at least 12 volunteers are available.

The total mean of pre-values for reference and test procedures are at least > 5.00 log-levels.

Neither of the two procedures gave rise to more than three single log reductions < 3.00 log-levels.

The validation of the test procedure was proved.

4. Results

For detailed results see tables 1a – 3.

In the practice-related test the product **TC WW Enriched Foam Instant Hand Sanitizer** (2 x 3 ml) showed within a contact time of 2 x 30 seconds, as well as the reference product (60% Propan-2-ol, 2 x 3 ml) within a contact time of 2 x 30 seconds good efficacy. The product **TC WW Enriched Foam Instant Hand Sanitizer** showed a mean log reduction of 4.20 ($n = 12$) compared to a mean log reduction of 4.22 ($n = 12$) for the reference product. The difference is not significant (nonparametric WILCOXON matched-pairs prognostic rank test), since the lower summation of rank (34) is greater than the value out of the WILCOXON table ($n = 12$; $p = 0.1$; value = 21).

Therefore, the product **TC WW Enriched Foam Instant Hand Sanitizer** fulfilled the function as a hygienic hand disinfectant according to the requirements of the EN 1500.

A handwritten signature in blue ink, appearing to read 'Anastasija Schlicht'.

Dipl-Biol Anastasija Schlicht
- head of department -

A handwritten signature in blue ink, appearing to read 'Thomas Meindl'.

Dr Thomas Meindl
- division manager -



Table 1a: Hygienic hand disinfection according to EN 1500

Reference hand disinfection with 60% Propan-2-ol

Test strain: *Escherichia (E.) coli* K 12, NCTC 10538

Colony count of test suspension: 7.20×10^8 cfu/ml / 7.72×10^8 cfu/ml

Instruction for use: 2 x 3 ml within 2 x 30 seconds

Test person no.	Hand	Pre-values Number cfu per plate / dilution level		Post-values Number cfu per plate / dilution level			
		10^{-3} / 0.1 ml	10^{-4} / 0.1 ml	10^0 / 1.0 ml	10^0 / 0.1 ml	10^{-1} / 0.1 ml	10^{-2} / 0.1 ml
1	left	> 300	<u>92</u>	> 300	<u>37</u>	8	2
	right	> 300	<u>114</u>	> 300	<u>52</u>	8	1
2	left	> 300	<u>124</u>	<u>184*</u>	<u>22*</u>	4	1
	right	> 300	<u>68</u>	> 300	<u>33</u>	3	1
3	left	> 300	<u>100</u>	> 300	> 300	<u>56</u>	6
	right	> 300	<u>132</u>	> 300	<u>110</u>	13	2
4	left	> 300	<u>160</u>	> 300	> 300	<u>84</u>	11
	right	> 300	<u>158</u>	> 300	<u>120*</u>	<u>22*</u>	4
5	left	> 300	<u>42</u>	> 300	> 300	<u>38</u>	3
	right	> 300	<u>43</u>	> 300	> 300	<u>76</u>	6
6	left	> 300	<u>192</u>	> 300	> 300	<u>140*</u>	<u>25*</u>
	right	> 300	<u>120</u>	> 300	> 300	<u>32</u>	5
7	left	> 300	<u>140</u>	> 300	<u>44</u>	9	0
	right	> 300	<u>184</u>	> 300	<u>96*</u>	<u>38*</u>	5
8	left	> 300	<u>180</u>	> 300	> 300	<u>35</u>	5
	right	> 300	<u>184</u>	> 300	<u>106</u>	9	1
9	left	> 300	<u>102</u>	<u>72*</u>	<u>19*</u>	3	0
	right	> 300	<u>152</u>	> 300	<u>35</u>	4	0
10	left	> 300	<u>33</u>	> 300	<u>140*</u>	<u>27*</u>	7
	right	> 300	<u>42</u>	> 300	<u>86*</u>	<u>22*</u>	2
11	left	> 300	<u>74</u>	<u>90*</u>	<u>17*</u>	2	1
	right	> 300	<u>66</u>	> 300	<u>32</u>	3	0
12	left	<u>128*</u>	<u>16*</u>	<u>16</u>	2	0	0
	right	<u>76</u>	9	<u>48</u>	14	0	0
13	left	> 300	<u>104</u>	> 300	<u>61</u>	6	0
	right	> 300	<u>212</u>	> 300	<u>106*</u>	<u>16*</u>	1
14	left	> 300	<u>80</u>	> 300	> 300	<u>41</u>	11
	right	> 300	<u>110</u>	> 300	> 300	<u>60</u>	3
15	left	> 300	<u>68</u>	<u>72</u>	11	1	0
	right	> 300	<u>36</u>	<u>140*</u>	<u>20*</u>	3	0
16	left	<u>112*</u>	<u>19*</u>	<u>124</u>	11	1	0
	right	<u>66</u>	3	<u>128</u>	10	1	0
17	left	> 300	<u>124</u>	<u>68</u>	9	1	0
	right	> 300	<u>136</u>	<u>94*</u>	<u>28*</u>	6	0
18	left	> 300	<u>146</u>	> 300	> 300	<u>164*</u>	<u>52*</u>
	right	> 300	<u>240</u>	> 300	> 300	> 300	<u>35</u>
19	left	<u>198*</u>	<u>22*</u>	> 300	> 300	<u>31</u>	6
	right	> 300	<u>40</u>	> 300	> 300	<u>60</u>	9
20	left	> 300	<u>116</u>	> 300	> 300	<u>164*</u>	<u>23*</u>
	right	> 300	<u>70</u>	> 300	> 300	<u>168</u>	13

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Table 1b: Hygienic hand disinfection according to EN 1500

Hand disinfection with TC WW Enriched Foam Instant Hand Sanitizer

Test strain: *Escherichia (E.) coli* K 12, NCTC 10538

Colony count of test suspension: 7.20×10^8 cfu/ml / 7.72×10^8 cfu/ml

Instruction for use: 2 x 3 ml within 2 x 30 seconds

Test person no.	Hand	Pre-values Number cfu per plate / dilution level		Post-values Number cfu per plate / dilution level			
		$10^{-3} / 0.1$ ml	$10^{-4} / 0.1$ ml	$10^0 / 1.0$ ml	$10^0 / 0.1$ ml	$10^{-1} / 0.1$ ml	$10^{-2} / 0.1$ ml
1	left	> 300	<u>106</u>	> 300	<u>66</u>	8	0
	right	> 300	<u>102</u>	> 300	<u>43</u>	4	1
2	left	> 300	<u>120</u>	> 300	<u>58</u>	13	0
	right	> 300	<u>126</u>	> 300	<u>54</u>	10	1
3	left	> 300	<u>74</u>	> 300	> 300	<u>48</u>	12
	right	> 300	<u>80</u>	> 300	<u>74</u>	11	1
4	left	> 300	<u>120</u>	> 300	> 300	<u>128*</u>	<u>21*</u>
	right	> 300	<u>118</u>	> 300	<u>94*</u>	<u>23*</u>	1
5	left	> 300	<u>34</u>	> 300	> 300	<u>33</u>	7
	right	> 300	<u>76</u>	> 300	> 300	<u>48</u>	6
6	left	> 300	<u>64</u>	> 300	> 300	<u>90</u>	8
	right	> 300	<u>120</u>	> 300	<u>84*</u>	<u>15*</u>	2
7	left	> 300	<u>168</u>	> 300	> 300	<u>58</u>	10
	right	> 300	<u>160</u>	> 300	<u>84</u>	11	1
8	left	> 300	<u>172</u>	> 300	> 300	<u>96</u>	9
	right	> 300	<u>132</u>	> 300	> 300	<u>50</u>	7
9	left	> 300	<u>118</u>	<u>44</u>	3	1	0
	right	> 300	<u>84</u>	<u>104</u>	7	1	0
10	left	> 300	<u>56</u>	> 300	<u>108*</u>	<u>16*</u>	0
	right	> 300	<u>40</u>	> 300	<u>82*</u>	<u>15*</u>	2
11	left	> 300	<u>100</u>	> 300	<u>42</u>	6	0
	right	> 300	<u>112</u>	> 300	<u>40</u>	7	0
12	left	> 300	<u>130</u>	<u>96</u>	8	1	0
	right	> 300	<u>65</u>	<u>132*</u>	<u>16*</u>	3	0
13	left	> 300	<u>104</u>	> 300	<u>100</u>	14	1
	right	> 300	<u>114</u>	> 300	<u>72</u>	10	0
14	left	> 300	<u>128</u>	> 300	> 300	<u>62</u>	6
	right	> 300	<u>200</u>	> 300	> 300	<u>90*</u>	<u>16*</u>
15	left	> 300	<u>104</u>	<u>24</u>	3	0	0
	right	> 300	<u>120</u>	<u>48</u>	6	0	0
16	left	<u>130*</u>	<u>18*</u>	> 300	<u>68</u>	5	0
	right	<u>114*</u>	<u>15*</u>	<u>120</u>	8	4	0
17	left	> 300	<u>124</u>	<u>62</u>	11	0	0
	right	> 300	<u>192</u>	> 300	<u>35</u>	5	1
18	left	> 300	<u>110</u>	> 300	> 300	<u>110</u>	6
	right	> 300	<u>148</u>	> 300	> 300	<u>228*</u>	<u>27*</u>
19	left	> 300	<u>76</u>	> 300	> 300	<u>82</u>	8
	right	> 300	<u>76</u>	> 300	> 300	<u>56</u>	8
20	left	> 300	<u>76</u>	> 300	> 300	<u>38</u>	3
	right	> 300	<u>68</u>	> 300	> 300	<u>124*</u>	<u>25*</u>

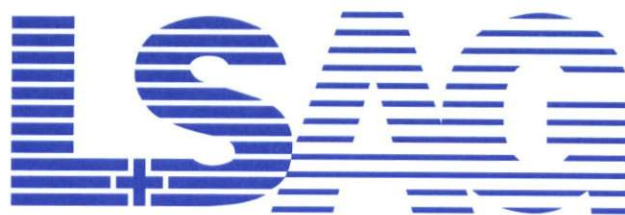


Table 2: Hygienic hand disinfection according to EN 1500

List of calculated log-values (average from left and right hand) and log-reduction calculated from the test results (Table 1a and 1b)

Test person no.	Reference hand disinfection (R) with 60% Propan-2-ol			Hand disinfection with the test product (P) TC WW Enriched Foam Instant Hand Sanitizer		
	log x	log y	log z	log x	log y	log z
1	7.01	2.65	4.36	7.02	2.73	4.29
2	6.96	2.40	4.56	7.09	2.75	4.34
3	7.06	3.40	3.66	6.89	3.28	3.61
4	7.20	3.52	3.68	7.08	3.58	3.50
5	6.63	3.73	2.90	6.71	3.60	3.11
6	7.18	3.85	3.33	6.95	3.45	3.50
7	7.21	2.87	4.34	7.22	3.34	3.88
8	7.26	3.29	3.97	7.18	3.84	3.34
9	7.10	2.23	4.87	7.00	1.83	5.17
10	6.57	3.09	3.48	6.68	3.00	3.68
11	6.85	2.25	4.60	7.03	2.61	4.42
12	6.00	1.44	4.56	6.96	2.06	4.90
13	7.18	2.92	4.26	7.04	2.93	4.11
14	6.97	3.70	3.27	7.21	3.89	3.32
15	6.70	2.01	4.69	7.05	1.53	5.52
16	5.95	2.10	3.85	6.10	2.46	3.64
17	7.11	1.94	5.17	7.19	2.17	5.02
18	7.27	4.42	2.85	7.11	4.21	2.90
19	6.45	3.64	2.81	6.88	3.83	3.05
20	6.96	4.23	2.73	6.86	3.86	3.00
m	6.86	2.64	4.22	6.99	2.79	4.20
s	0.45	0.72	0.52	0.29	0.75	0.72
N	12	12	12	12	12	12
log x	log pre-value			m	Total mean	
log y	log post-value			s	Standard deviation	
log z	log reduction			N	Number of volunteers	



Table 3: Hygienic hand disinfection according to EN 1500

The Wilcoxon Matched-Pairs Prognostic Ranks Test

Test person	log z of		Difference R - P	Rank of difference	
	R	P		unsigned	signed
1	4.36	4.29	0.07	2	2
2	4.56	4.34	0.22	7	7
3	3.66	3.61	0.05		
4	3.68	3.50	0.18		
5	2.90	3.11	- 0.21		
6	3.33	3.50	- 0.17	4	- 4
7	4.34	3.88	0.46	10	10
8	3.97	3.34	0.63	11	11
9	4.87	5.17	- 0.30	8	- 8
10	3.48	3.68	- 0.20		
11	4.60	4.42	0.18	5	5
12	4.56	4.90	- 0.34	9	- 9
13	4.26	4.11	0.15	3	3
14	3.27	3.32	- 0.05	1	- 1
15	4.69	5.52	- 0.83	12	- 12
16	3.85	3.64	0.21	6	6
17	5.17	5.02	0.15		
18	2.85	2.90	- 0.05		
19	2.81	3.05	- 0.24		
20	2.73	3.00	- 0.27		

log z: Reduction factor

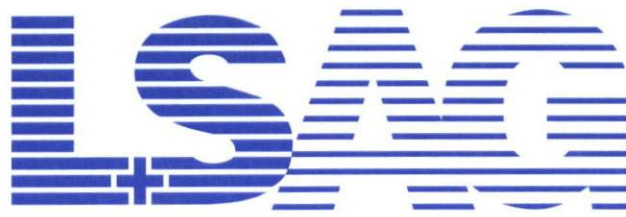
Summation of positive ranks (+): 44

Summation of negative ranks (-): 34

Critical value (n = 12, p = 0,1): 21 Since the lower summation of ranks (34) is greater than the critical value (21) the difference is not significant

Notes to table 1a - 3:

The underlined values were used for calculations.
 All values marked by an * were used for creation of the weighted mean.
 All bold typed values were used for calculating the Wilcoxon test.



Appendix

QAU Certificate

The results given in the above test report were compared with the raw data of the study and checked for correct transfer. No deviations were detected.

A handwritten signature in blue ink, appearing to read 'Könnemann', with a long, sweeping horizontal line extending to the right.

Dipl.-Ing (FH) Annette Könnemann
QAU

27 Jan 2010
Date