

iki GmbH • Siemensstraße 18 • D-35394 Gießen

iki - Institut für Krankenhaushygiene
und Infektionskontrolle GmbH

Telefon: 0641 / 97 90 5-0
Telefax: 0641 / 97 90 5-34

E-Mail: info@iki-giessen.de
www.iki-giessen.de

Geschäftsführer:
PD Dr. med. Frank-Albert Pitten

Our sign:
Dr. Pi/cs

Date:
09 October 2020

TEST REPORT

of the product: Desiform

to be intended for: hygienic handrub

Test method: Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2); German version EN 1500:2013

Requirements and Methods for VAH Certification of Chemical Disinfection Procedures”
(issued: 02.04.2015)

Client: Emanto GmbH, D-63150 Heusenstamm

Sample-No.: PL 20-140

Product: Desiform

Producer: Emanto GmbH, D-63150 Heusenstamm

Lot-No.: N-87823

Date of delivery of the product: 15 September 2020

Test period: 21 September to 30 September 2020

Storage conditions: dark, room temperature

Active substances and their concentrations in 100 g
(according to manufacturer's instructions): 83.3 % Ethanol, 11 % Aqua purificata
4.2 % hydrogen peroxide 3 %, 1.5 % glycerin

Appearance of the product: liquid, colourless

Odour of the product: alcoholic

pH-values: 100 % - 8.24 50 % - 7.74

25 % - 7.37 10 % - 7.29

5 % - 7.22

Test organisms:

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Escherichia coli K12 NCTC 10538

Proteus mirabilis ATCC 14153

Pseudomonas aeruginosa ATCC 15442

Candida albicans ATCC 10231

Table 1

Assessment of the bactericidal and yeasticidal efficacy in the qualitative suspension test (VAH method 8)

Test product: Desiform
 Test date: 21 September 2020
 Test temperature: 20 ± 1 °C
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l,
 Tryptic soy broth 30 g/l, demineralized water ad 1000 ml
 Incubation of the subcultures: $36 \text{ °C} \pm 1 \text{ °C}$ for 48 h

Test without organic burden

Test organisms (lg cfu/ml) Concentration of the test product (%)	Time of action (s)		
	15	30	60
<i>P. aeruginosa</i> 2.8 x 10 ⁸ cfu/ml			
100	-	-	-
50	-	-	-
25	+	+	+
10	+	+	+
5	+	+	+
WSH	+	+	+
<i>E. coli</i> 3.8 x 10 ⁸ cfu/ml			
100	-	-	-
50	-	-	-
25	+	+	+
10	+	+	+
5	+	+	+
WSH	+	+	+
<i>P. mirabilis</i> 3.7 x 10 ⁸ cfu/ml			
100	-	-	-
50	-	-	-
25	+	+	+
10	+	+	+
5	+	+	+
WSH	+	+	+

+ = visible growth of the microorganisms
 - = no visible growth of the microorganisms

Table 2

Assessment of the bactericidal efficacy in the quantitative suspension test (VAH method 9)

Test product: Desiform
 Test date: 23 September 2020
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l, demineralized water ad 1000 ml
 Test suspension: *Staphylococcus aureus* ATCC 6538 2.8 x 10⁸ cfu/ml
 Test temperature: 20 ± 1 °C
 Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes

Concentration (%)	Reduction factor (lg) after time of action in s									
	15			30			60			
	cfu	lg cfu	RF	cfu	lg cfu	RF	cfu	lg cfu	RF	
Control 1	10 ⁻⁴ 10 ⁻⁵ 10 ⁻⁶	>330 <u>49</u> 8	6.69		>330 <u>46</u> 2	6.66		>330 <u>43</u> 4	6.63	
Control 2	10 ⁻¹ 10 ⁻²							>330 <u>86</u>	3.93	
Control 3	10 ⁻¹ 10 ⁻²							>330 <u>152</u>	4.18	
80	10 ⁰ 10 ⁻¹ 10 ⁻² 10 ⁻³	<u>0</u> 0 0 0	0	6.69	<u>0</u> 0 0 0	0	6.66	<u>0</u> 0 0 0	0	6.63
50	10 ⁰ 10 ⁻¹ 10 ⁻² 10 ⁻³	>330 >330 <u>86</u> 11	3.93	2.76	>330 <u>84</u> 12 1	2.92	3.74	<u>0</u> 0 0 0	0	6.63
25	10 ⁰ 10 ⁻¹ 10 ⁻² 10 ⁻³	>330 >330 >330 <u>≥330</u>	>5.52	<1.17	>330 >330 >330 <u>≥330</u>	>5.52	<1.14	>330 >330 >330 <u>≥330</u>	>5.52	<1.11

underlined = used for further calculation
 RF = reduction factor

Table 3

Assessment of the bactericidal efficacy in the quantitative suspension test (VAH method 9)

Test product: Desiform
 Test date: 24 September 2020
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l, demineralized water ad 1000 ml
 Test suspension: *Enterococcus hirae* ATCC 10541 4.4 x 10⁸ cfu/ml
 Test temperature: 20 ± 1 °C
 Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes

Concentration (%)	Reduction factor (lg) after time of action in s									
	15			30			60			
	cfu	lg cfu	RF	cfu	lg cfu	RF	cfu	lg cfu	RF	
Control 1	10 ⁻⁴	>330			>330			>330		
	10 ⁻⁵	<u>56</u>	6.75		<u>48</u>	6.68		<u>52</u>	6.72	
	10 ⁻⁶	3			8			9		
Control 2	10 ⁻¹							>330	3.99	
	10 ⁻²							<u>98</u>		
Control 3	10 ⁻¹							>330	4.15	
	10 ⁻²							<u>142</u>		
80	10 ⁰	<u>0</u>			<u>0</u>			<u>0</u>		
	10 ⁻¹	0	0	6.75	0	0	6.68	0	0	6.72
	10 ⁻²	0			0			0		
	10 ⁻³	0			0			0		
50	10 ⁰	>330			>330			<u>0</u>		
	10 ⁻¹	>330	4.62	2.13	<u>62</u>	2.79	3.89	0	0	6.72
	10 ⁻²	>330			8			0		
	10 ⁻³	<u>42</u>			0			0		
25	10 ⁰	>330			>330			>330		
	10 ⁻¹	>330	>5.52	<1.23	>330	>5.52	<1.16	>330	5.24	1.48
	10 ⁻²	>330			>330			>330		
	10 ⁻³	<u>≥330</u>			<u>≥330</u>			<u>175</u>		

underlined = used for further calculation
 RF = reduction factor

Table 4

Assessment of the bactericidal efficacy in the quantitative suspension test (VAH method 9)

Test product: Desiform
 Test date: 23 September 2020
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l,
 demineralized water ad 1000 ml
 Test suspension: *Pseudomonas aeruginosa* ATCC 15442 3.8 x 10⁸ cfu/ml
 Test temperature: 20 ± 1 °C
 Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes

Concentration (%)	Reduction factor (lg) after time of action in s									
	15			30			60			
	cfu	lg cfu	RF	cfu	lg cfu	RF	cfu	lg cfu	RF	
Control 1	10 ⁻⁴	>330			>330			>330		
	10 ⁻⁵	<u>46</u>	6.66		<u>48</u>	6.68		<u>42</u>	6.62	
	10 ⁻⁶	4			6			6		
Control 2	10 ⁻¹							>330	3.82	
	10 ⁻²							<u>66</u>		
Control 3	10 ⁻¹							>330	4.05	
	10 ⁻²							<u>111</u>		
80	10 ⁰	<u>0</u>			<u>0</u>			<u>0</u>		
	10 ⁻¹	0	0	6.66	0	0	6.68	0	0	6.62
	10 ⁻²	0			0			0		
	10 ⁻³	0			0			0		
50	10 ⁰	<u>0</u>			<u>0</u>			<u>0</u>		
	10 ⁻¹	0	0	6.66	0	0	6.68	0	0	6.62
	10 ⁻²	0			0			0		
	10 ⁻³	0			0			0		
25	10 ⁰	>330			>330			>330		
	10 ⁻¹	>330	>5.52	<1.14	>330	5.16	1.52	>330	4.99	1.63
	10 ⁻²	>330			>330			>330		
	10 ⁻³	<u>≥330</u>			<u>146</u>			<u>98</u>		

underlined = used for further calculation
 RF = reduction factor

Table 5

Assessment of the levurocidal efficacy in the quantitative suspension test (VAH method 9)

Test product: Desiform
 Test date: 23 September 2020
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l,
 demineralized water ad 1000 ml
 Test suspension: **Candida albicans** ATCC 10231 4.2 x 10⁷ cfu/ml
 Test temperature: 20 ± 1 °C
 Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes

Concentration (%)	Reduction factor (lg) after time of action in s									
	15			30			60			
	cfu	lg cfu	RF	cfu	lg cfu	RF	cfu	lg cfu	RF	
Control 1	10 ⁻³	>330			>330			>330		
	10 ⁻⁴	<u>47</u>	5.67		<u>46</u>	5.66		<u>44</u>	5.64	
	10 ⁻⁵	4			3			2		
Control 2	10 ⁻¹							>330		
	10 ⁻²							<u>83</u>	3.92	
Control 3	10 ⁻¹							>330		
	10 ⁻²							<u>128</u>	4.11	
80	10 ⁰	<u>0</u>			<u>0</u>			<u>0</u>		
	10 ⁻¹	0	0	5.67	0	0	5.66	0	0	5.64
	10 ⁻²	0			0			0		
	10 ⁻³	0			0			0		
50	10 ⁰	<u>9</u>			<u>0</u>			<u>0</u>		
	10 ⁻¹	0	0.95	4.72	0	0	5.66	0	0	5.64
	10 ⁻²	0			0			0		
	10 ⁻³	0			0			0		
25	10 ⁰	>330			>330			>330		
	10 ⁻¹	>330	5.28	0.39	>330	5.09	0.57	>330	4.93	0.71
	10 ⁻²	>330			>330			>330		
	10 ⁻³	<u>189</u>			<u>124</u>			<u>86</u>		

underlined = used for further calculation
 RF = reduction factor

Table 6

Hygienic handrub according to DIN EN 1500
Reference – hand disinfection – Test results

Product: Propan-2-ol vol. 60 % (R)
 Application: rub-in 3 ml/30 s, repeat once
 Test period: 29 to 30 September 2020
 Test organism: *E. coli* K 12 NCTC 10538
 Number in contamination fluid (N): 2.7×10^8 CFU/ml to 2.8×10^8 CFU/ml

Test persons		Colony forming unit cfu per plate of dilution 10^x					
No.	Hand left or right	Prevalues			Postvalues		
		10^{-3}	10^{-4}	10^{-5}	10^0	10^{-1}	10^{-2}
1	l	<u>154*</u>	<u>29*</u>	0	<u>0</u>	0	0
	r	>330	46	1	0	0	0
2	l	<u>272*</u>	<u>26*</u>	3	<u>36</u>	3	0
	r	>330	69	5	4	0	0
3	l	<u>138*</u>	<u>14*</u>	1	<u>0</u>	0	0
	r	61	9	2	0	0	0
4	l	>330	49	9	>330	48	3
	r	<u>113</u>	13	1	47	11	0
5	l	38	7	1	0	0	0
	r	48	3	0	5	1	0
6	l	>330	114	12	>330	<u>59</u>	6
	r	>330	<u>169*</u>	<u>23*</u>	21	1	0
7	l	<u>185*</u>	<u>20*</u>	2	<u>29</u>	3	0
	r	<u>152*</u>	<u>29*</u>	3	48	5	0
8	l	>330	<u>125*</u>	<u>17*</u>	<u>18</u>	1	0
	r	>330	<u>139*</u>	<u>20*</u>	22	2	0
9	l	<u>148</u>	9	3	1	0	0
	r	<u>106</u>	12	1	0	0	0
10	l	>330	146	12	21	4	0
	r	>330	<u>184</u>	12	>330	69	9
11	l	8	1	0	1	0	0
	r	11	1	0	5	0	0
12	l	>330	<u>35</u>	3	2	0	0
	r	>330	<u>30</u>	4	2	0	0
13	l	>330	<u>95</u>	9	<u>10</u>	0	0
	r	>330	<u>67</u>	10	13	0	0
14	l	>330	<u>72</u>	8	>330	<u>58</u>	7
	r	32	3	0	>330	<u>62</u>	7
15	l	<u>160*</u>	<u>18*</u>	1	<u>63</u>	6	0
	r	<u>135*</u>	<u>18*</u>	0	<u>129*</u>	<u>20*</u>	2
16	l	>330	<u>33</u>	5	1	0	0
	r	>330	<u>42</u>	6	4	0	0
17	l	<u>75*</u>	<u>15*</u>	0	1	0	0
	r	<u>172*</u>	<u>33*</u>	0	2	1	0
18	l	>330	<u>135*</u>	<u>15*</u>	0	0	0
	r	>330	<u>136*</u>	<u>16*</u>	13	1	0
19	l	>330	<u>77</u>	13	1	0	0
	r	>330	<u>101</u>	12	3	0	0
20	l	>330	<u>152*</u>	<u>22*</u>	<u>18</u>	0	0
	r	>330	<u>172</u>	12	4	0	0
21	l	>330	<u>104*</u>	<u>14*</u>	>330	<u>74</u>	11
	r	>330	59	5	>330	38	10
22	l	>330	<u>94</u>	6	>330	>330	<u>90</u>
	r	>330	<u>118*</u>	<u>15*</u>	>330	<u>168*</u>	<u>23*</u>

underlined = number for further calculations used
 * indicate adjacent dilutions used for computation

Table 7

Hygienic handrub according to DIN EN 1500
Test results

Product: Desiform
 Application: rub-in 3 or 4 ml/30 s
 Test period: 29 to 30 September 2020
 Test organism: *E. coli* K 12 NCTC 10538
 Number in contamination fluid (N): 2.7×10^8 CFU/ml to 2.8×10^8 CFU/ml

Test persons			Colony forming unit cfu per plate of dilution 10^x					
No.	Hand left or right	Application	Prevalues			Postvalues		
			10^{-3}	10^{-4}	10^{-5}	10^0	10^{-1}	10^{-2}
1	l	4 ml	<u>295*</u>	<u>26*</u>	3	<u>3</u>	0	0
	r		>330	53	8	1	0	0
2	l	4 ml	>330	<u>62</u>	10	<u>22</u>	2	0
	r		>330	70	7	<u>23</u>	2	0
3	l	3 ml	<u>111*</u>	<u>14*</u>	1	<u>19</u>	2	0
	r		<u>162*</u>	<u>21*</u>	2	0	0	0
4	l	4 ml	<u>134*</u>	<u>18*</u>	1	<u>84</u>	12	3
	r		75	7	0	5	0	0
5	l	4 ml	49	2	0	0	0	0
	r		46	9	1	0	0	0
6	l	4 ml	>330	<u>75</u>	12	ne	<u>19</u>	4
	r		>330	<u>166*</u>	<u>22*</u>	74	5	0
7	l	4 ml	<u>182*</u>	<u>19*</u>	2	<u>10</u>	1	0
	r		<u>195*</u>	<u>19*</u>	1	<u>27</u>	3	0
8	l	3 ml	<u>162*</u>	<u>22*</u>	1	<u>10</u>	1	0
	r		>330	38	4	8	0	0
9	l	4 ml	31	4	0	8	0	0
	r		141	6	0	1	0	0
10	l	4 ml	>330	<u>136*</u>	<u>21*</u>	<u>36</u>	5	0
	r		>330	<u>186*</u>	<u>27*</u>	>330	<u>37</u>	1
11	l	4 ml	25	0	0	1	0	0
	r		23	3	0	5	0	0
12	l	3 ml	>330	<u>84</u>	10	0	0	0
	r		>330	<u>80</u>	9	1	0	0
13	l	4 ml	>330	<u>135</u>	13	<u>29</u>	3	1
	r		>330	<u>116</u>	11	<u>36</u>	10	0
14	l	4 ml	>330	<u>73</u>	10	>330	<u>45</u>	4
	r		<u>233*</u>	<u>31*</u>	4	>330	<u>115</u>	13
15	l	4 ml	<u>129*</u>	<u>14*</u>	1	>330	<u>57</u>	3
	r		<u>202*</u>	<u>26*</u>	3	31	4	0
16	l	3 ml	>330	<u>41</u>	2	<u>130*</u>	<u>22*</u>	1
	r		>330	40	4	1	0	0
17	l	3 ml	<u>111*</u>	<u>17*</u>	3	0	0	0
	r		>330	36	3	4	0	0
18	l	4 ml	>330	<u>66</u>	4	11	1	0
	r		>330	<u>193*</u>	<u>20*</u>	<u>189*</u>	<u>22*</u>	1
19	l	4 ml	>330	112	10	0	0	0
	r		>330	<u>108*</u>	<u>15*</u>	11	0	0
20	l	4 ml	>330	<u>163*</u>	<u>21*</u>	0	0	0
	r		>330	<u>191*</u>	<u>28*</u>	1	0	0
21	l	4 ml	>330	<u>97</u>	11	>330	<u>112</u>	11
	r		>330	38	6	>330	64	13
22	l	4 ml	>330	>330	37	>330	>330	<u>137</u>
	r		>330	<u>211*</u>	<u>24*</u>	>330	>330	<u>80</u>

underlined = number for further calculations used

ne = not evaluable

* indicate adjacent dilutions used for computation

Table 8

Hygienic handrub according to DIN EN 1500

 Calculated lg-values (medium from left and right hand) and
 lg-reduction factors from the test results

Test persons	Sequence	Reference hand disinfection (RP) (Propan-2-ol. 60 %)			Hand disinfection with the product (PP)		
		lg pre values	lg post values	lg reduction	lg pre values	lg post values	lg reduction
1	RP→PP	5.44	0.00	5.44	5.59	0.24	5.35
2	PP→RP	5.64	1.08	4.56	5.82	1.35	4.47
3	RP→PP	4.96	0.00	4.96	5.14	0.64	4.50
4	PP→RP	5.37	2.18	3.19	5.01	1.31	3.70
5	RP→PP	4.63	0.35	4.28	4.68	0.00	4.68
6	PP→RP	6.15	2.05	4.10	6.05	2.07	3.98
7	RP→PP	5.24	1.57	3.67	5.28	1.22	4.06
8	PP→RP	6.14	1.30	4.84	5.40	0.95	4.45
9	RP→PP	5.10	0.00	5.10	4.82	0.45	4.37
10	PP→RP	6.21	2.08	4.13	6.22	2.06	4.16
11	RP→PP	---	---	---	---	---	---
12	PP→RP	5.51	0.30	5.21	5.91	0.00	5.91
13	RP→PP	5.90	1.06	4.84	6.10	1.51	4.59
14	PP→RP	5.18	2.78	2.40	5.62	2.86	2.76
15	RP→PP	5.18	1.97	3.21	5.22	2.12	3.10
16	PP→RP	5.57	0.30	5.27	5.61	1.07	4.54
17	RP→PP	5.09	0.15	4.94	5.31	0.30	5.01
18	PP→RP	6.14	0.56	5.58	6.05	1.66	4.39
19	RP→PP	5.95	0.24	5.71	6.05	0.52	5.53
20	PP→RP	6.22	0.93	5.29	6.26	0.00	6.26
21	RP→PP	5.90	2.72	3.18	5.78	2.93	2.85
22	PP→RP	6.03	3.60	2.43	6.45	4.02	2.43

RP → PP = sequence: first RP, than PP
 PP → RP = sequence: first PP, than RP

Table 8 (continuation)

Test persons	Sequence	Reference hand disinfection (RP) (Propan-2-ol. 60 %)			Hand disinfection with the product (PP)		
		lg pre values	lg post values	lg reduction	lg pre values	lg post values	lg reduction
X	complete	5.60	1.20	4.40	5.64	1.30	4.34
S		0.48	1.07	1.02	0.50	1.09	1.00
NN		21	21	21	21	21	21
X	RP → PP	5.34	0.81	4.53	5.40	0.99	4.40
S		0.45	0.98	0.90	0.48	0.94	0.87
NN		10	10	10	10	10	10
X	PP → RP	5.83	1.56	4.27	5.85	1.58	4.28
S		0.38	1.07	1.15	0.42	1.18	1.14
NN		11	11	11	11	11	11
RP → PP = sequence: first RP. than PP				X = Mean			
PP → RP = sequence: first PP. than RP				s = Standard deviation			
NN = Number of values							

Difference of mean Rs (RP → PP): $4.53 - 4.40 = 0.13$
 Difference of mean Rs (PP → RP): $4.27 - 4.28 = -0.01$
 Absolute difference of differences: $\text{abs} [(0.13) - (-0.01)] = 0.14$

Check of acceptance criteria

- Complete set of results from 21 volunteers available (hence, more than the minimum of 18);
- Mean of lg prevalues for RP = 5.60 and for PP = 5.64 (hence both greater than 5.00);
- Individual lg reductions less than 3.00 for RP = 2 (less than 3.00);
- For group with sequence RP → PP difference of lg R: $4.53 - 4.40 = 0.13$,
 For group with sequence PP → RP difference of log R: $4.27 - 4.28 = -0.01$,
 Absolute difference of mean differences: $\text{abs} [(0.13) - (-0.01)] = 0.14$ (hence = less than 2.00);
- The critical values (table next page) are observed;
 The results of table 6 and 7 were used for weighted means. All quotients of weighted mean counts between 5 and 15.

All acceptance criteria are fulfilled.

Table 8 (continuation)

Critical value

Test product: Desiform
 Test date: 29 September 2020
 Neutralizer: Polysorbate 80 30 g/l, Saponin 30 g/l, L-histidine 1 g/l, L-cysteine 1 g/l, demineralized water ad 1000 ml
 Test organism: *E. coli* K 12 NCTC 10538
 Incubation: 36 ± 1 °C, 48 h

	Dilution	V _{C1}	V _{C2}	Results	Limit	Limit value maintained	
						yes	no
Test suspension (N)	10 ⁻⁶ 10 ⁻⁷	212 24	186 34	N = 2.07 x 10 ⁸	1.5 x 10 ⁸ ≤ N ≤ 5.0 x 10 ⁸	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Validation suspension (N _V)	10 ⁻¹	70	52	N _V = 6.1 x 10 ²	3.0 x 10 ² ≤ N ≤ 1.6 x 10 ³	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Validation suspension (N _{V0})				N _{V0} = N _V /10 = 61	30 ≤ N _{V0} ≤ 160	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Validation suspension (N _{VB})	10 ⁻³	66	94	N _{VB} = 8.0 x 10 ⁴	3.0 x 10 ⁴ ≤ N ≤ 1.6 x 10 ⁵	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Control neutralization (B)		124	136	B = 130	B ≥ 0.0005 x N _{VB}	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Method validation (C)		78	88	C = 83	C ≥ 0.5 x N _{V0}	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Table 9

Hygienic handrub according to DIN EN 1500

Computation of individual differences of lg R of RP - PP

Test person No.	lg reduction immediate effect		
	R	P	Difference R-P
1	5.44	5.35	0.09
2	4.56	4.47	0.09
3	4.96	4.50	0.46
4	3.19	3.70	-0.51
5	4.28	4.68	-0.40
6	4.10	3.98	0.12
7	3.67	4.06	-0.39
8	4.84	4.45	0.39
9	5.10	4.37	0.73
10	4.13	4.16	-0.03
11	---	---	---
12	5.21	5.91	-0.70
13	4.84	4.59	0.25
14	2.40	2.76	-0.36
15	3.21	3.10	0.11
16	5.27	4.54	0.73
17	4.94	5.01	-0.07
18	5.58	4.39	1.19
19	5.71	5.53	0.18
20	5.29	6.26	-0.97
21	3.18	2.85	0.33
22	2.43	2.43	0.00

Table 10

Hygienic handrub according to DIN EN 1500

Sorting of individual differences and computation for Hodges-Lehmann 97.5 upper confidence limits

Sorted differences (downward)		Mean pairwise differences $(d_i + d_{ii})/2$																				
		1.19	0.73	0.73	0.46	0.39	0.33	0.25	0.18	0.12	0.11	0.09										
1	1.19	1.19 ¹																				
2	0.73	0.96 ²	0.73 ⁷																			
3	0.73	0.96 ³	0.73 ⁸	0.73 ⁹																		
4	0.46	0.83 ⁴	0.60 ¹⁷	0.60 ¹⁸	0.46 ²⁹																	
5	0.39	0.79 ⁵	0.56 ²¹	0.56 ²²	0.43 ³²	0.39 ⁴³																
6	0.33	0.76 ⁶	0.53 ²³	0.53 ²⁴	0.40 ⁴²	0.36 ⁴⁷	0.33 ⁵³															
7	0.25	0.72 ¹⁰	0.49 ²⁵	0.49 ²⁶	0.36 ⁴⁶	0.32 ⁵⁵	0.29 ⁵⁹	0.25														
8	0.18	0.69 ¹¹	0.46 ²⁷	0.46 ²⁸	0.32 ⁵⁴	0.29 ⁵⁸	0.26	0.22	0.18													
9	0.12	0.66 ¹²	0.43 ³⁰	0.43 ³¹	0.29 ⁵⁶	0.26	0.23	0.19	0.15	0.12												
10	0.11	0.65 ¹³	0.42 ³⁴	0.42 ³⁵	0.29 ⁵⁷	0.25	0.22	0.18	0.15	0.12	0.11											
11	0.09	0.64 ¹⁴	0.41 ³⁶	0.41 ³⁷	0.28⁶⁰	0.24	0.21	0.17	0.14	0.11	0.10	0.09										
12	0.09	0.64 ¹⁵	0.41 ³⁸	0.41 ³⁹	0.27	0.24	0.21	0.17	0.14	0.11	0.10	0.09										
13	0.00	0.60 ¹⁶	0.37 ⁴⁴	0.37 ⁴⁵	0.23	0.20	0.17	0.13	0.09													
14	-0.03	0.58 ¹⁹	0.35 ⁴⁸	0.35 ⁴⁹	0.22	0.18	0.15	0.11														
15	-0.07	0.56 ²⁰	0.33 ⁵¹	0.33 ⁵²	0.20	0.16	0.13	0.09														
16	-0.36	0.42 ³³	0.19	0.19																		
17	-0.39	0.40 ⁴⁰	0.17	0.17																		
18	-0.40	0.40 ⁴¹	0.17	0.17																		
19	-0.51	0.34 ⁵⁰	0.11	0.11																		
20	-0.70	0.25																				
21	-0.97	0.11																				

 The median is the 11th value: 0.09. The small exponents represent the ranks.

Test for non-inferiority

 The mean pairwise differences that do not exceed the median (here: 0.09) are computed. From table of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for $n=21$ and a one-sided 0.025 level of significance the critical value of 59 is found. Hence $c = 59 + 1 = 60$. The pairwise differences are sorted in descending order. **The 60rd value is 0.28.** Hence the Hodges-Lehmann upper one-sided 97.5 % confidence limit for the difference in $\lg R_s$ between RP and PP is 0.28, which is less than the agreed inferiority margin of 0.6. Therefore, the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP is noninferior to RP.

Product: **Desiform**

Note: The test results only relate to the test product under investigation. Partial reproduction of this report only with written consent of the iki - Institut für Krankenhaushygiene und Infektionskontrolle GmbH, Gießen.

PD Dr. med. F.-A. Pitten
Managing director

Dipl.-Ing. agr. M. Meckel
Laboratory manager