

HygCen GmbH • Postfach 11 01 35 • D-19001 Schwerin

Saebefabriken A/S  
Aarhusvej 5

DK- 4800 Nykøbing



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
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 **AKS** Akkreditierung: AKS-PL-21301  
Verzeichnis: www.aks-hannover.de  
Staatliche Akkreditierungsstelle Hannover

2011-12-14  
Prof. We/ku

**Händedes Gel**  
**prEN 12054 (July 2001)**  
**bactericidal activity – phase 2, step 1**  
**Hygienic hand rub**

## TEST REPORT

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 12874.1 prEN 12054 page 1 of 8

Test method:	prEN 12054 (July 2001) Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine (phase 2 / step 1)
Test period:	2011-11-30 to 2011-12-02
Neutralisation:	dilution neutralisation
Diluent:	water of standardised hardness
Test temperature:	20 °C ± 1 °C
Product test concentrations:	80% , 50%, 10% (v/v) end concentrations
Contact times:	30, 60 and 120 seconds
Stability and appearance of the mixture during the procedure:	clear
Counting procedure:	pour plate method
Incubation:	48 h - 36 °C ± 1 °C
Neutralizer or rinsing liquid:	3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine
Test strains:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Escherichia coli</i> NCTC 10538 <i>Pseudomonas aeruginosa</i> ATCC 15442

**Test results - prEN 12054**

**Test product:**

**Händedes Gel**

**Test strain:**

***Staphylococcus aureus* ATCC 6538**

**Validation:**

Test suspension for validation (Nv and Nv <sub>0</sub> )	Validation of the neutralisation end the experimental conditions		
	Control (A)	Control (B)	Control (C)
10 <sup>-1</sup> : 128 129 Nv <sub>0</sub> : 128.5 Nv: 1.28x10 <sup>3</sup>	30 seconds: Vc: 158 134 A: 146	30 seconds: Vc: 121 132 B: 126.5	30 seconds: Vc: 131 129 C: 130
	60 seconds: Vc: 120 120 A: 120	60 seconds: Vc: 121 132 B: 126.5	60 seconds: Vc: 101 109 C: 105
	120 seconds: Vc: 138 123 A: 130.5	120 seconds: Vc: 121 132 B: 126.5	120 seconds: Vc: 134 129 C: 131.5

**Test results:**

Bacterial test suspension (N and N <sub>0</sub> )	Concentration of the test product (v/v)		After contact time (seconds)		
			30	60	120
10 <sup>-6</sup> : 293 312 10 <sup>-7</sup> : 42 38 N: 4.0x10 <sup>8</sup> LgN: 8.60 LgNo: 7.60	80%	10 <sup>0</sup> :	0 0	0 0	0 0
10 <sup>-1</sup> :		0 0	0 0	0 0	
N <sub>a</sub> :		<150	<150	<150	
		LgN <sub>a</sub> :	<2.18	<2.18	<2.18
		LgR:	>5.42	>5.42	>5.42
	50%	10 <sup>-2</sup> :	0 0	0 0	0 0
		10 <sup>-3</sup> :	0 0	0 0	0 0
		N <sub>a</sub> :	<150	<150	<150
		LgN <sub>a</sub> :	<2.18	<2.18	<2.18
		LgR:	>5.42	>5.42	>5.42
	10%	10 <sup>-2</sup> :	76 91	0 0	0 0
		10 <sup>-3</sup> :	6 8	0 0	0 0
		N <sub>a</sub> :	835	<150	<150
		LgN <sub>a</sub> :	2.92	<2.18	<2.18
		LgR:	4.68	>5.42	>5.42

**Test results - prEN 12054**

**Test product:**

**Händedes Gel**

**Test strain:**

***Enterococcus hirae* ATCC 10541**

**Validation:**

Test suspension for validation (Nv and Nv <sub>0</sub> )	Validation of the neutralisation end the experimental conditions		
	Control (A)	Control (B)	Control (C)
10 <sup>-1</sup> : 69 77 Nv <sub>0</sub> : 73 Nv: 730	30 seconds: Vc: 87 74 A: 80.5	30 seconds: Vc: 90 97 B: 93.5	30 seconds: Vc: 76 79 C: 77.5
	60 seconds: Vc: 86 83 A: 84.5	60 seconds: Vc: 90 97 B: 93.5	60 seconds: Vc: 74 79 C: 76.5
	120 seconds: Vc: 71 79 A: 75	120 seconds: Vc: 90 97 B: 93.5	120 seconds: Vc: 84 72 C: 78

**Test results:**

Bacterial test suspension (N and N <sub>0</sub> )	Concentration of the test product (v/v)		After contact time (seconds)		
			30	60	120
10 <sup>-6</sup> : 223 223 10 <sup>-7</sup> : 28 29 N: 2.29x10 <sup>8</sup> LgN: 8.36 LgNo: 7.36	80%	10 <sup>0</sup> :	0 0	0 0	0 0
10 <sup>-1</sup> :		0 0	0 0	0 0	
N <sub>a</sub> :		<150	<150	<150	
		lgN <sub>a</sub> :	<2.18	<2.18	<2.18
		lgR:	>5.18	>5.18	>5.18
	50%	10 <sup>-2</sup> :	50 62	0 0	0 0
		10 <sup>-3</sup> :	2 2	0 0	0 0
		N <sub>a</sub> :	560	<150	<150
		lgN <sub>a</sub> :	2.75	<2.18	<2.18
		lgR:	4.61	>5.18	>5.18
	10%	10 <sup>-2</sup> :	>300 >300	>300 >300	>300 >300
		10 <sup>-3</sup> :	>300 >300	>300 >300	>300 >300
		N <sub>a</sub> :	>3.0x10 <sup>4</sup>	>3.0x10 <sup>4</sup>	>3.0x10 <sup>4</sup>
		lgN <sub>a</sub> :	>4.48	>4.48	>4.48
		lgR:	<2.88	<2.88	<2.88

**Test results - prEN 12054**

**Test product:**

**Händedes Gel**

**Test strain:**

***Escherichia coli* NCTC 10538**

**Validation:**

Test suspension for validation (Nv and Nv <sub>0</sub> )	Validation of the neutralisation end the experimental conditions		
	Control (A)	Control (B)	Control (C)
10 <sup>-1</sup> : 81 88 Nv <sub>0</sub> : 84.5 Nv: 845	30 seconds: Vc: 87 87 A: 87	30 seconds: Vc: 84 89 B: 86.5	30 seconds: Vc: 77 88 C: 82.5
	60 seconds: Vc: 90 73 A: 81.5	60 seconds: Vc: 84 89 B: 86.5	60 seconds: Vc: 67 86 C: 76.5
	120 seconds: Vc: 76 84 A: 80	120 seconds: Vc: 84 89 B: 86.5	120 seconds: Vc: 82 86 C: 84

**Test results:**

Bacterial test suspension (N and N <sub>0</sub> )	Concentration of the test product (v/v)		After contact time (seconds)		
			30	60	120
10 <sup>-6</sup> : 240 231 10 <sup>-7</sup> : 26 27 N: 2.38x10 <sup>8</sup> LgN: 8.38 LgNo: 7.38	80%	10 <sup>0</sup> :	0 0	0 0	0 0
10 <sup>-1</sup> :		0 0	0 0	0 0	
N <sub>a</sub> :		<150	<150	<150	
LgN <sub>a</sub> :	<2.18	<2.18	<2.18		
LgR:	>5.20	>5.20	>5.20		
	50%	10 <sup>-2</sup> :	0 0	0 0	0 0
10 <sup>-3</sup> :		0 0	0 0	0 0	
N <sub>a</sub> :		<150	<150	<150	
LgN <sub>a</sub> :	<2.18	<2.18	<2.18		
LgR:	>5.20	>5.20	>5.20		
	10%	10 <sup>-2</sup> :	>300 >300	>300 >300	>300 >300
10 <sup>-3</sup> :		>300 >300	>300 >300	>300 >300	
N <sub>a</sub> :		>3.0x10 <sup>4</sup>	>3.0x10 <sup>4</sup>	>3.0x10 <sup>4</sup>	
LgN <sub>a</sub> :	>4.48	>4.48	>4.48		
LgR:	<2.90	<2.90	<2.90		

**Test results - prEN 12054**

**Test product:**

**Händedes Gel**

**Test strain:**

***Pseudomonas aeruginosa* ATCC 15442**

**Validation:**

Test suspension for validation (Nv and Nv <sub>0</sub> )	Validation of the neutralisation end the experimental conditions		
	Control (A)	Control (B)	Control (C)
10 <sup>-1</sup> : 121 131 Nv <sub>0</sub> : 126 Nv: 1.25x10 <sup>3</sup>	30 seconds: Vc: 99 101 A: 100	30 seconds: Vc: 87 88 B: 87.5	30 seconds: Vc: 91 98 C: 94.5
	60 seconds: Vc: 101 90 A: 95.5	60 seconds: Vc: 87 88 B: 87.5	60 seconds: Vc: 97 96 C: 96.5
	120 seconds: Vc: 101 100 A: 100.5	120 seconds: Vc: 87 88 B: 87.5	120 seconds: Vc: 96 86 C: 91

**Test results:**

Bacterial test suspension (N and N <sub>0</sub> )	Concentration of the test product (v/v)		After contact time (seconds)		
			30	60	120
10 <sup>-6</sup> : >300 >300 10 <sup>-7</sup> : 36 41 N: 3.85x10 <sup>8</sup> LgN: 8.58 LgNo: 7.58	80%	10 <sup>0</sup> : 10 <sup>-1</sup> : N <sub>a</sub> : lgN <sub>a</sub> : lgR:	0 0 0 0 <150 <2.18 >5.40	0 0 0 0 <150 <2.18 >5.40	0 0 0 0 <150 <2.18 >5.40
		10 <sup>-2</sup> : 10 <sup>-3</sup> : N <sub>a</sub> : lgN <sub>a</sub> : lgR:	0 0 0 0 <150 <2.18 >5.40	0 0 0 0 <150 <2.18 >5.40	0 0 0 0 <150 <2.18 >5.40
		10 <sup>-2</sup> : 10 <sup>-3</sup> : N <sub>a</sub> : lgN <sub>a</sub> : lgR:	>300 >300 >300 >300 >3.0x10 <sup>4</sup> >4.48 <3.10	>300 >300 >300 >300 >3.0x10 <sup>4</sup> >4.48 <3.10	>300 >300 >300 >300 >3.0x10 <sup>4</sup> >4.48 <3.10

**Verification and Legend of page 3 – 6:**

**Verification:**

N	is between $1.5$ and $5.0 \times 10^8$ cfu/ml ( $8.17 \leq \lg N \leq 8.70$ )
$N_0$	is between $1.5$ and $5.0 \times 10^7$ cfu/ml ( $7.17 \leq \lg N \leq 7.70$ )
$N_{V_0}$	is between $45$ and $300$ cfu/ml ( $4.5 \times 10^1$ und $3.0 \times 10^2$ )
$N_V$	is between $4.5 \times 10^2$ and $3.0 \times 10^3$
A.B.C	is equal or greater than $0.5 \times N_{V_0}$ is greater than $0.5 \times B$
nd	is not done

**Legend:**

N	is mean number of cfu/ml of the test suspension
$N_V$	is the mean number of cfu/ml of the bacterial test suspension for validation
R	is the reduction of viability
$N_A$	is the mean number of cfu/ml in the test mixture
A	is the mean number of cfu/ml of the test with water of standardised hardness
B	is the mean number of cfu/ml of the control of the toxicity of the neutralisation or filtration
C	is the mean number of cfu/ml in the control of the neutralisation of the dilution neutralisation method or membrane filtration

**Conclusion:**

According to prEN 12054 (Juli 2001), the product Händedes Gel shows a bactericidal activity at 20 °C in 30 seconds for the referenced test strains *S. aureus*, *E. hirae*, *Escherichia coli* and *Pseudomonas aeruginosa* when diluted at 80% and 50% (v/v) in water of standardised hardness.

**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.

Prof. Dr. med. H.-P. Werner  
Manager of scientific-technical affairs

Kathrin Naujox  
Department manager