

B. Braun Medical AG
CoE Infection Control
Seesatz 17

Re-writing of the original-expertise
Helix ultra, dated 26.03.2008

CH – 6204 Sempach

2014-11-18

Stabimed ultra
Disinfection of instruments
Bactericidal and yeasticidal (C. albicans) activity
Dirty conditions

EXPERTISE

After testing the disinfectant **Stabimed ultra** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes“
(Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report 2008-03-26
(SN 7527):

Results of the in vitro-tests

The quantitative suspension tests were carried out **under dirty conditions**.

Stabimed ultra resulted in sufficient reductions (5 lg. units of S. aureus, E. hirae and P. aeruginosa as well as 4 lg. units of C. albicans) **under dirty conditions**

in 0.5 % within 2, 5, 10 and 15 minutes.

Results under practical conditions

The efficacy of the disinfectant **Stabimed ultra** was tested in these test series also **under dirty conditions**.

Under these conditions the test product showed

in 0.25 % within 2, 5, 10 and 15 minutes

a sufficient efficacy against *W. aureus*, *E. hirae*, *P. aeruginosa* and *C. albicans*.

Application recommendation for Stabimed ultra for disinfection of instruments

According to the results obtained, **Stabimed ultra** complies with the

„Requirements Specification for the Admission of Chemical Disinfection Processes”
of the Disinfectant commission of the VAH.

under dirty conditions against *S. aureus*, *E. hirae*, *P. aeruginosa* and *C. albicans*

in 0.5 % within 2, 5, 10 and 15 minutes.



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CH – 6204 Sempach



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

2008-03-26

Rezeptur Nr. 02/01/22-01 - Instrumentendesinfektion
Bakterizide und fungizide Wirksamkeit
Hohe Belastung

Rezeptur Nr. 02/01/22-01 – Disinfection of instruments
bactericidal and fungicidal activity
Dirty conditions

PRÜFBERICHT / TESTREPORT

Labor-Nr. / Identification of the test
laboratory:

SN 7527

Prüfprodukt / Test product:

Rezeptur Nr. 02/01/22-01

Chargen-Bez. / Batch number:

0705BH0013

Herstelldatum / Production date:

May 2007

Hersteller / Manufacturer:

Du Pont

Auftragsdatum / Date of order:

2008-01-17

Materialeingang / Date of delivery:

2008-01-18

Wirkstoff(e) laut Herstellerangabe /
Active ingredient(s):

0.16 % Peracetic acid in situ (diluted at 10 g/l in water)

Aussehen / Appearance:

weißes Pulver / white powder

Geruch / Odour:

aromatisch / aromatic

pH-Werte / pH-values:

5.0%	in WSH ¹⁾ :	7.38
2.0%	in WSH:	7.85
1.0%	in WSH:	8.04
0.5%	in WSH:	8.03

Neutralisationsmittel / Neutralizer:

3,0 % Tween 80 + 0,3 % Lezithin + 0,1 % Histidin + 0,5 %
Natrium- Thiosulfat / 3.0 % polysorbate 80 + 0.3 % lezithine +
0.1 % histidine + 0.5 % sodium thiosulphate

Prüfzeitraum / Period of analysis:

2008-01-25 – 2008-03-21

Methodik / Method:

„Standardmethoden der DGHM zur Prüfung und Bewertung
chemischer Desinfektionsverfahren“ (Stand: 01.09.2001) /
„Standard methods of the DGHM²⁾ for Testing Chemical
Disinfection Procedures“ (2001-09-01)

¹⁾ water of standardised hardness

²⁾ German society for hygiene and microbiology

Bakteriostatische und fungistatische Wirkung sowie geeigneter Neutralisationsmittel
/ Bacteriostatic and Fungistatic Effectiveness as well as of Adequate Neutralising

Agents

(„Guideline I/2.1)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Raumtemperatur / Room temperature: 22.5 °C
Relative Feuchte / relative humidity: 41 %
Inkubation / Incubation: 48 h at 36°C (C. albicans 30 °C) ± 1°C

KBE der Ausgangskeimsuspensionen / Cfu of the test suspensions (lg/ml)

<i>Staphylococcus aureus</i>	ATCC 6538	8,24
<i>Enterococcus hirae</i>	ATCC 10541	8,40
<i>Escherichia coli</i>	NCTC 10538	8,20
<i>Proteus mirabilis</i>	ATCC 14153	8,10
<i>Pseudomonas aeruginosa</i>	ATCC 15442	8,80
<i>Candida albicans</i>	ATCC 10231	8,59

Neutralisation / Neutralizer	Endkonzentrationen (%) von Rezeptur Nr. 02/01/22-01 End concentrations (%) of Rezeptur Nr. 02/01/22-01									
Testkeime / Test strains	4,0	2,0	1,0	0,5	0,25	0,0125	0,0625	0,03125	0,0156	0,0078
Ohne Neutralisationsmittelzusätze / Without Neutralizer										
<i>S. aureus</i>	-	-	-	-	-	-	+	+	+	+
<i>E. hirae</i>	-	-	-	-	-	+	+	+	+	+
<i>E. coli</i>	-	-	-	-	+	+	+	+	+	+
<i>P. mirabilis</i>	-	-	-	-	-	+	+	+	+	+
<i>P. aeruginosa</i>	-	-	-	-	-	+	+	+	+	+
<i>C. albicans</i>	-	-	-	-	-	+	+	+	+	+
3,0% Tween 80 + 0,3% Lezithin + 0,1% Cystein (TLC) 3.0% polysorbate 80 + 0.3% lecithine + 0.1% cysteine (TLC)										
<i>S. aureus</i>	-	-	-	-	-	+	+	+	+	+
<i>E. hirae</i>	-	-	-	-	-	+	+	+	+	+
<i>E. coli</i>	-	-	-	-	-	+	+	+	+	+
<i>P. mirabilis</i>	-	-	-	-	+	+	+	+	+	+
<i>P. aeruginosa</i>	-	-	-	-	-	+	+	+	+	+
<i>C. albicans</i>	-	-	-	-	-	+	+	+	+	+
3,0% Tween 80 + 3,0% Saponin + 0,1% Histidin + 0,1% Cystein (TSHC) 3.0% polysorbate 80 + 3.0% saponine + 0.1% histidine + 0.1% cysteine (TSHC)										
<i>S. aureus</i>	-	-	-	-	-	-	-	+	+	+
<i>E. hirae</i>	-	-	-	-	-	-	+	+	+	+
<i>E. coli</i>	-	-	-	-	-	+	+	+	+	+
<i>P. mirabilis</i>	-	-	-	-	-	+	+	+	+	+
<i>P. aeruginosa</i>	-	-	-	-	-	+	+	+	+	+
<i>C. albicans</i>	-	-	-	-	+	+	+	+	+	+
3,0% Tween 80 + 0,3% Lezithin + 0,1% Histidin + 0,5% Na-Thiosulfat (TLH-Thio) 3.0% polysorbate 80 + 0.3% lecithine + 0.1% histidine + 0.5% sodium-thiosulphate (TLH-Thio)										
<i>S. aureus</i>	-	-	-	-	+	+	+	+	+	+
<i>E. hirae</i>	-	-	+	+	+	+	+	+	+	+
<i>E. coli</i>	-	-	+	+	+	+	+	+	+	+
<i>P. mirabilis</i>	-	-	-	+	+	+	+	+	+	+
<i>P. aeruginosa</i>	-	-	+	+	+	+	+	+	+	+
<i>C. albicans</i>	-	-	-	+	+	+	+	+	+	+

+ = Trübung infolge Keimvermehrung / growth of test-organism

- = fehlende Trübung / no growth of test-organism

Neutralisationskombination in den weiteren Versuchen / Neutralizer for further tests:

3,0% Tween 80 + 0,3% Lezithin + 0,1% Histidin + 0,5% Na-Thiosulfat
3.0% polysorbate 80 + 0.3% lecithine + 0.1% histidine + 0.5% sodium-thiosulphate

Bakterizide und fungizide Wirkung im qualitativen Suspensionsversuch /
Bactericidal and Fungicidal Effectiveness in the Qualitative Suspension Test

(Guideline I/2.2)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Versuchstemperatur/Test temperature: 20°C
Inkubation / Incubation: 48 h at 36 °C (C.albicans 30 °C) ± 1°C
Versuch ohne organische Belastung / Test without organic load

KBE der Ausgangskeimsuspensionen / Cfu of the test suspensions (lg/ml)

<i>Staphylococcus aureus</i>	ATCC 6538	9,24
<i>Enterococcus hirae</i>	ATCC 10541	9,40
<i>Escherichia coli</i>	NCTC 10538	9,20
<i>Proteus mirabilis</i>	ATCC 14153	9,10
<i>Pseudomonas aeruginosa</i>	ATCC 15442	9,80
<i>Candida albicans</i>	ATCC 10231	8,59

Testkeime Test strains	Konzentrationen (%) des Prüfproduktes/ Concentrations (%) of the test product	Einwirkzeiten / Exposure times (min)			
		5	15	30	60
S. aureus	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	+	-	-	-
	WSH-Kontrolle/Water control (WSH)				+
E. hirae	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	-	-	-	-
	WSH-Kontrolle/Water control (WSH)				+
E. coli	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	-	-	-	-
	WSH-Kontrolle/Water control (WSH)				+
P. mirabilis	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	-	-	-	-
	WSH-Kontrolle/Water control (WSH)				+
P. aeruginosa	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	-	-	-	-
	WSH-Kontrolle/Water control (WSH)				+
C. albicans	2,0	-	-	-	-
	1,0	-	-	-	-
	0,5	-	-	-	-
	0,25	-	-	-	-
	0,01	-	-	-	-
	WSH-Kontrolle/Water control (WSH)				+

+ = Trübung infolge Keimvermehrung / growth of test-organism - = fehlende Trübung / no growth of test-organism

Bakterizide Wirkung im quantitativen Suspensionstest /
Bactericidal Effectiveness in the Quantitative Suspension Test
 („Standardmethoden“ / “Standard methods“, 9.1; SOP 02003)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
 Versuchstemperatur / Test temperature: 20°C
 Inkubation / Incubation: 48 h at 36°C ± 1°C
 Methodik / Method: Verdünnungs-Neutralisations-Verfahren /
 Dilution neutralisation method
 Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe
 Belastung) /
 0.3% albumine + 0.3% sheep erythrocytes (dirty
 conditions)

Staphylococcus aureus ATCC 6538 Ausgangskeimsuspension /
 Cfu in the test suspension - lg/ml: 9.51

 Co 2 (Neutr.-co.) - lg/ml 10^{-1} 278 3.47
 10^{-2} 47
 Co 3 (Tox.-co.) - lg/ml 10^{-1} 273 3.45
 10^{-2} 35

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)									
		1		2		5		10		15	
		KBE/ Platte / cfu/ plate	Ig RF	KBE/ Platte / cfu/ plate	Ig RF	KBE/ Platte / cfu/ plate	Ig RF	KBE/ Platte / cfu/ plate	Ig RF	KBE/ Platte / cfu/ plate	Ig RF
1.5%	10^0	0	≥7.30	0	≥7.27	0	≥7.27	0	≥7.20	0	≥7.05
	10^{-1}	0		0		0		0		0	
	10^{-2}	0		0		0		0		0	
	10^{-3}	0		0		0		0		0	
1.0%	10^0	0	≥7.30	0	≥7.27	0	≥7.27	0	≥7.20	0	≥7.05
	10^{-1}	0		0		0		0		0	
	10^{-2}	0		0		0		0		0	
	10^{-3}	0		0		0		0		0	
0.5%	10^0	0	≥7.30	0	≥7.27	0	≥7.27	0	≥7.20	0	≥7.05
	10^{-1}	0		0		0		0		0	
	10^{-2}	0		0		0		0		0	
	10^{-3}	0		0		0		0		0	
0.1%	10^0	n		0	≥7.27	0	≥7.27	0	≥7.20	0	≥7.05
	10^{-1}	n		1		0		0		0	
	10^{-2}	248		0		0		0		0	
	10^{-3}	29	2.90	0		0		0		0	
Co1 (lg) WSH	10^{-4}	n		n		n		n		n	
	10^{-5}	200	7.30	188	7.27	188	7.27	159	7.20	113	7.05

Legende / Legend:

KBE = Koloniebildende Einheiten
 RF = Reduktionsfaktor
 n = nicht zählbar
 nd = nicht durchgeführt
 (E) = Eigenhemmung
 WSH = Wasser standardisierter Härte

cfu = colony forming units
 RF = reduction factor
 n = not countable
 nd = not done
 (E) = inhibition
 WSH = water of standardised hardness

Bakterizide Wirkung im quantitativen Suspensionstest /
Bactericidal Effectiveness in the Quantitative Suspension Test
 („Standardmethoden“ / „Standard methods“, 9.1; SOP 02003)

Prüfprodukt / *Test product*: Rezeptur Nr. 02/01/22-01
 Versuchstemperatur / *Test temperature*: 20°C
 Inkubation / *Incubation*: 48 h at 36°C ± 1°C
 Methodik / *Method*: Verdünnungs-Neutralisations-Verfahren /
Dilution neutralisation method
 Belastung / *Loading*: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe
 Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Enterococcus hirae **ATCC 10541** Ausgangskeimsuspension /
Cfu in the test suspension - lg/ml: 9.60

Co 2 (Neutr.-co.) - lg/ml	10 ⁻¹	192	3.33
	10 ⁻²	45	
Co 3 (Tox.-co.) - lg/ml	10 ⁻¹	291	3.49
	10 ⁻²	51	

Konzentra- tion (%) des Prüf- produktes (m/v) <i>Concentra- tion (%) of the test product (m/v)</i>	Verdün- nung / <i>Dilution</i>	Einwirkzeit in Minuten / <i>Exposure time (min)</i>									
		1		2		5		10		15	
		KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF
1.5%	10 ⁰	0	≥7.40	0	≥7.36	0	≥7.32	0	≥7.31	0	≥7.15
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
1.0%	10 ⁰	0	≥7.40	0	≥7.36	0	≥7.32	0	≥7.31	0	≥7.15
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.5%	10 ⁰	0	≥7.40	0	≥7.36	0	≥7.32	0	≥7.31	0	≥7.15
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.1%	10 ⁰	n		0	≥7.36	0	≥7.32	0	≥7.31	0	≥7.15
	10 ⁻¹	55	4.66	0		0		0		0	
	10 ⁻²	4		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
Co1 (lg) WSH	10 ⁻⁴	n		n		n		n		n	
	10 ⁻⁵	254	7.40	228	7.36	211	7.32	205	7.31	142	7.15

Legende / Legend:

KBE = Koloniebildende Einheiten
 RF = Reduktionsfaktor
 n = nicht zählbar
 nd = nicht durchgeführt
 (E) = Eigenhemmung
 WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Bakterizide Wirkung im quantitativen Suspensionstest /
Bactericidal Effectiveness in the Quantitative Suspension Test
(„Standardmethoden“ / “Standard methods“, 9.1; SOP 02003)

Prüfprodukt / *Test product*: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / *Test temperature*: 20°C
Inkubation / *Incubation*: 48 h at 36°C ± 1°C
Methodik / *Method*: Verdünnungs-Neutralisations-Verfahren /
Dilution neutralisation method
Belastung / *Loading*: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe
Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty
conditions)

***Pseudomonas aeruginosa* ATCC 15442** Ausgangskeimsuspension /
Cfu in the test suspension - lg/ml: 9.51

Co 2 (Neutr.-co.) - lg/ml	10 ⁻¹	178	3.28
	10 ⁻²	30	
Co 3 (Tox.-co.) - lg/ml	10 ⁻¹	206	3.32
	10 ⁻²	26	

Konzentra- tion (%) des Prüf- produktes (m/v) <i>Concentra- tion (%) of the test product (m/v)</i>	Verdün- nung / <i>Dilution</i>	Einwirkzeit in Minuten / <i>Exposure time (min)</i>									
		1		2		5		10		15	
		KBE/ Platte / <i>cfu/ plate</i>	Ig RF	KBE/ Platte / <i>cfu/ plate</i>	Ig RF	KBE/ Platte / <i>cfu/ plate</i>	Ig RF	KBE/ Platte / <i>cfu/ plate</i>	Ig RF	KBE/ Platte / <i>cfu/ plate</i>	Ig RF
1.5%	10 ⁰	0	≥7.20	0	≥7.13	0	≥7.12	0	≥7.12	0	≥7.09
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
1.0%	10 ⁰	0	≥7.20	0	≥7.13	0	≥7.12	0	≥7.12	0	≥7.09
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.5%	10 ⁰	0	≥7.20	0	≥7.13	0	≥7.12	0	≥7.12	0	≥7.09
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.1%	10 ⁰	49	5.51	1	7.13	0	≥7.12	0	≥7.12	0	≥7.09
	10 ⁻¹	6		0		0		0		0	
	10 ⁻²	2		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
Co1 (Ig) WSH	10 ⁻⁴	n		n		n		n		n	
	10 ⁻⁵	159	7.20	134	7.13	132	7.12	133	7.12	124	7.09

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(*E*) = inhibition
WSH = water of standardised hardness

Fungizide Wirkung im quantitativen Suspensionstest /
Fungicidal Effectiveness in the Quantitative Suspension Test
(„Standardmethoden“ / “Standard methods“, 9.1; SOP 02003)

Prüfprodukt / *Test product*: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / *Test temperature*: 20°C
Inkubation / *Incubation*: 48 h at 30°C ± 1°C
Methodik / *Method*: Verdünnungs-Neutralisations-Verfahren /
Dilution neutralisation method
Belastung / *Loading*: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Candida albicans **ATCC 10231** Ausgangskeimsuspension /
Cfu in the test suspension - lg/ml: 8.40

Co 2 (Neutr.-co.) - lg/ml	10 ⁻¹	189	3.29
	10 ⁻²	25	
Co 3 (Tox.-co.) - lg/ml	10 ⁻¹	148	3.18
	10 ⁻²	17	

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / <i>Exposure time (min)</i>									
		1		2		5		10		15	
		KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF	KBE/ Platte / cfu/ plate	lg RF
1.5%	10 ⁰	0	≥6.28	0	≥6.26	0	≥6.22	0	≥6.18	0	≥6.15
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
1.0%	10 ⁰	0	≥6.28	0	≥6.26	0	≥6.22	0	≥6.18	0	≥6.15
	10 ⁻¹	0		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.5%	10 ⁰	26	4.87	0	≥6.26	0	≥6.22	0	≥6.18	0	≥6.15
	10 ⁻¹	1		0		0		0		0	
	10 ⁻²	0		0		0		0		0	
	10 ⁻³	0		0		0		0		0	
0.1%	10 ⁰	n		n		n		n		n	
	10 ⁻¹	n		n		n		n		n	
	10 ⁻²	n		n		n		n		n	
	10 ⁻³	n	<0.28	n	<0.26	n	<0.22	259	0.77	271	0.72
Co1 (lg) WSH	10 ⁻³	n		n		n		n		n	
	10 ⁻⁴	191	6.28	183	6.26	167	6.22	150	6.18	142	6.15

Legende / *Legend*:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / “Standard methods”, 15; SOP 02054)

(1. Durchgang / 1. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / Test temperature: 20°C
Inkubation / Incubation: 48h at 36°C ± 1°C
Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Staphylococcus aureus ATCC 6538

Ausgangskeimsuspension /
Cfu in the test suspension – lg/ml: 9.29

Co 2 (Neutr.-co.) – lg/ml 10^{-1} 263 3.43
 10^{-2} 33

Co 3 (Tox.-co.) – lg/ml 10^{-1} 225 3.38
 10^{-2} 40

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
1.0%	0,5ml dir	0	≥6.39	0	≥6.49	0	≥6.36	0	≥6.42
	10^{-1}	0		0		0		0	
	10^{-2}	0		0		0		0	
	10^{-3}	0		0		0		0	
0.5%	0,5ml dir	0	≥6.39	0	≥6.49	0	≥6.36	0	≥6.42
	10^{-1}	0		0		0		0	
	10^{-2}	0		0		0		0	
	10^{-3}	0		0		0		0	
0.25%	0,5ml dir	0	≥6.39	0	≥6.49	0	≥6.36	0	≥6.42
	10^{-1}	0		0		0		0	
	10^{-2}	0		0		0		0	
	10^{-3}	0		0		0		0	
0.1%	0,5ml dir	0	≥6.39	0	≥6.49	0	≥6.36	0	≥6.42
	10^{-1}	0		0		0		0	
	10^{-2}	0		0		0		0	
	10^{-3}	0		0		0		0	
Co1 (lg) WSH	10^{-4}	n		n		n		n	
	10^{-5}	49	6.69	62	6.79	46	6.66	52	6.72

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgeretest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / „Standard methods“, 15; SOP 02054)

(2. Durchgang / 2. Test run)

Prüfprodukt / *Test product*: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / *Test temperature*: 20°C
Inkubation / *Incubation*: 48h at 36°C ± 1°C
Belastung / *Loading*: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (*dirty conditions*)

Staphylococcus aureus ATCC 6538 Ausgangskeimsuspension / 9.39
Cfu in the test suspension – lg/ml:

Co 2 (Neutr.-co.) – lg/ml 10^{-1} 240 3.39
 10^{-2} 28
Co 3 (Tox.-co.) - lg/ml 10^{-1} 243 3.40
 10^{-2} 32

Konzentra- tion (%) des Prüf- produktes (m/v) <i>Concentra- tion (%) of the test product (m/v)</i>	Verdün- nung / <i>Dilution</i>	Einwirkzeit in Minuten / <i>Exposure time (min)</i>							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
0.5%	0,5ml dir	0 0	≥6.40	0 0	≥6.33	0 0	≥6.26	0 0	≥6.28
	10^{-1}	0 0		0 0		0 0		0 0	
	10^{-2}	0 0		0 0		0 0		0 0	
	10^{-3}	0 0		0 0		0 0		0 0	
0.25%	0,5ml dir	0 0	≥6.40	0 0	≥6.33	0 0	≥6.26	0 0	≥6.28
	10^{-1}	0 0		0 0		0 0		0 0	
	10^{-2}	0 0		0 0		0 0		0 0	
	10^{-3}	0 0		0 0		0 0		0 0	
0.1%	0,5ml dir	14 27	5.25/4.97	0 0	≥6.33	0 0	≥6.26	0 0	≥6.28
	10^{-1}	3 6		0 0		0 0		0 0	
	10^{-2}	0 0		0 0		0 0		0 0	
	10^{-3}	0 0		0 0		0 0		0 0	
Co1 (lg) WSH	10^{-4}	n		n		n		n	
	10^{-5}	50	6.70	43	6.63	36	6.56	38	6.58

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / “Standard methods”, 15; SOP 02054)

(1. Durchgang / 1. Test run)

Prüfprodukt / *Test product*: Rezeptur Nr. 02/01/22-01
 Versuchstemperatur / *Test temperature*: 20°C
 Inkubation / *Incubation*: 48h at 36°C ± 1°C
 Belastung / *Loading*: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
 0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Enterococcus hirae	ATCC 10541	Ausgangskeimsuspension / <i>Cfu in the test suspension – lg/ml:</i>	9.17
		Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹ 148 10 ⁻² 16 3.17
		Co 3 (Tox.-co.) - lg/ml	10 ⁻¹ 94 10 ⁻² 17 3.00

Konzentra- tion (%) des Prüf- produktes (m/v) <i>Concentra- tion (%) of the test product (m/v)</i>	Verdün- nung / <i>Dilution</i>	Einwirkzeit in Minuten / <i>Exposure time (min)</i>							
		2		5		10		15	
		KBE/ Platte <i>cfu/ plate</i>	Ig RF	KBE/ Platte <i>cfu/ plate</i>	Ig RF	KBE/ Platte <i>cfu/ plate</i>	Ig RF	KBE/ Platte <i>cfu/ plate</i>	Ig RF
1.0%	0,5ml dir	0	≥6.53	0	≥6.48	0	≥6.47	0	≥6.18
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.5%	0,5ml dir	0	≥6.53	0	≥6.48	0	≥6.47	0	≥6.18
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.25%	0,5ml dir	0	≥6.53	0	≥6.48	0	≥6.47	0	≥6.18
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.1%	0,5ml dir	n		n		n		n	
	10 ⁻¹	n		n		n		n	
	10 ⁻²	n		n		n		n	
	10 ⁻³	n	<0.83	n	<0.78	n	<0.77	n	<0.78
Co1 (Ig) WSH	10 ⁻⁴	n		288		282		285	
	10 ⁻⁵	68	6.83	60	6.78	59	6.77	49	6.48

Legende / Legend:

KBE = Koloniebildende Einheiten
 RF = Reduktionsfaktor
 n = nicht zählbar
 nd = nicht durchgeführt
 (E) = Eigenhemmung
 WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / “Standard methods”, 15; SOP 02054)

(2. Durchgang / 2. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
 Versuchstemperatur / Test temperature: 20°C
 Inkubation / Incubation: 48h at 36°C ± 1°C
 Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
 0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Enterococcus hirae	ATCC 10541	Ausgangskeimsuspension / Cfu in the test suspension – lg/ml:				9.24
		Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹	119		3.09
			10 ⁻²	15		
		Co 3 (Tox.-co.) - lg/ml	10 ⁻¹	106		3.04
			10 ⁻²	15		

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
0.5%	0,5ml dir	0 0	≥6.28	0 0	≥6.13	0 0	≥6.10	0 0	≥5.90
	10 ⁻¹	0 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
0.25%	0,5ml dir	0 0	≥6.28	0 0	≥6.13	0 0	≥6.10	0 0	≥5.90
	10 ⁻¹	0 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
Co1 (lg) WSH	10 ⁻⁴	n		260		250		152	
	10 ⁻⁵	38	6.58	35	6.43	24	6.40	22	6.20

Legende / Legend:

KBE = Koloniebildende Einheiten
 RF = Reduktionsfaktor
 n = nicht zählbar
 nd = nicht durchgeführt
 (E) = Eigenhemmung
 WSH = Wasser standardisierter Härte

cfu = colony forming units
 RF = reduction factor
 n = not countable
 nd = not done
 (E) = inhibition
 WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / “Standard methods”, 15; SOP 02054)

(1. Durchgang / 1. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / Test temperature: 20°C
Inkubation / Incubation: 48h at 36°C ± 1°C
Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Pseudomonas aeruginosa ATCC 15442 Ausgangskeimsuspension /
Cfu in the test suspension – lg/ml: 9.17

Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹	85	2.93
	10 ⁻²	6	
Co 3 (Tox.-co.) - lg/ml	10 ⁻¹	85	2.93
	10 ⁻²	14	

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
1.0%	0,5ml dir	0	≥5.47	0	≥5.40	0	≥5.36	0	≥5.00
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.5%	0,5ml dir	0	≥5.47	0	≥5.40	0	≥5.36	0	≥5.00
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.25%	0,5ml dir	0	≥5.47	0	≥5.40	0	≥5.36	0	≥5.00
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.1%	0,5ml dir	n		0	≥5.40	0	≥5.36	0	≥5.00
	10 ⁻¹	104	2.75	0		0		0	
	10 ⁻²	12		0		0		0	
	10 ⁻³	1		0		0		0	
Co1 (lg) WSH	10 ⁻³	n		n		n		201	
	10 ⁻⁴	59	5.77	50	5.70	46	5.66	19	5.30

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / „Standard methods“, 15; SOP 02054)

(2. Durchgang / 2. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / Test temperature: 20°C
Inkubation / Incubation: 48h at 36°C ± 1°C
Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

<i>Pseudomonas aeruginosa</i> ATCC 15442	Ausgangskeimsuspension / Cfu in the test suspension – lg/ml:		9.40
	Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹ 138 10 ⁻² 24	3.17
	Co 3 (Tox.-co.) - lg/ml	10 ⁻¹ 168 10 ⁻² 31	3.26

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
0.5%	0,5ml dir	0 0	≥5.47	0 0	≥5.36	0 0	≥5.26	0 0	≥5.23
	10 ⁻¹	0 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
0.25%	0,5ml dir	0 0	≥5.47	0 0	≥5.36	0 0	≥5.26	0 0	≥5.23
	10 ⁻¹	0 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
Co1 (lg) WSH	10 ⁻³	n		n		n		n	
	10 ⁻⁴	59	5.97	46	5.66	36	5.56	34	5.53

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / „Standard methods“, 15; SOP 02054)

(1. Durchgang / 1. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
 Versuchstemperatur / Test temperature: 20°C
 Inkubation / Incubation: 48h at 30°C ± 1°C
 Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
 0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Candida albicans	ATCC 10231	Ausgangskeimsuspension /		
		Cfu in the test suspension – lg/ml:		8.18
	Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹	125	3.11
		10 ⁻²	18	
	Co 3 (Tox.-co.) – lg/ml	10 ⁻¹	128	3.12
		10 ⁻²	17	

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
1.0%	0,5ml dir	0	≥5.11	0	≥5.17	0	≥5.20	0	≥5.17
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.5%	0,5ml dir	0	≥5.11	0	≥5.17	0	≥5.20	0	≥5.17
	10 ⁻¹	0		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.25%	0,5ml dir	22	4.07	0	≥5.17	0	≥5.20	0	≥5.17
	10 ⁻¹	2		0		0		0	
	10 ⁻²	0		0		0		0	
	10 ⁻³	0		0		0		0	
0.1%	0,5ml dir	n		n		n		n	
	10 ⁻¹	n		n		141		91	
	10 ⁻²	77	1.52	77	1.58	20	2.33	22	2.13
	10 ⁻³	9		12		2		1	
Co1 (lg) WSH	10 ⁻³	237		273		297		279	
	10 ⁻⁴	47	5.41	52	5.47	49	5.50	49	5.47

Legende / Legend:

KBE = Koloniebildende Einheiten
 RF = Reduktionsfaktor
 n = nicht zählbar
 nd = nicht durchgeführt
 (E) = Eigenhemmung
 WSH = Wasser standardisierter Härte

cfu = colony forming units
 RF = reduction factor
 n = not countable
 nd = not done
 (E) = inhibition
 WSH = water of standardised hardness

Instrumentendesinfektion – praxisnaher quantitativer Keimträgertest /
Chemical Disinfection of Instruments – Carrier test under conditions of practice
(phase 2, step 2)

(„Standardmethoden“ / “Standard methods”, 15; SOP 02054)

(2. Durchgang / 2. Test run)

Prüfprodukt / Test product: Rezeptur Nr. 02/01/22-01
Versuchstemperatur / Test temperature: 20°C
Inkubation / Incubation: 72h at 30°C ± 1°C
Belastung / Loading: mit 0,3% Albumin + 0,3% Schaf-Erythrozyten (hohe Belastung) /
0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)

Candida albicans	ATCC 10231	Ausgangskeimsuspension / Cfu in the test suspension – lg/ml:	8.30
		Co 2 (Neutr.-co.) – lg/ml	10 ⁻¹ 138 10 ⁻² 24 3.17
		Co 3 (Tox.-co.) – lg/ml	10 ⁻¹ 168 10 ⁻² 31 3.26

Konzentra- tion (%) des Prüf- produktes (m/v) Concentra- tion (%) of the test product (m/v)	Verdün- nung / Dilution	Einwirkzeit in Minuten / Exposure time (min)							
		2		5		10		15	
		KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF	KBE/ Platte cfu/ plate	lg RF
0.5%	0,5ml dir	0 0	≥5.27	0 0	≥5.03	0 0	≥5.02	0 0	≥4.94
	10 ⁻¹	0 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
0.25%	0,5ml dir	7 3	4.42/4.79	0 0	≥5.03	0 0	≥5.02	0 0	≥4.94
	10 ⁻¹	2 0		0 0		0 0		0 0	
	10 ⁻²	0 0		0 0		0 0		0 0	
	10 ⁻³	0 0		0 0		0 0		0 0	
Co1 (lg) WSH	10 ⁻³	n		199		200		172	
	10 ⁻⁴	37	5.57	36	5.33	30	5.32	20	5.24

Legende / Legend:

KBE = Koloniebildende Einheiten
RF = Reduktionsfaktor
n = nicht zählbar
nd = nicht durchgeführt
(E) = Eigenhemmung
WSH = Wasser standardisierter Härte

cfu = colony forming units
RF = reduction factor
n = not countable
nd = not done
(E) = inhibition
WSH = water of standardised hardness

Prüfbericht / Test report 2008-03-26 - Rezeptur Nr. 02/01/22-01 – SN 7527

Bakterizide und fungizide Wirksamkeit

Hohe Belastung

bactericidal and fungicidal activity

Dirty conditions

Archivierung: **Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv des Auftragnehmers aufbewahrt.**


Hinweis: Die Prüfergebnisse beziehen sich ausschließlich auf den genannten Prüfgegenstand. Auszugsweise Wiedergabe dieses Berichtes nur mit schriftlicher Genehmigung der HygCen GmbH.

Archiving: ***The raw data with respect to this test and a copy of the report will be stored in the archive of HygCen.***

Information: *The test results exclusively refer to the samples described above. Account of extracts of this test report is only possible by written approval from HygCen.*



Prof. Dr. med. H.-P. Werner
Wissenschaftlich-technischer Leiter



Kathrin Naujox
Bereichsleiterin