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Our Sign
Dr.Pi/mo

Date
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Expert Opinion

Of the product: **Sekusept aktiv**

To be intended for: **Chemical disinfection of instruments used in
the medical area**

The testing of the product was carried out according to

standard methods of the German Society of Hygiene and Microbiology (DGHM) for the efficacy testing of chemical disinfectants dating Sep. 2001 ("Standardmethoden der DGHM zur Prüfung chemischer Desinfektionsverfahren").

DIN EN 13727 (2004), Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 1)

DIN EN 13624 (2004), Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 1)

DIN EN 14561 (2006), Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)

DIN EN 14562 (2006), Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2).

The test report dates 2008-08-22. The investigated disinfectant sample was denominated "MD 11554-62-1". According to the manufacturer the composition of "MD 11554-62-1" is identical with the product "Sekusept aktiv".

The obtained data was evaluated using the requirements for the acceptance of chemical disinfectants in the list of disinfectants published by the DGHM ("Desinfektionsmittel-Liste der DGHM") dating Feb. 2002.

Assessment of the bactericidal and yeasticidal efficacy in the quantitative suspension test (Tab. 1 – 12d in the test report dating 2008-08-22)

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **low organic burden** (0.03% albumin):

Test organism	Effective concentration (%) at time of action			
	5 min	15 min	30 min	60 min
<i>S. aureus</i>	0.03125	0.015625	0.015625	0.015625
<i>E. hirae</i>	0.03125	0.015625	0.015625	0.015625
<i>P. aeruginosa</i>	0.03125	0.015625	0.015625	0.015625
<i>C. albicans</i>	0.25	0.125	0.125	0.0625
<i>E. coli K12</i>	0.015625	0.015625	0.015625	0.015625
<i>P. mirabilis</i>	0.015625	0.015625	0.015625	0.015625
All test organisms	0.25	0.125	0.125	0.0625

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% albumin and 0.3% sheep erythrocytes):

Test organism	Effective concentration (%) at time of action			
	5 min	15 min	30 min	60 min
<i>S. aureus</i>	0.03125	0.03125	0.03125	0.03125
<i>E. hirae</i>	0.0625	0.0625	0.03125	0.03125
<i>P. aeruginosa</i>	0.03125	0.03125	0.03125	0.03125
<i>C. albicans</i>	0.25	0.125	0.125	0.125
<i>E. coli K12</i>	0.015625	0.015625	0.015625	0.015625
<i>P. mirabilis</i>	0.015625	0.015625	0.015625	0.015625
All test organisms	0.25	0.125	0.125	0.125

Quantitative germ carrier tests (Tab. 13 - 28 in the test report dating 2008-08-22)

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **low organic burden** (0.03% albumin):

Test organism	Effective concentration (%) at time of action			
	5 min		60 min	
	1. SR	2. SR	1. SR	2. SR
<i>S. aureus</i>	0.1	1.0	0.05	0.5
<i>E. hirae</i>	1.0	1.0	0.5	0.5
<i>P. aeruginosa</i>	0.1	1.0	0.05	0.5
<i>C. albicans</i>	0.1	1.0	0.5	0.5
All test organisms	1.0	1.0	0.5	0.5

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% albumin and 0.3% sheep erythrocytes):

Test organism	Effective concentration (%) at time of action			
	5 min		60 min	
	1. SR	2. SR	1. SR	2. SR
<i>S. aureus</i>	0.1	1.0	0.5	0.5
<i>E. hirae</i>	1.0	1.0	0.5	0.5
<i>P. aeruginosa</i>	0.1	1.0	0.5	0.5
<i>C. albicans</i>	0.1	1.0	0.5	0.5
All test organisms	1.0	1.0	0.5	0.5

Recommendation for the application as chemical disinfection of instruments in the medical area

The product meets the requirements of **DIN EN 13727 (2004)** in the following relations of time of action and concentration:

Low organic burden:

5 min	time of action and	0.03125	% concentration,
15 min	time of action and	0.015625	% concentration,
30 min	time of action and	0.015625	% concentration and
60 min	time of action and	0.015625	% concentration.

High organic burden:

5 min	time of action and	0.0625	% concentration,
15 min	time of action and	0.0625	% concentration,
30 min	time of action and	0.03125	% concentration and
60 min	time of action and	0.3125	% concentration.

The product meets the requirements of **DIN EN 13624 (2004)** in the following relations of time of action and concentration:

Low organic burden:

<i>C. albicans</i>	5 min	time of action and	0.25	% concentration,
	15 min	time of action and	0.125	% concentration,
	30 min	time of action and	0.125	% concentration and
	60 min	time of action and	0.0625	% concentration.

High organic burden:

<i>C. albicans</i>	5 min	time of action and	0.25	% concentration,
	15 min	time of action and	0.125	% concentration,
	30 min	time of action and	0.125	% concentration and
	60 min	time of action and	0.125	% concentration.

The product meets the requirements of **DIN EN 14561 (2006)** in the following relations of time of action and concentration:

Low organic burden:

5 min	time of action and	1.0	% concentration and
60 min	time of action and	0.5	% concentration.

High organic burden:

5 min	time of action and	1.0	% concentration and
60 min	time of action and	0.5	% concentration.

The product meets the requirements of **DIN EN 14562 (2006)** in the following relations of time of action and concentration:

Low organic burden:

<i>C. albicans</i>	5 min time of action and 0.1 % concentration and
	60 min time of action and 0.5 % concentration.

High organic burden:

<i>C. albicans</i>	5 min time of action and 0.1 % concentration and
	60 min time of action and 0.5 % concentration.

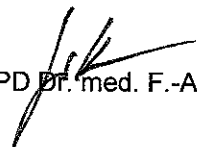
The product meets the requirements of the "**Anforderungskatalog** für die Aufnahme von chemischen Desinfektionsverfahren in die Desinfektionsmittel-Liste der **DGHM (2001)**" in the following relations of time of action and concentration:

Low organic burden:

5 min	time of action and 2.0 %	concentration and
60 min	time of action and 1.0 %	concentration.

High organic burden:

5 min	time of action and 2.0 %	concentration and
60 min	time of action and 1.0 %	concentration.


PD Dr. med. F.-A. Pitten