

Ecolab Deutschland GmbH  
Reisholzer Wertstraße 38 - 42

**40589 Düsseldorf**

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Our Sign  
Dr.Pi/mo

Date  
4<sup>th</sup> September 2008

## **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 14348 (2005), Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2, step 1)

DIN EN 14563 (2005), Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test methods and requirements (phase 2, step 2)

The test report dates 2008-09-03. The investigated disinfectant sample was denominated "MD 11554-62-1". According to the manufactures 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 tuberculocidal efficacy in the quantitative suspension test (Tab. 1 – 2 in the test report dating 2008-09-03)**

Sufficient reductions 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>M. terrae</i>	1.0	0.5	0.5	0.25

Sufficient reductions 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>M. terrae</i>	1.0	0.5	0.5	0.25

**Quantitative germ carrier tests (Tab. 3 - 6 in the test report dating 2008-09-03)**

Sufficient reductions 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>M. terrae</i>	1.0	1.0	0.25	0.5

Sufficient reductions 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>M. terrae</i>	1.0	1.0	0.25	0.5

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

The product meets the requirements of **DIN EN 14348 (2005)** in the following relations of time of action and concentration:

#### Low and high organic burden:

5 min time of action and 1.0 % concentration.  
15 min time of action and 0.5 % concentration,  
30 min time of action and 0.5 % concentration and  
60 min time of action and 0.25 % concentration.

The product meets the requirements of **DIN EN 14563 (2005)** 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 0.25 % concentration.

#### High organic burden:

5 min time of action and 1.0 % concentration and  
60 min time of action and 0.25 % 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