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Schülke & Mayr GmbH
Robert-Koch-Straße 2
DE - 22851 Norderstedt

Hamburg, 10 December 2015

Additional expert opinion

Suitability of **rotasept** for disinfection of instruments according to DGHM Catalogue of Requirements - Bactericidal Activity in the quantitative suspension test according to DIN EN 13727:2013

The disinfectant **rotasept** was tested and evaluated according to DIN EN 13727:2013 "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)".

According to the test report no. L15/0192.1 dated 10/12/2015 of Dr. Brill + Partner GmbH the ready for use preparation showed bactericidal activity according to DIN EN 13727:2013 (phase 2, step 1) under dirty conditions within 1 minute exposure time.

The obtained results correspond to the results of the quantitative suspension test according to DIN EN 13727:2003 summarised in test report L09/074.9 dated 09/01/2012 of Dr. Brill + Partner GmbH. Therefore, technical changes in the current version of the standard, a neutralization time of 10 ± 1 seconds for short exposure times, do not have an influence on the evaluation of the bactericidal efficacy of **rotasept**.

Thus, the recommendation for VAH listing of **rotasept** dated 09/01/2012 can be assigned to current requirements of the DIN EN 13727:2013.

Dr. Fl

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Our Sign: Dr.Pi/bh

Date: 2009-10-05

Expert Opinion

Of the product: **Rotasept**

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

The testing of the product was carried out according to the standard methods of the German Society of Hygiene and Microbiology (DGHM) for the efficacy testing of chemical disinfectants dating Sep. 2001.

The relating test report dates 2009-10-05.

The obtained data was evaluated using the list of requirements of the DGHM (dating 2002-02-04).

I. Suspension tests

Determination of the bacteriostatic and yeastistatic efficacy and appropriate neutralizers (table 1 of test report dating 2009-10-05):

Test organism	Concentration of the test product (%)	
	without neutralizer	with optimal neutralizer
S. aureus	10	25
E. hirae	25	50
P. aeruginosa	25	25
E. coli	10	25
P. mirabilis	25	25
C. albicans	10	25

The most effective neutralizer was a combination of

3.0 polysorbate 80, 3.0 % saponine, 0.1 % L-histidine.

This combination was used as neutralizer in all subsequent trials.

Determination of the bacteriocidal and yeasticidal efficacy in the qualitative suspension test *(table 2 of test report dating 2009-10-05)*

Test organism	Effective concentration (%) at time of action		
	1 min	5 min	15 min
S. aureus	80	80	80
E. hirae	80	80	80
P. aeruginosa	25	25	25
E. coli	10	10	10
P. mirabilis	25	10	10
C. albicans	50	50	25

Determination of the bactericidal and yeasticidal efficacy in the quantitative suspension test *(Table 3 – 6 of test report dating 2009-10-05)*

Sufficient reductions of the test organisms were yielded using the following relations of time of action and concentration of the test product under **high organic burden** (0.3% albumine and 0.3% sheep erythrocytes):

Test organism	Effective concentration (%) at time of action		
	1 min	5 min	15 min
S. aureus	80	50	50
E. hirae	80	50	50
P. aeruginosa	25	25	10
C. albicans	50	25	25
All test organisms	**80**	**50**	**50**

Determination of the mycobactericidal and tuberculocidal efficacy in the quantitative suspension test *(Table 7 – 8 of test report dating 2009-10-05)*

Sufficient reductions of the test organisms were yielded using the following relations of time of action and concentration of the test product under **high organic burden** (0.3% albumine and 0.3% sheep erythrocytes):

Test organism	Effective concentration (%) at time of action	
	15 min	30 min
M. avium	80	80
M. terrae	80	80

II. Germ carrier tests

Practical test: Instrument disinfection *(Table 9 - 20 of test report dating 2009-10-05)*

The required efficacy for the test organisms *S. aureus, E. hirae, P. aeruginosa and C. albicans* was achieved **under high organic burden** (0.3% albumine and 0.3% sheep erythrocytes) using the following relations of time of action (2nd series):

Test organism	Effective concentration (%) at time of action			
	5 min		15 min	
	1st series	2nd series	1st series	2nd series
S. aureus	100	80	100	nd
E. hirae	100	80	100	nd
P. aeruginosa	100	80	100	nd
C. albicans	100	80	100	nd
Alle Testkeime	**100**	**80**	**100**	**nd**

The required efficacy for the test organisms *M. avium and M. terrae* was achieved **under high organic burden** (0.3% albumine and 0.3% sheep erythrocytes) using the following relations of time of action:

Test organism	Effective concentration (%) at time of action					
	5 min		15 min		30 min	
	1st series	2nd series	1st series	2nd series	1st series	2nd series
M. avium	100	n.d.	100	80	100	n.d.
M. terrae	100	n.d.	100	80	100	n.d.

nd = not done

III. Recommendation for the application as chemical disinfectant for instruments in the medical area

The product meets the standards for the bactericidal and yeasticidal efficacy given by the list of requirements of the DGHM (dating 2002-02-04)

under high organic burden

at 5 min time of action and 100 % concentration

and the standards for tuberculocidal and mycobactericidal efficacy

under high organic burden

at 15 min time of action and 80 % concentration.

PD Dr. Mayr ltten

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Hamburg, 30 November 2015

Expert opinion

Mycobactericidal Activity of **rotasept** in the quantitative suspension test according to DIN EN 14348:2005 (Phase 2, Step 1)

The disinfectant **rotasept** was tested and evaluated according to DIN EN 14348:2005 "Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Mycobactericidal Activity of Chemical Disinfectants Used in the Medical Area Including Instrument Disinfectants – Test Methods and Requirements (Phase 2, Step 1)".

According to the test report no. L09/074.13 dated 30/11/2015 of Dr. Brill + Partner GmbH the preparation showed mycobactericidal activity under dirty conditions.

rotasept complies with the requirements of DIN EN 14348:2005 (phase 2, step 1) with the following concentration-time relationship:

Mycobactericidal:	**dirty conditions**	**100 %**	**15 minutes**

Dr. Florian H. H. Brill

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Poliovirus efficacy of rotasept in a quantitative suspension test at 20°C according to the EN 14476:2007-02 under clean and dirty conditions

EXPERT OPINION

This expert opinion is based on the test report S10ML995-1Po dated 10.03.2010.

The virus-inactivating properties of the instrument disinfectant rotasept of Schülke & Mayr GmbH against poliovirus type 1 were investigated by a quantitative suspension test according to the EN 14476:2007-02 under clean and dirty conditions.

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

rotasept was examined undiluted at 20°C. 1, 5 and 60 minutes were chosen as exposure times. After an exposure time of one minute virus reduction exceeded 4 $\log_{10}$-steps in all assays. Therefore, a virucidal activity was measured as follows:

clean conditions	**undiluted**	**1 min**
dirty conditions	**undiluted**	**1 min**

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Bremen, 17/09/2014

Expert opinion

Activity of rotasept according to the Guideline of DVV/RKI dating 01.08.2008 against vaccinia virus

This expert opinion is based on the test report S14ML1749V dating 17.09.2014.

The virus-inactivating properties of the instrument disinfectant rotasept of Schülke & Mayr GmbH against vaccinia virus strain Elstree were investigated by a quantitative suspension test according to the Guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and of the Robert Koch-Institute (RKI).

According to this Guideline, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation $\geq$ 99.99 %).

rotasept was examined undiluted at 20 °C. 5, 15, 30, 60 and 120 minutes were chosen as exposure times. After 5 minutes the virus titre was decreased by ≥ 4 $\log_{10}$ steps. Therefore, a virucidal activity against vaccinia virus was measured as follows:

undiluted 5 minutes

Dr. Jc

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Schülke & Mayr GmbH
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Bremen, 17/09/2014

Expert opinion

Activity of rotasept against BVDV according to the Guideline of DVV/RKI dating 01.08.2008

This expert opinion is based on the test report S14ML1749B dating 17.09.2014.

The virus-inactivating properties of the instrument disinfectant rotasept of Schülke & Mayr GmbH against BVDV strain NADL were investigated by a quantitative suspension test according to the Guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and of the Robert Koch-Institute (RKI).

According to this Guideline, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation $\geq$ 99.99 %).

rotasept was examined undiluted at 20 °C. 5 and 15 minutes were chosen as exposure times. The virus titre was decreased by ≥ 4 $\log_{10}$ steps after five minutes. Therefore, a virucidal activity against BVDV was measured as follows:

undiluted	**5 minutes**

Dr. Jochen Steinmann

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Bremen, 17/09/2014

Expert opinion

Activity of rotasept according to the Guideline of DVV/RKI dating 01.08.2008 against adenovirus type 5

This expert opinion is based on the test report S14ML1749A dating 17.09.2014.

The virus-inactivating properties of the instrument disinfectant rotasept of Schülke & Mayr GmbH against adenovirus type 5 were investigated by a quantitative suspension test according to the Guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and of the Robert Koch-Institute (RKI).

According to this Guideline, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation $\geq$ 99.99 %).

rotasept was examined undiluted at 20 °C. 5, 15, 30, 60 and 120 minutes were chosen as exposure times. After 5 minutes the virus titre was decreased by ≥ 4 $\log_{10}$ steps. Therefore, a virucidal activity against adenovirus type 5 was measured as follows:

undiluted 5 minutes

Dr. Jochen Steinmann

LABOR ENDERS

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Akkreditiert nach DIN EN ISO/IEC 15189, 17025 und CAP

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CAP ACCREDITED

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Ihre Nachricht	Ihre Zeichen	Unsere Zeichen	Datum
			2014-11-25

The efficacy of **rotasept** against Murine norovirus Strain S99 was tested in a suspension test according to the European standard EN 14476:2013. The effectiveness of the disinfectant was evaluated under dirty conditions (3.0 g/l BSA + 3.0 ml/l erythrocytes) as interfering substance. **Rotasept** was tested as a 25.0%, 50.0%, and 80.0% solution. The exposure times were 1, 3, 5, and 10 minutes.

In conclusion, the ready-to-use product rotasept is effective against Murine norovirus strain S99 at room temperature under dirty conditions (3.0 g/l BSA + 3.0 ml/l erythrocytes) as interfering substance with an application time of 1 minute.

PD Dr. med. Martin Enders

PD Dr. rer. nat. Maren Eggers

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Hamburg, 10 December 2015

Additional expert opinion

Suitability of **rotasept** for disinfection of instruments according to DGHM Catalogue of Requirements - Yeasticidal Activity in the quantitative suspension test according to DIN EN 13624:2013

The disinfectant **rotasept** was tested and evaluated according to DIN EN 13624:2013 „Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Fungicidal or Yeasticidal Activity of Chemical Disinfectants and Antiseptics for Instruments Used in the Medical Area – Test Method and Requirements (Phase 2, Step 1)".

According to the test report no. L15/0192.2 dated 10/12/2015 of Dr. Brill + Partner GmbH the ready for use preparation showed yeasticidal activity according to DIN EN 13624:2013 (phase 2, step 1) under dirty conditions within 1 minute exposure time.

The obtained results correspond to the results of the quantitative suspension test according to DIN EN 13624:2004 summarised in test report L09/074.9 dated 09/01/2012 of Dr. Brill + Partner GmbH. Therefore, technical changes in the current version of the standard, a neutralization time of 10 ± 1 seconds for short exposure times, do not have an influence on the evaluation of the yeasticidal efficacy of **rotasept**.

Thus, the recommendation for VAH listing of **rotasept** dated 09/01/2012 can be assigned to current requirements of the DIN EN 13624:2013.

Dr. Florian H. H. Brill