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# *Expert Opinion*

Complementary examination of

***DISIFIN<sup>®</sup> med***

On its effectiveness as a surface disinfectant  
for hospitalism prophylaxis in general practice

according to the new DGHM guidelines (state 09/2001)

of the company RMP chem.-techn.  
Spezialprodukte GmbH & Co. KG  
Hagenring 20,  
D-72119 Ammerbuch-Altingen

Examination number: KFSW/2005/1541

### 1. Aim of examination

The examination product **DISIFIN® med** has already been tested according to the „Richtlinien für die Prüfung und Bewertung chemischer Desinfektionsverfahren. 1. Teilabschnitt (Stand: 01.01.1981)“ and the „Prüfung und Bewertung chemischer Desinfektionsverfahren (Stand: 12.07.1991)“ of the Deutsche Gesellschaft für Hygiene und Mikrobiologie on its effectiveness as a surface disinfectant for hospitalism prophylaxis in general practice and has been included into the DGHM list.

A modification of the guidelines (state: 09/2001) required additional testing for effectiveness evaluation as a surface disinfectant. Aim of the examinations was to produce the retests that had been required according to the new guidelines.

### 2. Description of the test product:

Appearance: white tabs a 2.8 g  
Active substances: 2.5 g Chloramin T /tabs (manufacturer information)

#### Solutions in water

Smell: slight chlorous and citrus smell  
Appearance: light blue, cloudy, with residuum  
pH-Value: 2.0 % dilution\*: 7.5  
1.0 % dilution\*: 7.4  
0.5 % dilution\*: 7.2

\*concentration specifications in % g/v

For solution production the tabs were pulverised and dissolved in WSH.

Charge identifier: 25102005  
Date of production: 25.10.2005  
Durable until: 25.10.2009

Manufacturer/ distributor: RMP chem.- techn. Spezialprodukte GmbH & Co. KG  
D-72119 Ammerbuch

Date of assignment: 14.06.2006  
Sample entry: 11/2005  
Examination period: 11/2005 - 01/2006

### 3. Examination procedure

The tests were conducted according to the standard DGHM methods for the examination of chemical methods of disinfection (state: 1. September 2001).

Appropriate to the new listing modalities the method shall be listed as a surface disinfection method with mechanical effect (wiping disinfection) at low load. The bactericidal and fungicidal effectiveness shall be proved.

The comprehensiveness of the examinations has been defined according to the notification 3/2002 of the DGHM disinfectants commission.

#### 4. Examination results

##### 4.1 Determination of the bactericidal and fungicidal effectiveness in the quantitative suspension test at low load (0.03 % albumin)

The following test strains were used as test organisms:

- Enterococcus hirae (En. hirae) DSM 3320 = ATCC 10541
- Candida albicans (C. albicans) DSM 1386 = ATCC 10231

The results are shown in tables 1-3.

Applying an effecting time of 5 to 30 min, the specified germ reduction rates of at least 5 (at En. hirae) or 4 log-steps (at C. albicans), respectively, were reached at the following concentrations:

	5 min	15 min	30 min
- Enterococcus hirae	0.50 % g/v	0.10 % g/v	0.10 % g/v
- Candida albicans	> 0.50 % g/v	0.50 % g/v	0.50 % g/v



Quantitative suspension test with *Candida albicans*

Test temperature: 20°C

Protein load: 0.03 % Albumin

Inactivation agent: 3.0 % Tween 80, 0.3 % Lecithin, 0.1 % Histidin, 0.5 % Na-Thiosulfat

Table 2a: In the surface spatula technique determined number of germs/ plate (primary data)

Conc. g/v %	5 min				15 min				30 min			
	0/1ml	0/0.1ml	-1	-2	0/1ml	0/0.1ml	-1	-2	0/1ml	0/0.1ml	-1	-2
0.50	>300	>300	>300	>300	187*	<u>23*</u>	3	0	98	11	2	0
0.25	>300	>300	>300	<u>&gt;300</u>	>300	>300	>300	<u>&gt;300</u>	>300	>300	>300	>300
0.10	>300	>300	>300	<u>&gt;300</u>	>300	>300	>300	<u>&gt;300</u>	>300	>300	>300	<u>&gt;300</u>
Controls:												
		5 min			15 min			30 min				
Ko1 (WSH)	-3	174		-3	<u>227*</u>		-3	139*				
	-4	13		-4	<u>25*</u>		-4	21*				
Ko 2								0				<u>188*</u>
								-1				19*
Ko 3								0				<u>200*</u>
								-1				18*

Initial number of germs -5: 168\*-6: 19\*

For further analyses the underlined values were used

\* = weighted arithmetic mean calculated

Table 2b: In the surface spatula technique determined number of germs and reduction factors

Conc. g/v %	5 min			15 min			30 min		
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log
0.50	$>3.0 \times 10^5$	> 5.48	< 0.76	$1.91 \times 10^2$	2.28	<b>4.08</b>	$9.8 \times 10^1$	1.99	<b>4.17</b>
0.25	$>3.0 \times 10^5$	> 5.48	< 0.76	$>3.0 \times 10^5$	> 5.48	< 0.88	$>3.0 \times 10^5$	> 5.48	< 0.68
0.10	$>3.0 \times 10^5$	> 5.48	< 0.76	$>3.0 \times 10^5$	> 5.48	< 0.88	$>3.0 \times 10^5$	> 5.48	< 0.68
Controls:									
		5 min			15 min			30 min	
Ko 1 (WSH)	KBE/ml	$1.74 \times 10^6$		KBE/ml	$2.29 \times 10^6$		KBE/ml	$1.45 \times 10^6$	
	log KBE	6.24		log KBE	6.36		log KBE	6.16	
Ko 2							KBE/ml	$1.88 \times 10^3$	
							log KBE	3.27	
Ko 3							KBE/ml	$1.98 \times 10^3$	
							log KBE	3.30	

Initial number of germs KBE/ml:  $1.70 \times 10^6$ 

log KBE: 8.23

#### 4.2 Surface disinfection under practical conditions

The test was conducted according to the method for wiping disinfectants. For the examinations matt-glazed ceramic flagstones (50 x 50 mm) were used. Room temperatures lay between 20°C and 25°C, the relative humidity changed between 48 and 56 %. The tests were conducted with a low protein load (0.03 % Albumin).

The following test strains were used as test organisms:

- Staphylococcus aureus	(S. aureus)	DSM 799	= ATCC 6538
- Enterococcus hirae	(En. hirae)	DSM 3320	= ATCC 10541
- Pseudomonas aeruginosa	(P. aeruginosa)	DSM 939	= ATCC 15442
- Candida albicans	(C. albicans)	DSM 1386	= ATCC 10231

The results of the first orienting part of the investigation are shown in tables 4 to 8.

Applying an effecting time of 15 to 30 min, the specified germ reduction rates of at least 5 (at the bacteria strains) or 4 log-steps (at C. albicans), respectively, were reached at the following concentrations:

- Staphylococcus aureus	0.50 % g/v
- Enterococcus hirae	0.25 % g/v
- Pseudomonas aeruginosa	0.25 % g/v
- Candida albicans	0.50 % g/v

Thus, the former list entry (according to old guidelines) of 0.5 % g/v at 15 min effecting time could be confirmed.

The results of the confirmation tests are shown in tables 9 to 12.









Practical surface disinfection test with *C. albicans* - 2. orienting test

Tabelle 7a: In the surface spatula technique determined number of germs/ plate (primary data)

Conc. g/v %	5 min				15 min				30 min					
	0/1ml	0/0.1ml	-1	-2	0/1ml	0/0.1ml	-1	-2	0/1ml	0/0.1ml	-1	-2		
1.0	-	-	-	-	<u>0</u>	0	0	0	-	-	-	-		
0.5	-	-	-	-	<u>0</u>	0	0	0	-	-	-	-		
0.25	-	-	-	-	<u>54</u>	3	0	0	-	-	-	-		
Controls:														
	5 min					15 min					30 min			
Ko 1	-3	-			-3	> 300				-3	-			
(WSH)	-4	-			-4	<u>19</u>				-4	-			
Ko 2					0					0				
					-1					-1				
Ko 3					0					0				
					-1					-1				
Initial number of germs														
				-5:	> 300				-6:	<u>26</u>				

For further analyses the underlined values were used  
 \* = weighted arithmetic mean calculated

Tabelle 7b: In the surface spatula technique determined number of germs and reduction factors

Conc. g/v %	5 min			15 min			30 min				
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log		
1.0	-	-	-	0	0	6.72	-	-	-		
0.5	-	-	-	0	0	6.72	-	-	-		
0.25	-	-	-	54	1.73	4.79	-	-	-		
Controls:											
	5 min				15 min				30 min		
Ko 1	KBE/ml	-		KBE/ml	1.9 x 10 <sup>6</sup>			KBE/ml	-		
(WSH)	log KBE	-		log KBE	6.28			log KBE	-		
Ko 2				KBE/ml							
				log KBE							
Ko 3				KBE/ml							
				log KBE							
Initial number of germs											
				KBE/ml:	2.6 x 10 <sup>8</sup>				log KBE:		8.41

Practical surface disinfection test with *S. aureus*

Confirmation test at 15 min effecting time

Tabelle 8a: In the surface spatula technique determined number of germs/ plate (primary data)

Concentration in % g/v	Test surface 1				Test surface 2			
	0/0.5ml	0/0.5ml	0/0.1ml	-1	0/0.5ml	0/0.5ml	0/0.1ml	-1
0.5	<u>0</u>	<u>0</u>	0	0	<u>12</u>	0	0	0
WSH- control	-2	-3	-4	-5				
	> 300	> 300	33	-				
Initial number of germs	-5: > 300		-6: <u>43</u>					

For further analyses the underlined values were used  
 \* = weighted arithmetic mean calculated

Tabelle 8b: In the surface spatula technique determined number of germs and reduction factors

Concentration in % g/v	Test surface 1			Test surface 2		
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log
0.5	0	0	6.52	12	1.08	5.44
WSH- control	KBE/ml		log KBE			
	3.3 x 10 <sup>6</sup>		6.52			
Initial number of germs	KBE/ml:	4.3 x 10 <sup>8</sup>	(log KBE: 8.63)			

Practical surface disinfection test with *En. hirae*

Confirmation test at 15 min effecting time

Tabelle 9a: In the surface spatula technique determined number of germs/ plate (primary data)

Concentration in % g/v	Test surface 1				Test surface 2			
	0/0.5ml	0/0.5ml	0/0.1ml	-1	0/0.5ml	0/0.5ml	0/0.1ml	-1
0.5	<u>0</u>	<u>0</u>	0	0	<u>0</u>	<u>0</u>	0	1
WSH- control	-2	-3	-4	-5				
	>300	>300	20	-				
Initial number of germs	-5: > 300		-6: <u>26</u>					

For further analyses the underlined values were used

\* = weighted arithmetic mean calculated

Tabelle 9b: In the surface spatula technique determined number of germs and reduction factors

Concentration in % g/v	Test surface 1			Test surface 2		
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log
0.5	0	0	6.30	0	0	6.30
WSH- control	KBE/ml	log KBE				
	2.0 x 10 <sup>6</sup>	6.30				
Initial number of germs	KBE/ml: 2.6 x 10 <sup>8</sup>		(log KBE: 8.41)			

Practical surface disinfection test with *P. aeruginosa*

Confirmation test at 15 min effecting time

Tabelle 10a: In the surface spatula technique determined number of germs/ plate (primary data)

Concentration in % g/v	Test surface 1				Test surface 2			
	0/0.5ml	0/0.5ml	0/0.1ml	-1	0/0.5ml	0/0.5ml	0/0.1ml	-1
0.5	<u>0</u>	<u>0</u>	0	0	<u>0</u>	<u>0</u>	0	0
WSH- control	-2	-3	-4	-5				
	>300	> 300	<u>48</u>	-				
Initial number of germs	-5: > 300		-6: <u>53</u>					

For further analyses the underlined values were used

\* = weighted arithmetic mean calculated

Tabelle 10b: In the surface spatula technique determined number of germs and reduction factors

Concentration in % g/v	Test surface 1			Test surface 2		
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log
0.5	0	0	6.68	0	0	6.68
WSH- control	KBE/ml	log KBE				
	$4.8 \times 10^6$	6.68				
Initial number of germs	KBE/ml: $5.3 \times 10^8$	(log KBE: 8.72)				

Practical surface disinfection test with *C. albicans*

Confirmation test at 15 min effecting time

Tabelle 11a: In the surface spatula technique determined number of germs/ plate (primary data)

Concentration in % g/v	Test surface 1				Test surface 2			
	0/0.5ml	0/0.5ml	0/0.1ml	-1	0/0.5ml	0/0.5ml	0/0.1ml	-1
0.5	<u>0</u>	<u>0</u>	0	0	<u>12</u>	<u>13</u>	0	0
WSH- control	-2	-3	-4	-5				
	> 300	> 300	26	-				
Initial number of germs	-5: > 300		-6: <u>31</u>					

For further analyses the underlined values were used  
 \* = weighted arithmetic mean calculated

Tabelle 11b: In the surface spatula technique determined number of germs and reduction factors

Concentration in % g/v	Test surface 1			Test surface 2		
	KBE/ml	log KBE	RF log	KBE/ml	log KBE	RF log
0.5	0	0	6.41	25	1.40	5.01
WSH- control	KBE/ml		log KBE			
	2.6 x 10 <sup>6</sup>		6.41			
Initial number of germs	KBE/ml:	3.1 x 10 <sup>8</sup>	(log KBE: 8.49)			

## 5. Evaluation

The test product **DISIFIN® med** has already been examined and listed according to the „Richtlinien für die Prüfung und Bewertung chemischer Desinfektionsverfahren. 1. Teilschnitt (Stand: 01.01.1981)“ and the „Prüfung und Bewertung chemischer Desinfektionsverfahren (Stand: 12.07.1991)“ of the Deutsche Gesellschaft für Hygiene und Mikrobiologie on its effectiveness as a surface disinfectant for hospitalism prophylaxis in general practice (date of issue of certificate: 04.09.2002).

The former list entry for the category surface disinfection at 15 min effecting time was:  
0.5 % g/v.

Due to a modification of the guidelines (state: 09/2001) additional tests were necessary for evaluation of effectiveness as a surface disinfectant.

Aim of the examinations was to provide the retests required for evaluation according to the new guidelines.

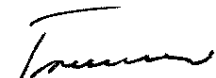
The tests were conducted corresponding to the standard DGHM methods for the evaluation of chemical disinfection techniques (state: 1. September 2001).

According to the new listing modalities the technique should be listed as a surface disinfection method with mechanical effect (wiping disinfection) at low load.

The comprehensiveness of the examinations conformed with the stipulations of the DGHM disinfectants commission (notification 3/2002).

The examination showed that **DISIFIN® med** with the previous list entry of **0.5 % g/v at 15 min effecting time** also meets the requirements of the new DGHM test guidelines (state: 09/2001) to a surface disinfectant for wiping disinfection against bacteria and *Candida albicans*.

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