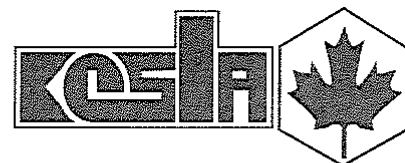


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# KESLA FORSCHUNG & SERVICE

GMBH + Co. KG

HYGIENELABOR WEIMAR



KESLA HYGIENELABOR · ERNST-THÄLMANN-STR. 89 · 99423 WEIMAR

AKKREDITIERUNG NACH DIN EN ISO/IEC 17025 IM  
BEREICH BIOLOGIE FÜR DIE MIKROBIOLOGIE DER ARZNEI-  
MITTEL, LEBENSMITTEL UND BEDARFSGEGENSTÄNDE SOWIE  
VERFAHREN DER TRINKWASSERVERORDNUNG 2001.

Accreditation pursuant to DIN EN ISO/IEC  
17025 in the area of **Biology** for Microbiology of  
drugs, food and utensils as well as procedures of  
the Drinking Water Ordinance 2001.  
Officially licenced testing authority pursuant to  
§19 section 2 Drinking Water Ordinance

## Test- Report

Test of

**DISIFIN ® med & clean**  
(Ch.: 080207)

pursuant to the new *VAH* guidelines  
[Association for applied hygiene]

Test number: KFSW/2007/1940

KOMMANDIT-  
GESELLSCHAFT  
D-06803 GREPPIN  
AMTSGERICHT STENDAL,  
HRA 11847

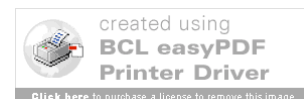
HAFTENDE  
GESELLSCHAFTERIN:  
KESLA  
VERWALTUNGS GMBH  
D-06803 GREPPIN  
AMTSGERICHT STENDAL,  
HRB 4182

GESCHÄFTSFÜHRER  
DR. GERD SCHREINER  
BIRGIT SCHREINER  
K.-CHEM. (FINANZEN)

BANK:  
DEUTSCHE BANK AG  
BLZ: 860 700 00  
KTO.: 611 24 03  
KREISSPARKASSE  
BITTERFELD  
BLZ: 800 537 22  
KTO.: 311 608 98

Client: RMP GmbH & Co. KG  
Hagenring 20  
D-72119 Ammerbuch- Altingen

UST-IDNR.:  
DE197589734  
FA-BITTEFELD



### 1. Objective of the test

The product **DISIFIN med & clean** to be tested was already tested for its efficiency as a surface disinfectant for hospitalism prophylaxis and in general practice pursuant to the "Guidelines for the testing and evaluation of chemical disinfection procedures, first partial section (version: 01 January 1981)" and the "testing and evaluation of chemical disinfection procedures (version: 12 July 1991)" of the German Society for Hygiene and Microbiology and adopted into the DGHM/VAH list. Due to the amendment of the guidelines (version: 09/2001), additional tests were required for the efficiency evaluation as a surface disinfectant.

The objective of the tests was to carry out the additional tests required for the expert's opinion according to the new guidelines.

### 2. Description of the test product

Appearance:	white powder
Odour:	green apple, light chloramine smell
Active agents:	26.05 g chloramine T in 100 g test product (manufacturer's information)
Charge designation:	080207
Date of manufacture:	02/2007
Manufacturer/Distributor:	<i>RMP chem.-techn. Spezialprodukte GmbH &amp; Co. KG</i> D-72119 Ammerbuch-Altingen
Sample receipt:	02/2007
Test period:	03/2007 to 04/2007
Characterisation of the solution for use in water (1.0 % g/v): foams while dissolving	
Appearance:	light turquoise, opaque, with bottom settlements
Odour:	green apple, light chloramine smell
ph value:	6.4

### 3. Test procedure

The tests were carried out according to the standard DGHM/VAH methods for the testing of the chemical disinfection procedures (version: 1 September 2001).

According to the new listing terms, the procedure shall be listed as a surface disinfection procedure with mechanical action (wipe disinfection) with low contamination. The bactericidal and fungicidal efficiency shall be proven.

The scope of the tests was stipulated according to the notification 3/2002 of the disinfectant commission of the DGHM.

#### 4. Test results

##### 4.1 Determination of the bactericidal and fungicidal efficiency in the quantitative suspension test

The following test strains were used as test organisms:

- <i>Enterococcus hirae</i>	( <i>E. hirae</i> )	DSM 3320	= ATCC 10541
- <i>Candida albicans</i>	( <i>C. albicans</i> )	DSM 1386	= ATCC 10231

A combination of 3.0 % tween 80, 0.3 % lecithin, 0.1 % histidine and 0.5 % sodium thiosulphate was used as an inactivation agent.

The results are stated in the tables 1 and 2.

With the test germ *Enterococcus hirae* and *Candida albicans*, the stipulated germ reduction rates of min. 5 and/or 4 log units were achieved after an exposure time of 5 minutes with a concentration of 0.75 % g/v.

Terms and abbreviations:

conc. = concentration

cfu = colony forming unit

R log = reduction in viability in log units

check 1 = cfu in water of standardised hardness without disinfecting agent

check 2 = validation of dilution-neutralization method

check 3 = non toxicity control of the neutralizer





#### 4.2 Surface disinfection under practically-oriented conditions

Testing was carried out according to the method for wipe disinfectants. The tests were performed on matt-finish ceramic tiles (50 x 50 mm) and the tests were executed with a low protein contamination (0.03 % albumin). Room temperature ranged between 20°C and 25°C, the relative air humidity between 48 and 56%.

The following test strains were used as test organisms:

- <i>Staphylococcus aureus</i>	DSM 799	= ATCC 6538
- <i>Enterococcus hirae</i>	DSM 3320	= ATCC 10541
- <i>Pseudomonas aeruginosa</i>	DSM 939	= ATCC 15442
- <i>Candida albicans</i>	DSM 1386	= ATCC 10231

The results of the first orientation test section are stated in the tables 3 to 6.

For the calculations, the underlined values were used. For the values marked with \*, the weighted arithmetic mean was formed.

Basing on an exposure time of 5 minutes, the stipulated germ reduction rates of at least 5 (with the bacterial strains) and/or 4 log units (with *C. albicans*) were achieved with concentrations of 1.0 % g/v.

The results of the confirmation tests for the listing variation 1.0 % g/v with 5 minutes exposure time are stated in the tables 7 to 10. According to these results, a concentration of 1.0 % g/v with an exposure time of 5 minutes can be regarded as sufficient.

The previous list entry (pursuant to the old guideline) of 1.0 % g/v with an exposure time of 5 minutes could thus be confirmed.

Terms and abbreviations:

conc. = concentration  
cfu = colony forming unit  
R log = reduction in viability in log units

check 1 = cfu in water of standardised hardness without disinfecting agent

check 2 = validation of dilution-neutralization method

check 3 = non toxicity control of the neutralizer

Practically oriented surface disinfection test with *Staphylococcus aureus* – 1<sup>st</sup> run with one tile

Table 3a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	5 min			
	0/0,5ml	0/0,1ml	-1	-2
2,0	<u>0</u>	0	0	0
1,0	<u>8</u>	0	0	0

tests for validation	5 min	
check 1	-3	<u>175</u>
	-4	12
check 2	-1	>300
	-2	<u>75</u>
check 3	-1	>300
	-2	<u>83</u>

output germ count      -6: 69              -7: 6

Table 3b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	5 min		
	cfu / ml	log cfu	R log
2,0	< 2	< 0,30	> <b>5,94</b>
1,0	16	1,20	<b>5,04</b>

tests for validation	5 min	
check 1	cfu / ml	$1,75 \times 10^6$
	log cfu	6,24
check 2	cfu / ml	$7,5 \times 10^3$
	log cfu	3,88
check 3	cfu / ml	$8,3 \times 10^3$
	log cfu	3,92

number of cells in the test solution  
 cfu/ml:  $6,9 \times 10^8$               log cfu: 8,84

Practically oriented surface disinfection test with *Enterococcus hirae* – 1<sup>st</sup> run with one tile

Table 4a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	5 min			
	0/0,5ml	0/0,1ml	-1	-2
2,0	<u>0</u>	0	0	0
1,0	<u>4</u>	0	0	0
<b>tests for validation</b>				
check 1	-3	<u>118</u>		
	-4	8		
check 2	-1	>300		
	-2	<u>39</u>		
check 3	-1	>300		
	-2	<u>104</u>		

output germ count      -6: 39              -7: 2

Table 4b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	5 min		
	cfu / ml	log cfu	R log
2,0	< 2	< 0,30	> 5,77
1,0	8	0,90	5,17

<b>tests for validation</b>		<b>5 min</b>
check 1	cfu / ml	1,18 x 10 <sup>6</sup>
	log cfu	6,07
check 2	cfu / ml	3,9 x 10 <sup>3</sup>
	log cfu	3,59
check 3	cfu / ml	1,04 x 10 <sup>4</sup>
	log cfu	4,01

number of cells in the test solution  
 cfu /ml: 3,9 x 10<sup>8</sup>      log cfu: 8,59



Practically oriented surface disinfection test with *Candida albicans* – 1<sup>st</sup> run with one tile

Table 6a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	5 min				15 min			
	0/0,5ml	0/0,1ml	-1	-2	0/0,5ml	0/0,1ml	-1	-2
2,0	<u>0</u>	0	0	0	<u>0</u>	0	0	0
1,0	<u>6</u>	0	0	0	<u>0</u>	0	0	0
tests for validation								
		5 min			15 min			
check 1	-3	<u>42</u>		-3	<u>36</u>			
	-4	4		-4	4			
check 2								
check 3				-1	<u>153</u>			
				-2	14			
check 1				-1	<u>138</u>			
				-2	12			

output germ count      -5: 94\*                      -6: 15\*

Table 6b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	5 min			15 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
2,0	< 2	< 0,30	> 5,32	< 2	< 0,30	> 5,26
1,0	12	1,08	4,54	< 2	< 0,30	> 5,26
tests for validation						
		5 min			15 min	
check 1	cfu / ml	4,2 x 10 <sup>5</sup>		cfu / ml	3,6 x 10 <sup>5</sup>	
	log cfu	5,62		log cfu	5,56	
check 2				cfu / ml	1,53 x 10 <sup>4</sup>	
				log cfu	4,18	
check 3				cfu / ml	1,38 x 10 <sup>4</sup>	
				log cfu	4,14	

number of cells in the test solution  
 cfu/ml: 9,91 x 10<sup>7</sup>      log cfu: 8,00

Practically oriented surface disinfection test with *Staphylococcus aureus* – 2<sup>nd</sup> run with two tiles

Table 7a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>86*</u>	<u>24*</u>	1	<u>0</u>	0	0
0,5	<u>104*</u>	<u>27*</u>	4	<u>97*</u>	<u>26*</u>	4

conc. g/v %	Test surface 2 / 1 min			Test surface e 2 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>81*</u>	<u>18*</u>	1	<u>0</u>	0	0
0,5	> 300	<u>198*</u>	<u>28*</u>	> 300	<u>43</u>	8

		1 min		5 min
check 1	-3	> 300	-3	> 300
	-4	<u>83</u>	-4	<u>92</u>
	-5	9	-5	9

output germ count      -6: 98      -7: 10

Table 7b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	Test surface / 1 min			Test surface / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	$1,78 \times 10^2$	2,25	4,67	< 2	< 0,30	> <b>6,66</b>
0,5	$2,14 \times 10^2$	2,33	4,59	$2,0 \times 10^2$	2,30	4,66

conc. g/v %	Test surface / 1 min			Test surface / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	$1,64 \times 10^2$	2,21	4,71	< 2	< 0,30	> <b>6,66</b>
0,5	$2,05 \times 10^3$	3,31	3,61	$4,3 \times 10^2$	2,65	4,31

		1 min		5 min
check 1	cfu / ml	$8,3 \times 10^6$	cfu / ml	$9,2 \times 10^6$
	log cfu	6,92	log cfu	6,96

number of cells in the test solution  
 cfu /ml:  $9,81 \times 10^8$       log cfu: 8,99

Practically oriented surface disinfection test with *Enterococcus hirae* – 2<sup>nd</sup> run with two tiles

Table 8a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>0</u>	0	0	<u>0</u>	0	0
0,5	<u>11</u>	1	0	<u>0</u>	0	0

conc. g/v %	Test surface 2 / 1 min			Test surface 2 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>15</u>	1	0	<u>0</u>	0	0
0,5	<u>20</u>	3	0	<u>4</u>	0	0

		1 min		5 min
check 1	-3	<u>268*</u>	-3	<u>245*</u>
	-4	<u>28*</u>	-4	<u>26*</u>
	-5	3	-5	2

output germ count      -6: 83      -7: 7

Table 8b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	< 2	< 0,30	> <b>6,13</b>	< 2	< 0,30	> <b>6,09</b>
0,5	22	1,34	<b>5,09</b>	< 2	< 0,30	> <b>6,09</b>

conc. g/v %	Test surface 2 / 1 min			Test surface 2 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	30	1,48	4,98	< 2	< 0,30	> <b>6,09</b>
0,5	40	1,60	4,83	8	0,90	<b>5,29</b>

		1 min		5 min
check 1	cfu / ml	$2,69 \times 10^6$	cfu / ml	$2,46 \times 10^6$
	log cfu	6,43	log cfu	6,39

number of cells in the test solution  
 cfu / ml:  $8,3 \times 10^8$       log cfu: 8,92

Practically oriented surface disinfection test with *Pseudomonas aeruginosa* – 2<sup>nd</sup> run with two tiles

Table 9a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>0</u>	0	0	<u>0</u>	0	0
0,5	<u>5</u>	1	0	<u>0</u>	0	0

conc. g/v %	Test surface 2 / 1 min			Test surface 2 / 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>0</u>	0	0	<u>0</u>	0	0
0,5	<u>1</u>	1	0	<u>0</u>	0	0

		1 min		5 min
check 1	-3	> 300	-3	> 300
	-4	<u>31</u>	-4	<u>48</u>
	-5	2	-5	2

output germ count      -5: 97                      -7: 12

Table 9b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	< 2	< 0,30	> <b>6,19</b>	< 2	< 0,30	> <b>6,38</b>
0,5	10	1,00	<b>5,49</b>	< 2	< 0,30	> <b>6,39</b>

conc. g/v %	Test surface 2 / 1 min			Test surface 2 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	< 2	< 0,30	> <b>6,19</b>	< 2	< 0,30	> <b>6,39</b>
0,5	< 2	< 0,30	> <b>6,19</b>	< 2	< 0,30	> <b>6,39</b>

		1 min		5 min
check 1	cfu / ml	$3,1 \times 10^6$	cfu / ml	$4,8 \times 10^6$
	log cfu	6,49	log cfu	6,68

number of cells in the test solution  
 cfu / ml:  $9,7 \times 10^8$                       log cfu: 8,99

Practically oriented surface disinfection test with *Candida albicans* – 2<sup>nd</sup> run with two tiles

Table 10a: Germ counts / plate (primary data) established via the surface spatula method

conc. g/v %	Test surface 1/ 1 min			Test surface 1/ 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>76*</u>	<u>24*</u>	2	<u>12</u>	8	0
0,5	> 300	<u>104</u>	14	<u>204*</u>	<u>31*</u>	4

conc. g/v %	Test surface 2/ 1 min			Test surface 2/ 5 min		
	0/0,5ml	0/0,1ml	-1	0/0,5ml	0/0,1ml	-1
1,0	<u>204*</u>	<u>66*</u>	10	<u>20</u>	3	0
0,5	> 300	<u>233*</u>	<u>36*</u>	<u>188*</u>	<u>24*</u>	2

		1 min			5 min
check 1	-3	<u>108</u>	-3	<u>127</u>	
	-4	7	-5	9	

output germ count      -6: 16              -7: 1

Table 10b: Germ counts and reduction factors established via the surface spatula method

conc. g/v %	Test surface 1 / 1 min			Test surface 1 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	$1,60 \times 10^2$	2,20	3,83	24	1,38	<b>4,72</b>
0,5	$1,04 \times 10^3$	3,02	3,01	$3,99 \times 10^2$	2,60	3,50

conc. g/v %	Test surface 2 / 1 min			Test surface 2 / 5 min		
	cfu / ml	log cfu	R log	cfu / ml	log cfu	R log
1,0	$4,31 \times 10^2$	2,63	3,40	40	1,60	<b>4,50</b>
0,5	$2,45 \times 10^3$	3,39	2,64	$3,64 \times 10^2$	2,56	3,54

		1 min			5 min
check 1	cfu / ml	$1,08 \times 10^6$	cfu / ml	$1,27 \times 10^6$	
	log cfu	6,03	log cfu	6,10	

number of cells in the test solution  
 cfu /ml:  $1,6 \times 10^8$       log cfu: 8,20

5. Beurteilung:

The product *DISIFIN® med & clean* was already tested for its efficiency as a surface disinfectant for hospitalism prophylaxis and in general practice pursuant to the "Guidelines for the testing and evaluation of chemical disinfection procedures, first partial section (version: 01 January 1981)" and the "testing and evaluation of chemical disinfection procedures (version: 12 July 1991)" of the German Society for Hygiene and Microbiology and adopted into the list.

The previous list entry for the category surface disinfection read as follows:  
1.0 % g/v with 5 minutes exposure time.

Due to the amendment of the guidelines (version: 09/2001), additional tests were required for the efficiency evaluation as a surface disinfectant.

The tests were carried out according to the standard DGHM/VAH methods for the testing of the chemical disinfection procedures (version: 1 September 2001).

According to the new listing terms, the procedure should be listed as a surface disinfection procedure with mechanical action (wipe disinfection) with low contamination.

The scope of the tests was governed by the definitions made by the disinfectant commission of the DGHM/VAH (notification 3/2002).

The test resulted in the fact that *DISIFIN® med & clean* (Ch. 080207) with the previous list entry 1.0 % g/v with an exposure time of 5 minutes fulfils the requirements made to a surface disinfectant for wipe disinfection against bacteria and *Candida albicans*.

A list entry of **1.0 % g/v with an exposure time of 5 minutes** would thus be possible in the category of surface disinfection with mechanical action with low contamination (0.03% albumin).

The final decision is, however, to be taken by the disinfectant commission of the Association for applied hygiene (VAH).

Weimar, 10 May 2007



Dr. M. Mitsching  
Test Manager Microbiology

All results refer to the examined sample only.