

P.J. Dahlhausen & Co. GmbH  
Emil-Hoffmann-Straße 53  
DE - 50996 Köln

Hamburg, 15 May 2017

## Expert opinion

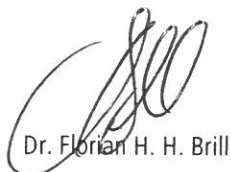
Yeasticidal Activity of **Feuchte Waschhandschuhe antibakteriell** in the quantitative suspension test according to DIN EN 13624:2013 (Phase 2, Step 1)

The liquid squeezed out of **Feuchte Waschhandschuhe antibakteriell** 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 in the medical area - Test Method and Requirements (Phase 2, Step 1)“.

According to the test report no. L17/0121.2 dated 15/05/2017 of Dr. Brill + Partner GmbH the preparation showed yeast-icidal activity under clean conditions.

The liquid squeezed out of **Feuchte Waschhandschuhe antibakteriell** complies with the requirements of DIN EN 13624:2013 (phase 2, step 1) with the following concentration-time relationship:

Yeasticidal:	clean conditions	100 %	5 minutes
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Dr. Florian H. H. Brill



## Test report no L17/0121.2

### Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of **Feuchte Waschhandschuhe antibakteriell** in the medical area according to DIN EN 13624:2013 (Phase 2, step 1)\*

In accordance with your order, we tested the liquid squeezed out of **Feuchte Waschhandschuhe antibakteriell** for its activity in the quantitative suspension test according to DIN EN 13624:2013\* under clean conditions.

#### 1 General Information and Material

##### 1.1 Client

Client: P.J. Dahlhausen & Co. GmbH, Frau Hardt, Emil-Hoffmann-Straße 53,  
DE - 50996 Köln  
Date of order: 14/02/2017  
Confirmation no.: 201281

##### 1.2 Identification of Test Laboratory

Location: Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology,  
Stiegstück 34, DE-22339 Hamburg, Germany  
Study manager: Dipl.-Biol. Dr. rer. nat. Jan-Hendrik Klock  
Scientific assistant: Dipl.-Ing. Dr. rer. nat. Andreas Kampe  
Laboratory technicians: Carmela Jänicke

##### 1.3 Table of Contents

General Information and Material	1
Methods	2
Results	3
Tables	4
List of Abbreviations	8

##### 1.4 Identification of Sample

Name of product: **Feuchte Waschhandschuhe antibakteriell (liquid squeezed out of gloves)**

\* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Germany, Telephone +49. 40. 557631-0, Telefax +49. 40. 557631-11, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results exclusively apply to the tested samples. Information on measurement uncertainty on request. © Dr. Brill + Partner GmbH 2017



Batch no.:	174017
Manufacturer:	P.J. Dahlhausen & Co. GmbH, DE - 50996 Köln
Date of delivery:	22/02/2017
Storage conditions:	room temperature and darkness
Appearance of product:	wet gloves
Odour:	characteristic
Product type:	wet gloves
pH value, concentrate:	not measured
Active agents (Manufacturer's data):	0.4 % DDAC 0.3 % chlorhexidine

### 1.5 Test Conditions

Test period:	12/04/ - 19/04/2017
Product test concentrations:	25 + 50 + 80 %
Exposure time:	1 + 5 + 15 + 60 minutes
Test temperature:	20°C ± 1°C
Incubation temperature:	30°C ± 1°C
Organic load:	clean conditions (0.3 g/L bovine albumin)
Neutraliser:	60 g/L polysorbate 80, 20 g/L sodium oleate, 8 g/L lecithin (TL-SO)
Test organisms:	<i>Candida albicans</i> ATCC 10231

## 2 Methods

The tests were carried out according to DIN EN 13624:2013 „Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test Method and Requirements (Phase 2, Step 1)“.

In order to test the yeasticidal efficacy of **Feuchte Waschhandschuhe antibakteriell** the liquid was squeezed out of the gloves. This liquid was used as stock solution and diluted to 25 + 50 % to perform the quantitative suspension test.

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**DR. BRILL + DR. STEINMANN**  
INSTITUT FÜR HYGIENE UND MIKROBIOLOGIE

Test report no L17/0121.2  
Author AK Version 02 Date 15/05/2017  
Replaces Version 01 Date 21/04/2017

Name of Product **Feuchte Waschhandschuhe antibakteriell**  
Method DIN EN 13624:2013\*

Page **3 of 8**

### 3 Results

The test results based on DIN EN 13624: 2013 are summarised in tables 1.

*C. albicans* was sufficiently (RF >4) inactivated with the following concentration-time relationship:

Yeasticidal:	clean conditions	50 %	5 minutes
	clean conditions	25 %	15 minutes

Hamburg, 15/05/2017

Dipl.-Biol. Dr. rer. nat. Jan-Hendrik Klock  
Study Manager

Dipl.-Ing. Dr. rer. nat. Andreas Kampe  
Quality control



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Table 1.1: Validation, Controls and Evaluation (DIN EN 13624:2013\*)

Product name: **Feuchte Waschhandschuhe antibakteriell**  
Test organism: *Candida albicans*  
Organic load: clean conditions  
Contact time: **1 minutes**

Batch: 174017  
Temperature: 20°C ± 1°C  
Neutraliser: TL-SO  
Lab task no.: L17/0121.2

Suspension for validation (N <sub>0</sub> )			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C) Conc.: 80,00 %		
Microbial count			Microbial count			Microbial count			Microbial count		
V <sub>c1</sub>	53		V <sub>c1</sub>	62		V <sub>c1</sub>	47		V <sub>c1</sub>	66	
V <sub>c2</sub>	60		V <sub>c2</sub>	57		V <sub>c2</sub>	51		V <sub>c2</sub>	47	
30 ≤ $\bar{x}$ of N <sub>0</sub> ≤ 160			$\bar{x}$ of A(1') is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?			$\bar{x}$ of B is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?			$\bar{x}$ of C(1') is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?		
Yes			Yes			Yes			Yes		
Suspension for Validation (N <sub>VB</sub> )			V <sub>c1</sub>			V <sub>c2</sub>			30 ≤ $\bar{x}$ of N <sub>0</sub> ≤ 160?		
			78			61			Yes		
Test suspension (N and N <sub>0</sub> )		N		Microbial count		V <sub>c1</sub>	V <sub>c2</sub>	$\bar{x}_{wm}$ / lg N	N <sub>0</sub> =N/10; lg N <sub>0</sub>	6,17 ≤ N <sub>0</sub> ≤ 6,70 ?	
		1,00E-05		>330		>660	>660	2,40E+07	6,38	Yes	
		1,00E-06		26		26	22	7,38			
Product-concentration [%]		N		Microbial count		V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub> = $\bar{x}$ x 10	lg N <sub>a</sub>	lg R (lg N <sub>0</sub> = 6,38)	
		1,00E+00		>330		>330	>330	>3,30E+04	> 4,52	≤ 1,86	
		1,00E-01		>330		>330	>330				
25,00		1,00E+00		>330		>330	>330	>3,30E+04	> 4,52	≤ 1,86	
		1,00E-01		>330		>330	>330				
50,00		1,00E+00		>330		>330	>330	>3,30E+04	> 4,52	≤ 1,86	
		1,00E-01		>330		>330	>330				
80,00		1,00E+00		>330		>330	>330	3,75E+03	3,57	2,81	
		1,00E-01		35		35	40				

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Table 1.2: Validation, Controls and Evaluation (DIN EN 13624:2013\*)

Product name: **Feuchte Waschhandschuhe antibakteriell**  
Test organism: *Candida albicans*  
Organic load: clean conditions  
Contact time: **5 minutes**

Batch: 174017  
Temperature: 20°C ± 1°C  
Neutraliser: TL-SO  
Lab task no.: L17/0121.2

Suspension for validation (N <sub>v0</sub> )				Control of test conditions (A)				Control of neutraliser (B)				Valid. of inactivation (C) Conc.: 80,00 %			
Microbial count			̄	Microbial count			̄	Microbial count			̄	Microbial count			̄
V <sub>c1</sub>	53		56,5	V <sub>c1</sub>	50		62,5	V <sub>c1</sub>	47		49	V <sub>c1</sub>	49		48
V <sub>c2</sub>	60			V <sub>c2</sub>	75			V <sub>c2</sub>	51			V <sub>c2</sub>	47		
30 ≤ ̄ of N <sub>v0</sub> ≤ 160			Yes	̄ of A(5') is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes	̄ of B is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes	̄ of C(5') is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes
Suspension for Validation (N <sub>vb</sub> )			V <sub>c1</sub>		V <sub>c2</sub>		̄		30 ≤ ̄ of N <sub>v0</sub> ≤ 160?						
			78		61		69,5		Yes						
Test suspension (N and N <sub>0</sub> )		N		Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	̄ <sub>wm</sub> / lg N		N <sub>0</sub> =N/10; lg N <sub>0</sub>		6,17 ≤ N <sub>0</sub> ≤ 6,70 ?	
		1,00E-05		>330		>330		>660	>660	2,40E+07		6,38		Yes	
		1,00E-06		26		22		26	22	7,38					
Product-concentration [%]		N		Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub> = ̄ x 10		lg N <sub>a</sub>		lg R (lg N <sub>0</sub> = 6,38)	
		25,00		1,00E+00	>330		>330		>330	>330	4,85E+03		3,69		2,69
		1,00E-01		48		49		48	49						
50,00		1,00E+00		11		8		<14	<14	<1,40E+02		< 2,15		≥ 4,23	
		1,00E-01		0		0		<14	<14						
80,00		1,00E+00		0		0		<14	<14	<1,40E+02		< 2,15		≥ 4,23	
		1,00E-01		0		0		<14	<14						

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Table 1.3: Validation, Controls and Evaluation (DIN EN 13624:2013\*)

Product name: **Feuchte Waschhandschuhe antibakteriell**  
Test organism: *Candida albicans*  
Organic load: clean conditions  
Contact time: **15 minutes**

Batch: 174017  
Temperature: 20°C ± 1°C  
Neutraliser: TL-SO  
Lab task no.: L17/0121.2

Suspension for validation (N <sub>v0</sub> )				Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count			̄	Microbial count			̄	Microbial count			̄	Microbial count			̄
V <sub>c1</sub>	53		56,5	V <sub>c1</sub>	65		64	V <sub>c1</sub>	47		49	V <sub>c1</sub>	39		47,5
V <sub>c2</sub>	60			V <sub>c2</sub>	63			V <sub>c2</sub>	51			V <sub>c2</sub>	56		
30 ≤ ̄ of N <sub>v0</sub> ≤ 160			Yes	̄ of A(15') is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes	̄ of B is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes	̄ of C(15') is ≥ 0,5 x ̄ of N <sub>v0</sub> ?			Yes
Suspension for Validation (N <sub>vB</sub> )			V <sub>c1</sub>		V <sub>c2</sub>		̄		30 ≤ ̄ of N <sub>v0</sub> ≤ 160?						
			78		61		69,5		Yes						

Test suspension (N and N <sub>0</sub> )	N	Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	̄ <sub>wm</sub> / lg N	N <sub>0</sub> =N/10; lg N <sub>0</sub>	6,17 ≤ N <sub>0</sub> ≤ 6,70 ?
	1,00E-05	>330		>330		>660	>660	2,40E+07	6,38	Yes
	1,00E-06	26		22		26	22	7,38		

Product-concentration [%]	N	Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub> = ̄ x 10	lg N <sub>a</sub>	lg R (lg N <sub>0</sub> = 6,38)
	25,00	1,00E+00	1		0		<14	<14	<1,40E+02	< 2,15
50,00	1,00E-01	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			
80,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			

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Table 1.4: Validation, Controls and Evaluation (DIN EN 13624:2013\*)

Product name: **Feuchte Waschhandschuhe antibakteriell**  
Test organism: *Candida albicans*  
Organic load: clean conditions  
Contact time: **60 minutes**

Batch: 174017  
Temperature: 20°C ± 1°C  
Neutraliser: TL-SO  
Lab task no.: L17/0121.2

Suspension for validation (N <sub>0</sub> )			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C)		
Microbial count			Microbial count			Microbial count			Conc.: 80,00 %		
V <sub>c1</sub>	53		V <sub>c1</sub>	49		V <sub>c1</sub>	47		V <sub>c1</sub>	66	
V <sub>c2</sub>	60		V <sub>c2</sub>	55		V <sub>c2</sub>	51		V <sub>c2</sub>	55	
30 ≤ $\bar{x}$ of N <sub>0</sub> ≤ 160			$\bar{x}$ of A(60') is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?			$\bar{x}$ of B is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?			$\bar{x}$ of C(60') is ≥ 0,5 x $\bar{x}$ of N <sub>0</sub> ?		
Yes			Yes			Yes			Yes		
Suspension for Validation (N <sub>0</sub> )			V <sub>c1</sub>			V <sub>c2</sub>			30 ≤ $\bar{x}$ of N <sub>0</sub> ≤ 160?		
			78			61			Yes		

Test suspension (N and N <sub>0</sub> )	N	Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	$\bar{x}_{wm}$ / lg N	N <sub>0</sub> =N/10; lg N <sub>0</sub>	6,17 ≤ N <sub>0</sub> ≤ 6,70 ?
	1,00E-05	>330		>330		>660	>660	2,40E+07		
	1,00E-06	26		22		26	22	7,38	6,38	Yes

Product-concentration [%]	N	Microbial count				V <sub>c1</sub>	V <sub>c2</sub>	N <sub>a</sub> = $\bar{x}$ x 10	lg N <sub>a</sub>	lg R (lg N <sub>0</sub> = 6,38)
25,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			
50,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			
80,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			

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Test report no L17/0121.2  
Author AK Version 02 Date 15/05/2017  
Replaces Version 01 Date 21/04/2017

Name of Product **Feuchte Waschhandschuhe antibakteriell**  
Method DIN EN 13624:2013\*

Page **8 of 8**

#### 4 List of Abbreviations

A	=	control of test conditions
B	=	control of neutraliser
C	=	validation of method at highest product concentration
N	=	test suspension
N <sub>vo</sub>	=	suspension for validation
n.t.	=	not tested
N <sub>0</sub>	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in log <sub>10</sub> -steps
V <sub>c</sub>	=	viable microbial count per ml
$\bar{x}$	=	weighted mean of N

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