

B. Braun Medical AG
Seesatz 17
CH - 6204 Sempach

Hamburg, 07 June 2019

Expert opinion

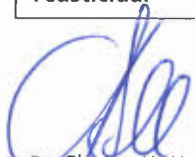
Yeasticidal Activity of **Hexaquart XL** in the quantitative surface test according to DIN EN 13697:2015 (Phase 2, Step 2)

The disinfectant **Hexaquart XL** was tested and evaluated according to DIN EN 13697:2015 "Quantitative Non-Porous Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants Used in Food, Industrial, Domestic, and Institutional Areas – Test Method without Mechanical Action (Phase 2, Step 2)".

According to the test report no. L19/0232.1 dated 07/06/2019 of Dr. Brill + Partner GmbH the preparation yeasticidal activity under dirty conditions human medicine.

Hexaquart XL complies with the requirements of DIN EN 13697:2015 (phase 2, step 2) with the following concentration-time relationship:

Claim	Organic load	Product concentration	Contact time
Bactericidal	dirty conditions human medicine	1.0 vol%	15 minutes
Yeasticidal	dirty conditions human medicine	1.0 vol%	15 minutes



Dr. Florian H. H. Brill

Test report no L19/0232.1

Quantitative Non-Porous Surface Test for the evaluation of bactericidal and/or fungicidal activity of
Hexaquart XL
in Food, Industrial, Domestic, and Institutional Areas according to DIN EN 13697:2015 (Phase 2, step 2)*

In accordance with your order, we tested the preparation **Hexaquart XL** for its activity in the quantitative surface test according to DIN EN 13697:2015* under dirty conditions human medicine.

1 General Information and Material

Client: B. Braun Medical AG, Mrs Bucher, Seesatz 17,
CH - 6204 Sempach
Date of order: 20/03/2019
Confirmation no.: 209190

1.1 Identification of Test Laboratory

Location: Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology,
Stiegstück 34, DE-22339 Hamburg, Germany
Study manager: Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Scientific assistant: Dipl.-Biol. Henrik Gabriel
Laboratory technicians: Eileen Bruder

1.2 Table of Contents

General Information and Material	1
Methods	3
Results	3
Tables	4
List of Abbreviations	9

1.3 Identification of Sample

Name of product: **Hexaquart XL**
Batch no.: R-40_25102016 (L17/0050), 18335M02 (L19/0232)
Manufacturer: B. Braun Medical AG, CH - 6204 Sempach

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Date of delivery:	26/01/2017 (L17/0050), 26/03/2019 (L19/0232)
Storage conditions:	room temperature and darkness
Appearance of product:	orange clear liquid
Odour:	characteristic
Recommended diluent:	Tap water
Diluent used:	water of standardised hardness (WSH, pH 7.0)
pH value, concentrate (L19/0232):	11.7
pH value, 1.5 % (measured in diluent):	10.4
pH value, 1.0 % (measured in diluent):	10.2
pH value, 0.5 % (measured in diluent):	10.0
Active agents (Manufacturer's data):	9.9 % N,N-Bis(3-Aminopropyl)dodecylamin 6.6 % DDAC

1.4 Test Conditions

Test period:	29/06/ - 04/07/2017 (L17/0050.13), 11/04/ - 27/05/2019 (L19/0232)
Lab task no.:	L17/0050.13, L19/0232.1 and .2
Test pieces:	stainless steel discs
Product test concentrations:	0.1 – 1.5 %
Exposure time:	15 minutes
Test temperature:	20°C ± 1°C
Incubation temperature:	36°C ± 1°C (Bacteria); 30°C ± 1°C (Fungi)
Organic load:	dirty conditions human medicine (3.0 g/L bovine albumin + 3.0 mL/L sheep erythrocytes)
Neutraliser:	80 g/L polysorbate 80, 60 g/L saponine, 8 g/L lecithin, 1 g/L histidine, 15 g/L SDS (TLSH-SDS)
Efficacy criterion:	4 log reduction against water control at contact time (Bacteria) 3 log reduction against water control at contact time (fungi)
Test organisms:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Escherichia coli</i> ATCC 10536 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Candida albicans</i> ATCC 10231

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



2 Methods

The tests were carried out according to DIN EN 13697:2015 "Quantitative Non-Porous Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants Used in Food, Industrial, Domestic, and Institutional Areas – Test Method without Mechanical Action (Phase 2, Step 2)".


3 Results

The test results based on DIN EN 13697:2015 are summarised in tables 1 and 2.

The test bacteria and the test yeast *Candida albicans* were sufficiently (RF >4 bacteria and RF >3 Candida) inactivated with the following concentration-time relationship:

Claim	Organic load	Product concentration	Contact time
Bactericidal	dirty conditions human medicine	1.0 vol%	15 minutes
Yeasticidal	dirty conditions human medicine	1.0 vol%	15 minutes

Hamburg, 07/06/2019


Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Study Manager

Dipl.-Biol. Henrik Gabriel
Quality control



* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Table 1.1: Validation, Controls and Evaluation

Product name: **Hexaquart XL** Batch: R-40_25102016
Test organism: *Staphylococcus aureus* Temperature: 20°C ± 1°C
Organic load: dirty conditions human medicine Neutraliser: TLSH-SDS
Lab task no.: L17/0050.13

Test and validation suspension (N)			Toxicity control (N _c)			Validation neutralisation medium / Neutralisation control (N _T)		
	x	x'		a	a'	Product	a	a'
1,00E-06	>330	>330	1,00E-04	52	45	1,00E-04	45	42
1,00E-07	22	26	1,00E-05	5	6	1,00E-05	8	5
$\bar{x} = 6,00E+06 = 6,78 \lg$			$\bar{x} = 4,85E+06 = 6,69 \lg$			$\bar{x} = 4,35E+06 = 6,64 \lg$		
6,57 ≤ lg N ≤ 7,1 ?			N _c > 0,5 x N _c ?			N _T > 0,5 x N _c ?		
Yes			Yes			Yes		

Water control

Water control (N _d):	N _c	a	a'	$\bar{x} = 4,50E+06$
	1,00E-04	45	45	lg N _c = 6,65
	1,00E-05	8	9	lg N _c ≥ 6,27 log ? Yes

Test

Concentration of product test solution [%]	Dilution step	a	a'	N _d ($\bar{x} \vee \bar{x} \cdot w_m$) cfu/ml	lg N _d lg ($\bar{x} \vee \bar{x} \cdot w_m$)	R (lgN _c =6,65) lgN _c - lgN _d	Exposure time (min)
0,1	1,00E+00	>330	>330	2,02E+05	5,31	1,35	15
	1,00E-01	>330	>330				
	1,00E-02	192	212				
	N _{ts} =	48		N _{ts} < 100 ?	Yes		
0,5	1,00E+00	1	4	< 1,40E+02	< 2,15	≥ 4,50	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	1		N _{ts} < 100 ?	Yes		
1,0	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,55	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0		N _{ts} < 100 ?	Yes		
1,5	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,55	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0		N _{ts} < 100 ?	Yes		

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Table 1.2: Validation, Controls and Evaluation

Product name: **Hexaquart XL** Batch: R-40_25102016
Test organism: *Enterococcus hirae* Temperature: 20°C ± 1°C
Organic load: dirty conditions human medicine Neutraliser: TLSH-SDS
Lab task no.: L17/0050.13

Test and validation suspension (N)			Toxicity control (N _c)			Validation neutralisation medium / Neutralisation control (N _T)		
	x	x'		a	a'	Product	1,5 %	
1,00E-06	>330	>330	1,00E-04	37	29	1,00E-04	27	49
1,00E-07	26	24	1,00E-05	3	5	1,00E-05	6	8
$\bar{x} = 6,25E+06 = 6,80 \lg$			$\bar{x} = 3,30E+06 = 6,52 \lg$			$\bar{x} = 3,80E+06 = 6,58 \lg$		
$6,57 \leq \lg N \leq 7,1 ?$			$N_c > 0,5 \times N_c ?$			$N_T > 0,5 \times N_c ?$		
Yes			Yes			Yes		

Water control

Water control (N _d):	N _c	a	a'	$\bar{x} = 4,05E+06$
	1,00E-04	32	49	$\lg N_c = 6,61$
	1,00E-05	3	4	$\lg N_c \geq 6,27 \log ?$
				Yes

Test

Concentration of product test solution [%]	Dilution step	a	a'	N _d ($\bar{x} \pm \sqrt{wm}$) cfu/ml	lg N _d lg ($\bar{x} \pm \sqrt{wm}$)	R (lgN _c =6,61) lgN _c - lgN _d	Exposure time (min)
0,1	1,00E+00	>330	>330	1,62E+05	5,21	1,40	15
	1,00E-01	>330	>330				
	1,00E-02	144	180				
	N _{ts} =	21	N _{ts} < 100 ?	Yes			
0,5	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,51	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0	N _{ts} < 100 ?	Yes			
1,0	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,51	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0	N _{ts} < 100 ?	Yes			
1,5	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,51	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0	N _{ts} < 100 ?	Yes			

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Table 1.3: Validation, Controls and Evaluation

Product name: **Hexaquart XL**
Test organism: *Escherichia coli*
Organic load: dirty conditions human medicine
Lab task no.: L19/0232.2

Batch: 18335M02
Temperature: 20°C ± 1°C
Neutraliser: TLSH-SDS

Test and validation suspension (N)			Toxicity control (N _c)			Validation neutralisation medium / Neutralisation control (N _T)		
	x	x'		a	a'	Product	a	a'
1,00E-06	>330	>330	1,00E-04	92	95	1,00E-04	86	98
1,00E-07	26	37	1,00E-05	10	10	1,00E-05	10	9
$\bar{x} = 7,88E+06 = 6,90 \lg$			$\bar{x} = 9,35E+06 = 6,97 \lg$			$\bar{x} = 9,20E+06 = 6,96 \lg$		
6,57 ≤ lg N ≤ 7,1 ?			N _c > 0,5 x N _c ?			N _T > 0,5 x N _c ?		
Yes			Yes			Yes		

Water control

Water control (N _d):	N _c	a	a'	$\bar{x} = 1,03E+07$ lg N _c = 7,01 lg N _c ≥ 6,27 log ? Yes
	1,00E-04	102	100	
	1,00E-05	14	12	

Test

Concentration of product test solution [%]	Dilution step	a	a'	N _d ($\bar{x} \pm \bar{x} \cdot w_m$) cfu/ml	Ig N _d lg ($\bar{x} \pm \bar{x} \cdot w_m$)	R (lgN _c =7,01) lgN _c - lgN _d	Exposure time (min)
0,1	1,00E+00	78	88	8,30E+02	2,92	4,09	15
	1,00E-01	4	18				
	1,00E-02	1	4				
	N _{ts} =	7	N _{ts} < 100 ?	Yes			
0,5	1,00E+00	1	3	< 1,40E+02	< 2,15	≥ 4,86	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0	N _{ts} < 100 ?	Yes			
1,0	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,91	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0	N _{ts} < 100 ?	Yes			

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Table 1.4: Validation, Controls and Evaluation

Product name: **Hexaquart XL**
Test organism: *Pseudomonas aeruginosa*
Organic load: dirty conditions human medicine
Lab task no.: L19/0232.1

Batch: 18335M02
Temperature: 20°C ± 1°C
Neutraliser: TLSH-SDS

Test and validation suspension (N)			Toxicity control (N _c)			Validation neutralisation medium / Neutralisation control (N _T)		
	x	x'		a	a'	Product	a	a'
1,00E-06	>330	>330	1,00E-04	89	75	1,00E-04	83	85
1,00E-07	51	48	1,00E-05	11	6	1,00E-05	9	9
$\bar{x} = 1,24E+07 = 7,09 \lg$			$\bar{x} = 8,20E+06 = 6,91 \lg$			$\bar{x} = 8,40E+06 = 6,92 \lg$		
6,57 ≤ lg N ≤ 7,1 ?			N _c > 0,5 x N _c ?			N _T > 0,5 x N _c ?		
Yes			Yes			Yes		

Water control

Water control (N _d):	N _c	a	a'	$\bar{x} = 7,65E+06$ lg N _c = 6,88 lg N _c ≥ 6,27 log ? Yes
	1,00E-04	77	76	
	1,00E-05	8	8	

Test

Concentration of product test solution [%]	Dilution step	a	a'	N _d ($\bar{x} \pm \sqrt{wm}$) cfu/ml	Ig N _d lg ($\bar{x} \pm \sqrt{wm}$)	R (lgN _c =6,88) lgN _c - lgN _d	Exposure time (min)
0,5	1,00E+00	>330	>330	3,95E+04	4,60	2,29	15
	1,00E-01	>330	>330				
	1,00E-02	39	40				
	N _{TS} =	>100		N _{TS} < 100 ?	No		
1,0	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,78	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{TS} =	0		N _{TS} < 100 ?	Yes		
1,5	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 6,78	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{TS} =	0		N _{TS} < 100 ?	Yes		

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



Table 2.1: Validation, Controls and Evaluation

Product name: **Hexaquart XL** Batch: R-40_25102016
Test organism: *Candida albicans* Temperature: 20°C ± 1°C
Organic load: dirty conditions human medicine Neutraliser: TLSH-SDS
Lab task no.: L17/0050.13

Test and validation suspension (N)			Toxicity control (N _c)			Validation neutralisation medium / Neutralisation control (N _T)		
	x	x'		a	a'	Product	1,5 %	
							a	a'
1,00E-05	>330	>330	1,00E-03	61	48	1,00E-03	44	45
1,00E-06	14	15	1,00E-04	9	13	1,00E-04	5	8
$\bar{x} = 3,73E+05 = 5,57 \lg$			$\bar{x} = 5,45E+05 = 5,74 \lg$			$\bar{x} = 4,45E+05 = 5,65 \lg$		
5,57 ≤ lg N ≤ 6,1 ?			N _c > 0,5 x N _c ?			N _T > 0,5 x N _c ?		
Yes			Yes			Yes		

Water control

Water control (N _d):	N _c	a	a'	$\bar{x} = 3,25E+05$
	1,00E-03	34	31	lg N _c = 5,51
	1,00E-04	3	2	lg N _c ≥ 5,27 log ? Yes

Test

Concentration of product test solution [%]	Dilution step	a	a'	N _d ($\bar{x} \pm \sqrt{\bar{x} \cdot w_m}$) cfu/ml	lg N _d lg ($\bar{x} \pm \sqrt{\bar{x} \cdot w_m}$)	R (lgN _c =5,51) lgN _c - lgN _d	Exposure time (min)
0,1	1,00E+00	>330	>330	> 3,30E+05	> 5,52	≤ -0,01	15
	1,00E-01	>330	>330				
	1,00E-02	>330	>330				
	N _{ts} =	>100		N _{ts} < 100 ?	No		
0,5	1,00E+00	>330	>330	3,60E+03	3,56	1,96	15
	1,00E-01	37	35				
	1,00E-02	4	1				
	N _{ts} =	40		N _{ts} < 100 ?	Yes		
1,0	1,00E+00	0	2	< 1,40E+02	< 2,15	≥ 3,36	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0		N _{ts} < 100 ?	Yes		
1,5	1,00E+00	0	0	< 1,26E+00	< 0,10	≥ 5,41	15
	1,00E-01	0	0				
	1,00E-02	0	0				
	N _{ts} =	0		N _{ts} < 100 ?	Yes		

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019



4 List of Abbreviations

cfu	=	colony forming units (viable microbial count)
N	=	test suspension
N_c	=	\log_{10} cfu per test surface of water control
N_d	=	\log_{10} cfu per test surface of disinfection test
N_T	=	neutralisation test
N_c	=	neutralisation control
N_{is}	=	remaining cfu on test surface
R	=	germicidal activity ($N_c - N_d$)
n.t.	=	not tested
x, x'	=	viable microbial count per ml of the test suspension
a, a'	=	viable microbial count per ml of the suspension after examination and validation
\bar{x}	=	mean of a and a' and x and x'

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Phone +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 and Version history on request. © Dr. Brill + Partner GmbH 2019