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Goodpoint Chemicals OÜ
Vabaohumuuseumi tee 3
EE – 13522 Talinn

Hamburg, 15 August 2017

Expert opinion

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

The disinfectant **Globacid AF** 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. L17/0389.2 dated 15/08/2017 of Dr. Brill + Partner GmbH the preparation showed yeasticidal activity under clean conditions.

Globacid AF complies with the requirements of DIN EN 13624:2013 (phase 2, step 1) with the following concentration-time relationship:

Yeasticidal:	**clean conditions**	**100 %**	**60 seconds**

Dr. Florian H. H. Brill

Test report no L17/0389.2

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

In accordance with your order, we tested the preparation **Globacid AF** for its activity in the quantitative suspension test according to DIN EN 13624:2013* under clean conditions.

1 General Information and Material

Client:	Goodpoint Chemicals OÜ, Dr. Kallikorm, Vabaohumuuseumi tee 3, EE – 13522 Talinn
Date of order:	16/06/2017
Confirmation no.:	202231

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.-Biol. Dr. rer. nat. Jan-Hendrik Klock
Scientific assistant:	Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Laboratory technicians:	Lea Küssner

1.2 Table of Contents

1.3 Identification of Sample

Name of product:	**Globacid AF**
Batch no.:	22052017
Manufacturer:	Goodpoint Chemicals OÜ, EE – 13522 Talinn
Date of delivery:	27/06/2017

Storage conditions:	room temperature and darkness
Appearance of product:	liquid
Odour:	characteristic
Product type:	Instrument disinfectant
Recommended diluent:	Product is ready for use
Diluent used:	distilled water (DW, pH 7.0)
pH value, concentrate:	8.0
pH value, 80 % (measured in diluent):	7.6
pH value, 50 % (measured in diluent):	6.5
pH value, 10 % (measured in diluent):	5.9
Active agents (Manufacturer's data):	60 % isopropanol 15 % ethanol

1.4 Test Conditions

Test period:	12/07/ - 18/07/2017
Lab task no.:	L17/0389.3
Product test concentrations:	10 + 50 + 80 %
Exposure time:	30 + 60 seconds
Test temperature:	20°C ± 1°C
Incubation temperature:	30°C ± 1°C
Organic load:	clean conditions (0.3 g/L bovine albumine)
Neutraliser:	30 g/L polysorbate 80, 30 g/L saponine, 3 g/L lecithin,1 g/L histidine (TLSH-Nt)
Test organisms:	*Candida albicans* 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)".

3 Results

The test results based on DIN EN 13624: 2013 are summarised in tables 1 and 2.

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

Yeasticidal:	clean conditions	50 %	60 seconds

Hamburg, 15/08/2017

Dipl.-Biol. Henrik Gabriel
Head of Laboratory

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: **Globacid AF**
Test organism: *Candida albicans*
Organic load: clean conditions
Contact time: **30 seconds**

Batch: 22052017
Temperature: 20°C ± 1°C
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	42		42,5	V_{c1}	34		39	V_{c1}	34		35	V_{c1}	50		53
V_{c2}	43			V_{c2}	44			V_{c2}	36			V_{c2}	56		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of A(30'') is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C(30'') is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**
Suspension for Validation (N_{vB})				V_{c1}		V_{c2}		$\bar{x}$				$30 \leq \bar{x}$ of $N_{v0} \leq 160$?			
				33		33		33				**Yes**			

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/10; lg N_0	6,17 ≤ N0 ≤ 6,70 ?
	1,00E-05	182		189		182	189	1,90E+07	6,28	**Yes**
	1,00E-06	24		22		24	22	7,28		

Product-concentration [%]	N	Microbial count				V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	lg N_a	lg R (lg N_0 =6,28)
10,00	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,52	≤ 1,76
	1,00E-01	>330		>330		>330	>330			
50,00	1,00E+00	129		116		129	116	<1,23E+03	3,09	3,19
	1,00E-01	9		11		<14	<14			
80,00	1,00E+00	33		37		33	37	<3,50E+02	2,54	3,73
	1,00E-01	6		4		<14	<14			

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

Product name: **Globacid AF**
Test organism: *Candida albicans*
Organic load: clean conditions
Contact time: **60 seconds**

Batch: 22052017
Temperature: 20°C ± 1°C
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 80,00 %			
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	42		42,5	V_{c1}	52		51,5	V_{c1}	34		35	V_{c1}	47		46
V_{c2}	43			V_{c2}	51			V_{c2}	36			V_{c2}	45		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of A(60'') is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C(60'') is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**
Suspension for Validation (N_{v8})				V_{c1}		V_{c2}		$\bar{x}$				$30 \leq \bar{x}$ of $N_{v0} \leq 160$?			
				33		33		33				**Yes**			

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/10; lg N_0	6,17 ≤ N0 ≤ 6,70 ?
	1,00E-05	182		189		182	189	1,90E+07	6,28	**Yes**
	1,00E-06	24		22		24	22	7,28		

Product-concentration [%]	N	Microbial count				V_{c1}	V_{c2}	$N_a = \bar{x} \times 10$	lg N_a	lg R (lg N_0 =6,28)
10,00	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,52	≤ 1,76
	1,00E-01	>330		>330		>330	>330			
50,00	1,00E+00	3		2		<14	<14	<1,40E+02	< 2,15	≥ 4,13
	1,00E-01	0		1		<14	<14			
80,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,13
	1,00E-01	0		0		<14	<14			

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_{V0}	=	suspension for validation
n.t.	=	not tested
N_0	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in $\log_{10}$-steps
V_C	=	viable microbial count per ml
$\bar{x}$	=	weighted mean of N

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Goodpoint Chemicals OÜ
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EE – 13522 Talinn

Hamburg, 16 August 2017

Expert opinion

Bactericidal Activity of **Globacid AF** in the quantitative suspension test according to DIN EN 13727:2015 (Phase 2, Step 1)

The disinfectant **Globacid AF** was tested and evaluated according to DIN EN 13727:2015 "Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)".

According to the test report no. L17/0389.1 dated 16/08/2017 of Dr. Brill + Partner GmbH the preparation showed bactericidal activity under clean conditions.

Globacid AF complies with the requirements of DIN EN 13727:2015 (phase 2, step 1) with the following concentration-time relationship:

Bactericidal:	**clean conditions**	**100 %**	**60 seconds**

Dr. Florian H. H. Brill