Test report no L17/0677.3

Quantitative test method for the evaluation of bactericidal and yeasticidal activity of **Allied Hygiene Sanisafe 3 disinfectant wipe- no Alcohol; 3600 ppm** on non-porous surfaces with mechanical action employing wipes
in the medical area according to DIN EN 16615:2015 (Phase 2, step 2)*

In accordance with your order, we tested the preparation **Allied Hygiene Sanisafe 3 disinfectant wipe- no Alcohol; 3600 ppm** for its activity in the quantitative surface test according to DIN EN 16615:2015* under clean conditions.

1 General Information and Material

1.1 Client

Client:	Evonik Nutrition & Care GmbH, Frau Trambitas, Rodenbacher Chaussee 4, DE – 63457 Hanau-Wolfgang
Date of order:	06/02/2018
Confirmation no.:	204303

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. Henrik Gabriel
Scientific assistant:	Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Laboratory technicians:	Martina Müller

1.3 Table of Contents

General Information and Material 1
Methods 2
Results 3
Tables 4
List of Abbreviations 7

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-216.11.02

1.4 Identification of Sample

Name of product:	**Allied Hygiene Sanisafe 3 disinfectant wipe- no Alcohol; 3600 ppm**
Batch no.:	171017L
Manufacturer:	Allied Hygiene Systems Limited, UK - Erith DA18 4AF
Date of delivery:	03/11/2017
Storage conditions:	room temperature and darkness
Odour:	characteristic
Product type:	Ready to use Product with presoaked wipes
Recommended diluent:	Product is ready for use
pH value, concentrate:	not measured
Active agents (Manufacturer's data):	ampholyte

1.5 Test Conditions

Test period:	13/03/ - 16/03/2018
Lab task no.:	L17/0677.7 + .8
Product test concentrations:	100 %
Exposure time:	15 minutes
Germ carrier:	PVC tile, 20 cm x 50 cm
Test temperature:	20°C ± 1°C
Incubation temperature:	36°C ± 1°C
Organic load:	clean conditions (0.3 g/L bovine albumin)
Neutraliser:	60 g/L polysorbate 80, 30 g/L saponine, 8 g/L lecithin, 3 g/L histidine, (TLSH)
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442

2 Methods

The tests were carried out according to EN 16615:2015 "Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) -Test method and requirements (phase 2, step 2)".

The screening was performed against *P. aeruginosa* as single organism.

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-216.11.02

3 Results

The test results based on DIN EN 16615: 2015 are summarised in tables 1.

P. aeruginosa was sufficiently (Bacteria RF ≥ 5; cell counts on test fields 2-4 below 50 KBE/25cm², wipe control above 10 KBE/25cm²) inactivated with the following concentration-time relationship

P. aeruginosa:	clean conditions	100 %	15 minutes

Hamburg, 26/03/2018

Dipl.-Biol. Henrik Gabriel
Study Manager

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

INSTITUTE FOR HYGIENE AND MICROBIOLOGY · DR. BRILL + DR. STEINMANN · CERTIFIED

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-AP-216.11.02

Table 1: Summary of 2 test runs (clean conditions)

Test organism	Contact time [min]	product concentration [%]	Field 1 log Reduction 1	2	3	Field 2-4 CFU/25cm² 1	2	3	Wipe control Field 2-4 CFU/25cm² 1	2+3
P. aeruginosa	15	100 %	≥5.20	≥5.32	≥5.31	0	11.67	1.67	523	70
mean 15 min		100 %	**5.28**			**4.45**				

 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 2018

Table 1.1: Validation, Controls and Evaluation

Product name:	**Allied Hygiene Sanisafe 3 disinfectant wipe- no Alcohol; 3600 ppm**	Batch:	171017L
Test organism:	*Pseudomonas aeruginosa*	Organic load:	clean conditions
Contact time:	**15 minutes**	Neutraliser:	TLSH
Lab task no.:	L17/0677.7	Test run:	1

Suspension for validation (N_{v0})				Control of neutraliser (**B**)				Vali. of inactivation (**C**) at			100,00 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	43		50,5	V_{c1}	64		68,5	V_{c1}	54		62,5
V_{c2}	58			V_{c2}	73			V_{c2}	71		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	>330		>330		>330	>330	2,80E+09	8,10	**Yes**
	1,00E-08	25		31		25	31	9,45		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	>330		>330		>330	>330	5,25E+07	7,72	**Yes**
	1,00E-05	108		102		108	102			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	213		220		213	220	1,10E+07	7,04	**Yes**
	1,00E-05	25		27		25	27			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,04)
100	1,00E+00	6		7		<14	<14	<7,00E+01	< 1,85	≥ 5,20
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
100	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	112	105	97	523	**Yes**
	1,00E-01	11	16	8		

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-AP-216.11.02

Table 1.2: Validation, Controls and Evaluation (DIN EN 16615:2013*)

Product name:	**Allied Hygiene Sanisafe 3 disinfectant wipe- no Alcohol; 3600 ppm**	Batch:	171017L
Test organism:	*Pseudomonas aeruginosa*	Organic load:	clean conditions
Contact time:	**5 minutes**	Neutraliser:	TLSH
Lab task no.:	L17/0677.8	Test run:	2

Suspension for validation (N_{V0})				Control of neutraliser (**B**)				Vali. of inactivation (**C**) at 100 %			
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	43		43,5	V_{c1}	57		59	V_{c1}	43		49
V_{c2}	44			V_{c2}	61			V_{c2}	55		
$30 \leq \bar{x}$ of $N_{V0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{V0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{V0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7,88 \leq N_{V0} \leq 8,40$?
	1,00E-07	>330		>330		>330	>330	2,05E+09	7,97	**Yes**
	1,00E-08	20		21		20	21	9,31		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6,88 \leq T_0 \leq 8,40$?
	1,00E-04	>330		>330		>330	>330	2,18E+07	7,34	**Yes**
	1,00E-05	36		51		36	51			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6,88 \leq T_t \leq 8,40$?
	1,00E-04	>330		>330		>330	>330	1,43E+07	7,15	**Yes**
	1,00E-05	27		30		27	30			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm} * 5$)	lg N_a	lg R (lg T_t =7,15)
100	1,00E+00	13		14		<14	<14	<6,75E+01	> 1,83	> 5,32
	1,00E-01	0		0		<14	<14			
100	1,00E+00	10		4		<14	<14	<7,00E+01	< 1,85	≥ 5,31
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
100	1,00E+00	6	1	0	11,67	**Yes**
100	1,00E+00	1	0	0	1,67	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	30	11	1	70	**Yes**
	1,00E-01	4	1	0		

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-AP-216.11.02

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

* 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 and Version history on request. © Dr. Brill + Partner GmbH 2018

DAkkS Deutsche Akkreditierungsstelle D-PL-13412-01-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-216.11.02