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Date: 2023.11.08 13:45:13 EET
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Location: Moldova


biosanitizer H1
SANITIZER
GEL
Spectrum Bactericide: EN 1500 (2013), EN 1040 (2006), EN 12791 (2016), EN
EN 1650 (2008) C. albicans. Fongicide: EN 13624 (2013). Mycobactericide: EN
norovius. Activity complies with standard EN 14476 (2013) rotavirus, vaccinia virus,
coronavirus (incl. RSV), herpes virus.
Composition Ethanol (CAS n° 64-17-5 72% w/w), moisturizing agents and superfatting
Direction for use For professional users, use on a dry, clean and healthy skin.
a hollow of hand, during 30 sec. Surgical disinfection: rub with a min. of 2 x 3 ml, a
Caution The packaging must be eliminated as hazardous waste under the full
drains and water-ways. Danger H225 - Highly flammable liquid and vapour. H319
Mode d'emploi Usage réservé aux professionnels, employé pur sur une peau saine,
frictionner avec au min. 3 ml, un creux de main, durant 30 sec. Désinfection
2 x 45 sec.
Précautions L'emballage doit être éliminé en tant que déchet dangereux sous
résidus dans les égouts et les cours d'eau. Danger H225 - Liquide et vapeurs
Anwendung Für professionelle Nutzer, auf trockener, sauberer und gesunder
Reiben Sie mit min. 3 ml, eine Handkuhle voll, während 30 Sek.
während 2 x 45 Sek.
Hinweise Die Verpackung muss als gefährlicher Abfall unter der vollen
die Kanalisation oder Wasser-wege entleeren. Gefahr H225 - Flüssigkeit und
Gebruiksaanwijzing Voor professionele gebruikers, gebruik rechtstreeks op
handontsmetting: inwrijven met een handpalm vol, min. 3 ml, gedurende 30 sec.
min. 3 ml, gedurende 45 sec.
Voorzorgsmaatregelen De verpakking moet worden verwijderd als gevaarlijk
afvalophaler. Gooi resten niet weg in de afvoeren en/of waterwegen. Gevaar H225
ernstige oogirritatie.
SAFE
1000 ml
Saniswiss SA • Geneva • Switzerland
T +41 22 718 75 75 • saniswiss.com


SAFE
sanitizer
HANDS H1
saniswiss
BIO ETHANOL
VIRUCIDE

MS ISO/IEC 17025
TESTING
SAMM NO. 823

Test Report No.: VX-TR-19-3072
Copy No.: 1

DETERMINATION OF THE VIRUCIDAL ACTIVITY (EN 14476) OF SANISWISS SANITIZER HANDS H1

Lab No.:	VX-43-19-0002
Sample Name:	**Saniswiss SANITIZER HANDS H1**
Method:	EN 14476:2013+A1:2015 (E) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)
Client:	Saniswiss SA Chemin des Tulipiers 19 1208 Geneva Switzerland
Sample Receipt Date:	3 May 2019
Report Date:	29 July 2019

Page 1 of 17

Kuala Lumpur, 29 July 2019

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Date: 2019.08.02 09:40:16 +08'00'

Dr Syazani Suhaimi
Microbiologist

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)

Lab No.: VX-43-19-0002	Client Name: Saniswiss SA
Test Period: 9 July – 23 July 2019	Sample Name: Saniswiss SANITIZER HANDS H1
Test Report No.: VX-TR-19-3072	Batch No.: Not specified
Report Date: 31 July 2019	Sample Receipt Date: 3 May 2019
Copy No.: 1	

Materials and Method

Quantitative suspension test for the evaluation of virucidal activity in the medical area according to EN 14476:2013+A1:2015 (E)

1.	**Testing laboratory identification**	Viroxy Sdn. Bhd. 6th Floor, Menara RKT 50300 Kuala Lumpur Malaysia
2.	**Sample identification**	
2.1	Sample name:	Saniswiss SANITIZER HANDS H1
2.2	Batch no.:	Not specified
2.3	Product appearance:	Clear, colourless solution
2.4	Manufacturer:	Saniswiss SA Chemin des Tulipiers 19 1208 Geneva Switzerland
2.5	Active substances per 100 g:	72 % w/w Bioethanol
2.6	Sample receipt date:	3 May 2019
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water
3.	**Experimental conditions**	
3.1	Testing period:	9 July – 23 July 2019
3.2	Test organism(s):	*Adenovirus type 5*, strain Adenoid 75, ATCC VR-5 *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651
3.3	Concentration/contact time:	100.00 %* / 15 and 30 seconds
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Incubation period:	7 days, 36 °C ± 1 °C

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

4. Test method and its validation

4.1 Testing method: Quantal test

4.2 Inactivation method: Immediate dilution
Molecular sieving using MicroSpin™ S 400 HR (for formaldehyde only)

The results of validation tests A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

Saniswiss SANITIZER HANDS H1 showed the required virus reduction of ≥4.0 $\log_{10}$ against test strains *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5 and *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651 in accordance with EN 14476:2013+A1:2015 (E) at 100.00 %* concentration after 15 and 30 seconds under the stated condition.

Kuala Lumpur, 29 July 2019

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Dr Syazani Suhaimi
Microbiologist

7. Note

Virucidal activity – the capability of a product to produce a reduction in the number of viable viruses belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = V_C/N_a$ = the reduction in viability, or $lg\ R = lg\ V_C - lg\ N_a$

* The product can only be tested at 97.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

saniswiss SAFE HYGIENE SOLUTIONS

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

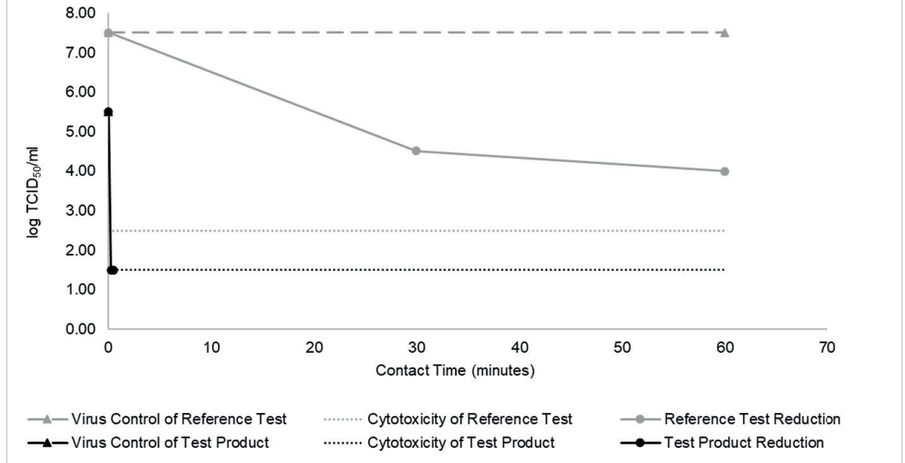
Table A: Evaluation of the virucidal activity of Saniswiss SANITIZER HANDS H1 on test strains according to EN 14476

Product: Saniswiss SANITIZER HANDS H1
Loading: 0.30 g/L bovine albumin solution

Test strain: *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 5.50 ± 0.00 V_{C2}: 5.50 ± 0.00	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

Test concentration (%) / contact time (sec)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 15	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥4.00 ± 0.00**	lg R: **≥4.00 ± 0.00**
100.00* / 30	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥4.00 ± 0.00**	lg R: **≥4.00 ± 0.00**



* The product can only be tested at 97.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

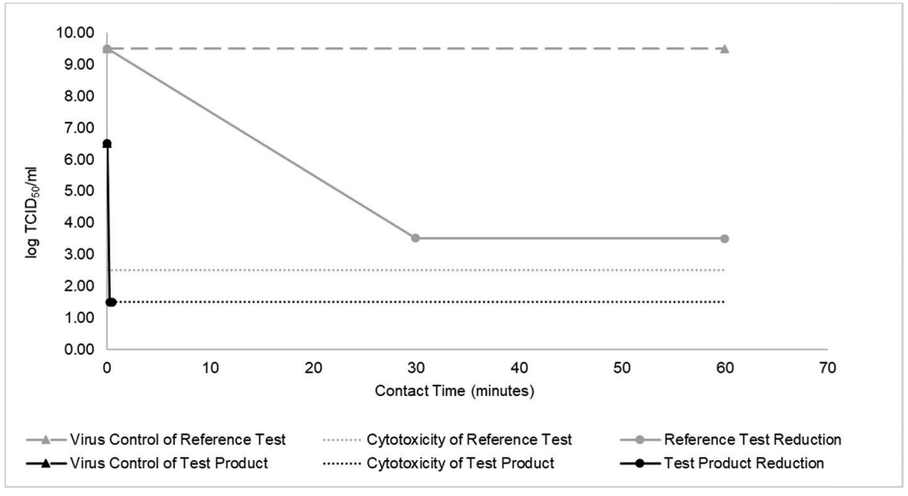
Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Test strain: *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 6.50 ± 0.00 V_{C2}: 6.50 ± 0.00	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

Test concentration (%) / contact time (sec)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 15	N_{a1}: ≤1.50 ± 0.00 lg R: **≥5.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R: **≥5.00 ± 0.00**	lg R: **≥5.00 ± 0.00**
100.00* / 30	N_{a1}: ≤1.50 ± 0.00 lg R: **≥5.00 ± 0.00**	N_{a1}: ≤1.50 ± 0.00 lg R: **≥5.00 ± 0.00**	lg R: **≥5.00 ± 0.00**



* The product can only be tested at 97.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

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saniswiss SAFE HYGIENE SOLUTIONS

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Table B: Control tests and method validation for Table A

Test strain	Cell susceptibility control	Suppression efficiency control	Reference test for virus inactivation
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	A:.6.50 ± 0.00 A_{PBS}: 6.75 ± 0.33	B: 5.50 ± 0.00 V_C: 5.88 ± 0.37	C_{30}: 3.00 ± 0.00 C_{60}: 3.50 ± 0.38
Murine norovirus, strain S99 Berlin, FLI-RVB-0651	A: 7.50 ± 0.00 A_{PBS}: 7.25 ± 0.33	B: 7.00 ± 0.38 V_C: 7.00 ± 0.38	C_{30}: 6.00 ± 0.00 C_{60}: 6.00 ± 0.00

Note

$TCID_{50}$: The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication.

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_a: log_{10} $TCID_{50}$ per ml in the test mixture at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution.

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vacciniavirus)

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

Table C: Summary of the log reductions of the quantitative suspension test according to EN 14476

Test strain	Test concentration (%) / contact time (sec)	Log reduction ($TCID_{50}$/ml)
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	100.00* / 15	**≥4.00 ± 0.00**
	100.00* / 30	**≥4.00 ± 0.00**
Murine norovirus, strain S99 Berlin, FLI-RVB-0651	100.00* / 15	**≥5.00 ± 0.00**
	100.00* / 30	**≥5.00 ± 0.00**

* The product can only be tested at 97.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

saniswiss SAFE HYGIENE SOLUTIONS

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Saniswiss SA
Chemin des Tulipiers 19
1208 Geneva
Switzerland

Efficacy of Saniswiss SANITIZER HANDS H1 against *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5 and *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651 in a quantitative suspension test at 20 °C according to EN14476:2013+A1:2015 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-19-3072 dated 29 July 2019.

The virucidal activity of the disinfectant Saniswiss SANITIZER HANDS H1 of Saniswiss SA against *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5 and *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651 was investigated by a quantitative suspension test according to EN14476:2013+A1:2015 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal activity if the virus titre is reduced by ≥ 4 log_{10} (inactivation ≥99.99 %) within the recommended exposure period.

Saniswiss SANITIZER HANDS H1 was examined at 20 °C at the concentration of 100.00 %** for the exposure time of 15 and 30 seconds. After the exposure times, the viral reduction exceeded 4 log_{10}-steps in all assays. Therefore, virucidal activity against *Adenovirus 5*, strain Adenoid 75, ATCC VR-5 and *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651 was measured as follow:

Clean condition	100.00 %**	15 seconds
Clean condition	100.00 %**	30 seconds

Kuala Lumpur, 29 July 2019

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Dr Cheng Shoou Lee
Head of Microbiological Testing

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

** The product can only be tested at 97.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)

Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1

Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-19-3072 dated 29 July 2019 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 29 July 2019

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Date: 2019.08.02 09:32:23 +08'00'

Zhao Min Khoo
Microbiologist

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saniswiss SAFE HYGIENE SOLUTIONS

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)

Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1

Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 2 Raw data

Test Method	EN 14476:2013+A1:2015			**Titration Method**	Quantal test		
Product	Saniswiss SANITIZER HANDS H1			**Batch No.**	N/A		
Product Diluent	Distilled water			**Lab No.**	VX-43-19-0002		
Test Organism	Adenovirus, strain Adenoid 75, ATCC VR-5			**Passage No.**	5		
Cell Line	Vero cells, ATCC CCL-81			**Passage No.**	17		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution		
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard		
First Assay Test Date	09/07/2019	**Second Assay Test Date**	10/07/2019	**Analyzed By**	SSU	**Verified By**	ZKH

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 0 0 0 4 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.75 ± 0.33	Pass? **Yes**
	100.00%	1:1000	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00%	30	t t t t t t t t	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	Pass? **Yes**
	Virus Control (V_C)	30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.88 ± 0.37	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	4.50 ± 0.00	3.00 ± 0.00
		60	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 0 0 4 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	4.00 ± 0.38	3.50 ± 0.38
	Virus Control (V_C)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	7.50 ± 0.00	
		60	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	7.50 ± 0.00	
	Cytotoxicity Effect (CE)	–	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	n.d.	2.50 ± 0.00	

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Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (seconds)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00%	15	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C1} - CE ≥ 4
	100.00 %	30	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
		30	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	–	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0		n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (seconds)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00%	15	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C2} - CE ≥ 4
	100.00 %	30	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
		30	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	–	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0		n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (seconds)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	First Assay (Na_1) lg $R_1 = V_{C1}$ - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	Second Assay (Na_2) lg $R_2 = V_{C2}$ - Na_2	Average Reduction (lg R)
	100.00%	15	≤1.50 ± 0.00	≥4.00 ± 0.00	≤1.50 ± 0.00	≥4.00 ± 0.00	≥4.00 ± 0.00
	100.00 %	30	≤1.50 ± 0.00	≥4.00 ± 0.00	≤1.50 ± 0.00	≥4.00 ± 0.00	≥4.00 ± 0.00

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

saniswiss SAFE HYGIENE SOLUTIONS

Description: Testing the efficacy of chemical disinfectants and antiseptics (EN 14476)
Lab No.: VX-43-19-0002
Test Period: 9 July – 23 July 2019
Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 2 Raw data

Test Method	EN 14476:2013+A1:2015			**Titration Method**	Quantal test	
Product	Saniswiss SANITIZER HANDS H1			**Batch No.**	N/A	
Product Diluent	Distilled water			**Lab No.**	VX-43-19-0002	
Test Organism	Murine norovirus, strain S99 Berlin			**Passage No.**	4	
Cell Line	RAW 264.7 cells, ATCC TIB-71			**Passage No.**	12	
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution	
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard	
First Assay Test Date	09/07/2019	**Second Assay Test Date**	10/07/2019	**Analyzed By**	SSU	**Verified By** ZKH

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 0 / 4 4 4 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	7.25 ± 0.33	Pass? **Yes**
	100.00%	1:1000	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	7.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00%	30	t t t t / t t t t	t t t t / t t t t	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 0 0 / 4 4 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	7.00 ± 0.38	Pass? **Yes**
	Virus Control (V_C)	30	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 0 0 / 4 4 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	7.00 ± 0.38	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t / t t t t	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	3.50 ± 0.00	6.00 ± 0.00
		60	t t t t / t t t t	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	3.50 ± 0.00	6.00 ± 0.00
	Virus Control (V_C)	0	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	n.d.	9.50 ± 0.00	
		60	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	0 0 0 0 / 0 0 0 0	n.d.	9.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	t t t t / t t t t	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	n.d.	n.d.	2.50 ± 0.00	

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

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Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (seconds)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00%	15	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C1} - CE ≥ 4
	100.00 %	30	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	6.50 ± 0.00	
		30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	6.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (seconds)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00%	15	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C2} - CE ≥ 4
	100.00 %	30	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	6.50 ± 0.00	
		30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	6.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (seconds)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	First Assay (Na_1) lg $R_1 = V_{C1}$ - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	Second Assay (Na_2) lg $R_2 = V_{C2}$ - Na_2	Average Reduction (lg R)
	100.00%	15	≤1.50 ± 0.00	≥5.00 ± 0.00	≤1.50 ± 0.00	≥5.00 ± 0.00	≥5.00 ± 0.00
	100.00 %	30	≤1.50 ± 0.00	≥5.00 ± 0.00	≤1.50 ± 0.00	≥5.00 ± 0.00	≥5.00 ± 0.00

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

saniswiss SAFE HYGIENE SOLUTIONS

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Test Report No.: VX-TR-19-3072
Report Date: 31 July 2019
Copy No.: 1
Client Name: Saniswiss SA
Sample Name: Saniswiss SANITIZER HANDS H1
Batch No.: Not specified
Sample Receipt Date: 3 May 2019

Appendix 3 Summary of test description

1. Virus and cells

1.1. *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5
- 1.1.1. Passage no.: 5
- 1.1.2. Cell line: Vero cells, ATCC CCL-81
- 1.1.3. Cell line passage no.: 17
- 1.1.4. Culture medium: EMEM

1.2. *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651
- 1.2.1. Passage no.: 4
- 1.2.2. Cell line: RAW 264.7 cells, ATCC TIB-71
- 1.2.3. Cell line passage no.: 12
- 1.2.4. Culture medium: DMEM

2. Materials and reagents

2.1. Eagle's Minimal Essential Medium (EMEM, Sigma, catalogue no. SLBW4162)
2.2. Dulbecco's Modified Eagle Medium (DMEM, Sigma, catalogue no. SLBZ1832)
2.3. Fetal Bovine Serum (FBS, Sigma, catalogue no. BCBX0613)
2.4. Formaldehyde (Merck, catalogue no. 1.0.4003.2500)
2.5. Dulbecco's Phosphate Buffered Saline (PBS, Biowest, catalogue no. L0615)
2.6. Bovine albumin fraction V (Merck, catalogue no. 1.12018.0100)

3. Apparatus and glassware

3.1. CO_2 incubator (Memmert, model ICO 105)
3.2. Cooling water bath (Memmert, model WNB7 with CDP115)
3.3. Inverted microscope (Optika, IM-2)
3.4. Vortex® mixer (Biosan model Biosan V-1 Plus)
3.5. Microtitre plate (NEST)
3.6. Tissue culture flask (Corning)

Test procedure accredited according to MS ISO/IEC 17025. The test report shall not be reproduced except in full without the written approval of the laboratory. The test result relates only to the sample stated in the test report. The above analysis is based solely on the sample submitted by the customer. Information on measurement uncertainty is available upon request.

4. Test procedure

4.1. **Preparation of test virus suspension**

4.1.1. Cell monolayers shall be >90 % confluent before inoculation. Cell lines are selected in accordance with their sensitivity to the test organisms.

4.1.2. The test organisms and their stock cultures shall be prepared and kept in accordance with EN 12353:2013 (E).

4.1.3. The stock virus suspension is multiplied in an appropriate cell line that produces high titres of infectious viruses for 1 hour at 36 °C with intermittent tilting every 15 minutes.

4.1.4. The cells are subjected to 3 freeze/thaw cycles once cytopathic effect (CPE) is observed in 80 % of the cell population.

4.1.5. Separate the cells debris is by centrifugation at 400 g_N for 15 minutes.

4.1.6. Aliquot the supernatant containing the test virus suspension and store at -80 °C.

4.2. **Test Na – Determination of virucidal concentrations**

4.2.1. Pipette 1 ml of interfering substance into a container of suitable capacity for appropriate mixing.

4.2.2. Add 1 ml of the virus test suspension to the container, carefully avoiding the upper part of the sides. Mix well.

4.2.3. Add 8 ml of the product test solution to the container.

4.2.4. Mix, start a stopwatch at once, and place the container in a water bath controlled at the chosen test temperature.

4.2.5. Immediately at the end of the chosen contact time, mix, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml ice-cold maintenance medium and put into an ice bath.

4.2.6. Within 30 minutes, prepare a series of ten-fold dilutions of this mixture (text mixture and maintenance medium).

4.2.7. Transfer 0.1 ml of each dilution into six or eight wells of a microtitre plate containing a confluent (>90 %) cell monolayer without any medium.

4.2.8. The last row of six or eight wells will receive 0.1 ml of culture medium and will serve as the cell control.

4.2.9. After 1 hour of incubation at 37 °C, 0.1 ml of cell culture medium is added to each well.

4.2.10. After incubation, the virus titre is calculated. The reduction of virus infectivity is determined from differences of $\log_{10}$ virus titres before and after treatment with the product.

4.3. **Cytotoxicity effect – determination of the morphological alteration of cells caused by the product test solution**

4.3.1. Mix 1 part of hard water and 1 part of interfering substances with 8 parts of the product test solution.

4.3.2. Serial dilutions are prepared in the culture medium and are inoculated into cell monolayers.

4.3.3. This test is done in parallel with Section 4.2.

4.3.4. Any microscopic changes in the cells are recorded when reading the tests for CPE.

4.3.5. If the cytotoxicity is so great that the residual infectivity titre is smaller than the required $\log_{10}$ $TCID_{50}$, special techniques have to be used, such as molecular sieving or ultrafiltration. Follow the instructions of the manufacturer.

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4.4. **Cell susceptibility control A – Verification of the susceptibility of the cells for virus infection is not influenced negatively by the treatment with the product test solution**

4.4.1. Comparative virus titrations are performed on cells that have or have not been treated with product test solution to check the reduction of the sensitivity to viruses.

4.4.2. 0.1 ml of the lowest apparently non-cytotoxic dilution (no microscopic alteration) of the product test solution or PBS and 0.1 ml of culture medium are distributed onto each of 6 established cell cultures in 96-well microtitre plates.

4.4.3. After 1 hour of incubation at 37 °C, the supernatant is discarded.

4.4.4. The virus is diluted from 10^{-1} to 10^{-10} and titrated on the treated or untreated cells.

4.4.5. Verify according to Section 4.8.

4.5. **Suppression efficiency control B – Immediate dilution method validation**

4.5.1. Immediately after preparation of the test mixture in Section 4.2, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml of ice-cold maintenance medium.

4.5.2. Mix again and start the clock. Incubate the mixture in the ice bath for 30 minutes ± 10 seconds.

4.5.3. Immediately prepare dilutions up to 10^{-8} and titrate the virus.

4.5.4. This control is performed in parallel to the test.

4.5.5. Verify according to Section 4.8.

4.6. **Reference test for virus inactivation C – Validation of the test system**

4.6.1. 2 ml of the test suspension shall be mixed with 8 ml of PBS and 10 ml of 1.4 % (w/v) formaldehyde.

4.6.2. Contact times are 30 and 60 minutes.

4.6.3. Immediately at the end of the contact time, mix and pipette 0.2 ml of the test mixture into a tube containing 1.8 ml ice-cold maintenance medium followed by a further 10-fold dilution.

4.6.4. Leave the mixture in the ice bath.

4.6.5. Dilutions up to 10^{-6} are prepared by pipetting the diluted test mixture into another tube containing ice-cold maintenance medium in the ice bath.

4.6.6. In exceptional cases, smaller volumes of the reagents and of the test suspension could be used, ensuring that the relative proportions are maintained.

4.6.7. The cytotoxic control of the formaldehyde shall be performed according to Section 4.3 whereby 8 ml of 1.4 % (w/v) formaldehyde is used instead of the product.

4.6.8. The mixture is further diluted to 10^{-5} in an ice bath.

4.6.9. Verify according to Section 4.8.

4.7. **Titration of the virus control**

4.7.1. The infectivity of the test suspension shall be determined under test conditions at the beginning of the contact time and at the maximum contact time used in the test.

4.7.2. Section 4.2 is repeated by substituting the product test solution with hard water or water for ready-to-use products.

4.7.3. Verify according to Section 4.8.

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4.8. **Verification of methodology**

4.8.1. The titre of the test suspension (virus control) of at least 10^8 $TCID_{50}$/mL is sufficiently high to at least enable a titre reduction of 4 log to verify the method. The detectable titre reduction shall be at least 4 log.

4.8.2. Cytotoxicity of the product test solution does not affect cell morphology and growth or susceptibility for the test organism in the dilutions of the test mixtures which are necessary to demonstrate a 4-log reduction of the virus.

4.8.3. Comparative virus titration on cells cultures treated with test mixture dilutions and in parallel with PBS (cell susceptibility control) result in a difference of <1 log of virus titre.

4.8.4. The difference to the test suspension in the control of efficiency for suppression of products' activity shall be ≤0.5 log.

4.8.5. The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test is:

4.8.5.1. Between -0.5 and -2.5 after 30 minutes and between -2 and -4.5 after 60 minutes for poliovirus

4.8.5.2. Between -3 and -5 after 30 minutes and between -3.5 and -5.5 after 60 minutes for adenovirus

4.8.5.3. Between 0.0 and -2.0 after 30 minutes and between -0.5 and -2.5 after 60 minutes for parvovirus

4.8.5.4. Between -0.75 and -3.5 after 20 and 30 minutes and between -2.0 and ≥-4.0 after 120 and 30 minutes for vacciniavirus.

5. Literature

5.1. EN 14476:2013+A1:2015 (E): Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)

5.2. EN 14885:2015 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

5.3. EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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[redacted]

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

10.09.2015

Test report C15L0111A

Evaluation of the effectiveness of

1592 – Saniswiss biosanitizer H1

Test virus: adenovirus type 5

Method: EN 14476:2013

quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine

TEST REPORT

Sponsor:
Saniswiss SA
Chemin des Tulipiers 19
CH – 1208 Geneva

Norderoog 2, D - 28259 Bremen
Tel.: +49 421-2781910 2, Fax: +49 421-2760283
info@brillhygiene.com , http://www.brillhygiene.com

saniswiss SAFE HYGIENE SOLUTIONS

1. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, DE - 28259 Bremen

2. Identification of sample

Manufacturer	Saniswiss SA
Name of product	1592 (Saniswiss biosanitizer H1)
Product diluent recommended by the manufacturer	-
Batch number	PR195-F10
Application	-
Production date	02.03.2015
Expiry date	-
Active compound (s) (kg)	72 % (w/w) ethanol
Appearance, odour	clear, colorless liquid, alcoholic
pH-values	not applicable
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	09.03.2015

3. Materials

3.1 Culture medium and reagents

- Eagle's Minimum Essential Medium with Earle's BSS (EMEM, Biozym Scientific GmbH, catalogue no. 880121)
- fetal calf serum (Biochrom AG, article no. S 0115)
- 1.4 % formaldehyde solution (dilution of Roti®-Histofix 4 %, Carl Roth GmbH)
- Aqua bidest. (SG ultrapure water system, type Ultra Clear; serial no. 86996-1)
- PBS (Invitrogen, article no. 18912-014)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153).

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, 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 2015

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Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-306.10.31

3.2 Virus and cells

The adenovirus type 5 strain adenoid 75 was obtained from PD Dr. A. Heim, Institute of Medical Virology, Hannover Medical School, Hannover, Germany. Before the inactivation assays, the virus had been passaged 3 times in *A549 cells* (human lung epithelial carcinoma cells).

The *A549 cells* (passage 121) originated from Vircell, S.L., Spain, 18320 Santa Fe (now BIOTRIN International GmbH, D-69126 Heidelberg).

The cells were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

3.3 Apparatus, glassware and small items of equipment

- CO_2 incubator, Nunc GmbH & Co. KG, model QWJ 350
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)
- Polysterol 96-well microtitre plate (Nunc GmbH & Co. KG, Wiesbaden)
- Cell culture flask (Nunc GmbH & Co. KG, Wiesbaden)
- Sealed test tubes (Sarstedt AG & Co., Nümbrecht).

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4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	undiluted (80.0 %) and as 50.0 %, 25.0% and 10.0 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	30 and 60 seconds and 30 minutes
Interfering substance	0.3 g/l bovine serum albumin (clean conditions EN 14476:2013)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water
Stability of product in the mix with virus and interfering substance (80.0 % solution)	no flocculation, minor precipitation
Virus strain	adenovirus type 5 strain adenoid 75 (ATCC VR-5)
Date of testing	09.03.2015– 10.07.2015
End of testing	10.09.2015

5. Methods

5.1 Preparation of test virus suspension

For preparation of test virus suspension according to EN 5.4.1 *A549 cells* were infected with a multiplicity of infection of 0.1 at 37 °C. After cells showed a cytopathic effect, they were subjected to a threefold freeze/thaw procedure followed by a low speed centrifugation in order to sediment cell debris. After aliquotation of the supernatant, test virus suspension was stored at -80 °C.

5.2 Preparation of disinfectant (dilutions)

The test product was evaluated undiluted. Due to the addition of test virus suspension and interfering substance an 80.0 % solution resulted.

Furthermore, the product was evaluated as 50.0 %, 25.0 % and 10.0 % solutions (demonstration of non-active range). These solutions were prepared with water immediately before the inactivation tests.

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5.3 Infectivity assay

Infectivity was determined as endpoint titration according to EN 5.5 transferring 0.1 ml of each dilution into eight wells of a microtitre plate, beginning with the highest dilution. This was followed by the addition of 0.1 ml of freshly trypsinized *A549 cells*. This cell suspension was adjusted to reach 10-15 x 10^3 cells per well. Microtitre plates were incubated at 37 °C in a 5 % CO_2-atmosphere. The cytopathic effect was read by using an inverted microscope after ten days. Calculation of the infective dose $TCID_{50}$/ml was calculated with the method of Spearman (2) and Kärber (3) with the following formula:

$$- \log_{10} TCID_{50} = X_0 - 0.5 + \sum r/n$$

meaning

X_0 = $\log_{10}$ of the lowest dilution with 100 % positive reaction

r = number of pos. determinations of lowest dilution step with 100 % positive and all higher positive dilution steps
n = number of determinations for each dilution step.

5.4 Calculation and verification of virucidal activity

The virucidal activity of the test disinfectant was evaluated by calculating the decrease in titre in comparison with the control titration without disinfectant. The difference is given as reduction factor (RF).

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by four $\log_{10}$ steps within the recommended exposure period. This corresponds to an inactivation of ≥ 99.99 %.

5.5 Inactivation assay

Determination of virucidal activity has been carried out in accordance to EN 5.5. The test product was examined undiluted (80.0 %) and as 50.0 %, 25.0 % and 10.0 % (demonstration of non-active range) solutions in water at 20 °C according to EN 14476:2013. 30 and 60 seconds and 30 minutes were chosen as contact times.

Immediately at the end of a chosen contact time, activity of the disinfectant was stopped by dilution to 10^{-8}.

Titrations of the virus control were performed after the longest exposure time (EN 5.5.7).

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Furthermore, a cell control (only addition of medium) was incorporated.

Inactivation tests were carried out in sealed test tubes in a water bath at 20 °C ± 1.0 °C. Aliquots were retained after appropriate exposure times and residual infectivity was determined.

5.6 Determination of cytotoxicity

Determination of cytotoxicity was performed according to EN 5.5.4.1.

5.7 Cell sensitivity to virus

For the control of cell sensitivity was performed according to EN 5.5.4.2b.
Here, finally, a comparative titration of the test virus suspension was performed on the pre-treated (disinfectant) and non-pre-treated (PBS) cells as described above.

5.8 Control of efficacy for suppression of disinfectant's activity

Furthermore, a control of efficiency for suppression of disinfectant's activity was included (EN 5.5.5).

5.9 Reference virus inactivation test

As reference for test validation a 0.7 % formaldehyde solution according to EN 5.5.6 was included. 5, 15, 30 and 60 minutes were chosen as contact times. In addition, cytotoxicity of formaldehyde test solution was determined following EN 5.5.6.2 with dilutions up to 10^{-5}.

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6. Verification of the methodology

The following criteria as mentioned in EN 5.7 were fulfilled:

a) The titre of the test virus suspension allowed the determination of a ≥ 4 $\log_{10}$ reduction (maximal virus reduction ≥ 5.13 ± 0.41).

b) The test product (undiluted) showed cytotoxicity in the 1:10 dilutions thus allowing the detection of a 4 $\log_{10}$ reduction of virus titre.

c) The difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test (see EN 5.7b) was ≥ 4.13 ± 0.29 (between 3.0 – 5.0) after 30 min and ≥ 4.13 ± 0.29 (between 3.5 – 5.5) after 60 min for adenovirus type 5.

d) The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) *A549 cells* showed no significant difference (< 1 $\log_{10}$; EN 5.7) of virus titre: 7.63 ± 0.25 (PBS) versus 7.63 ± 0.49 $\log_{10}TCID_{50}$/ml.

e) The control of efficacy for suppression of disinfectant's activity showed no decrease (< 0.5 $\log_{10}$; EN 5.5.5.1) in virus titre (7.63 ± 0.49 versus 7.63 ± 0.41 $\log_{10}TCID_{50}$/ml).

f) One concentration demonstrated a 4 $\log_{10}$ reduction and (at least) one concentration demonstrated a $\log_{10}$ reduction of less than 4.

Since all criteria according EN 5.7 were fulfilled, examination with adenovirus type 5 according to EN 14476:2013 is valid.

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

Author JS Version 02 Test report no C15L0111A
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Product name : 1592
Method EN 14476:2013*

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7. Results

Results of examination are shown in tables 1 to 10. Tables 1 to 9 demonstrate the raw data, whereas table 10 (a+b) gives a summary of results.

The undiluted test product (80.0 %) was able to inactivate adenovirus type 5 after 0.5 minutes in this quantitative suspension test. The reduction factor was ≥ 5.13 ± 0.41 (Table 3). This corresponded to an inactivation of ≥ 99.999 %.

Tested as 50.0 % solution the test product was not active within 30 seconds of exposure time (Table 4).

Examined as 10.0 % solution the test product was not active within 30 minutes of exposure time (Table 6).

8. Conclusion

The disinfectant 1592 tested undiluted demonstrated effectiveness against adenovirus type 5 after an exposure time of 30 seconds under clean conditions.
Therefore, the disinfectant 1592 can be declared as active against adenovirus type 5 as follows:

undiluted 30 seconds

Bremen, 10.09.2015

- Dr. Jochen Steinmann -
Scientific Director

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9. Quality control

The Quality Assurance of the results was maintained by performing the determination of the virus-inactivating properties of the disinfectant in accordance with Good Laboratory Practice regulations:

1) Chemicals Act of Germany, Appendix 1, dating of 01.08 1994 (BGBl. I, 1994, page 1703). Appendix revised at 14. 05. 1997 (BGBl. I, 1997, page 1060).
2) OECD Principles of Good Laboratory Practice (revised 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. Environment Directorate, Organization for Economic Co-operation and Development, Paris 1998.

The plausibility of the results was additionally confirmed by controls incorporated in the inactivation assays.

10. Records to be maintained

All testing data, protocol, protocol modifications, the final report, and correspondence between Dr. Brill + Partner GmbH and the sponsor will be stored in the archives at Dr. Brill + Partner GmbH.

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11. Literature

1. EN 14476:2013: Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemicals disinfectants and antiseptics in human medicine test - Test method and requirements (phase 2, step 1)

2. Spearman, C.: The method of `right or wrong cases` (constant stimuli) without Gauss's formulae.
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3. Kärber, G.: Beitrag zur kollektiven Behandlung pharmakologischer Reihenversuche.
Arch Exp Path Pharmak; 162, 1931, 480-487

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Appendix:

Legend to the Tables

Legend to the Figures

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Table 1: Raw data for 1592 (80.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (3965)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10}) 1	2	3	4	5	6	7	8	9
test product	80.0%	clean conditions	0,5	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			1	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	80.0%	clean conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3444 0333	0030 0000	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3323 3440	0004 2000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
ADENOVIRUS TYPE 5

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

Author JS Version 02 Test report no C15L0111A Date 10/09/2015 Product name 1592 Method EN 14476:2013*

Table 2: Raw data for 1592 (50.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (3965)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})									
				1	2	3	4	5	6	7	8	9	
test product	50.0%	clean conditions	0.5	4444 4444	4444 4444	4330 3423	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	
			1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
			2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
			5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
test product cytotoxicity	50.0%	clean conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3444 0333	0030 0000	0000 0000	0000 0000	
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3323 3440	0004 2000	0000 0000	0000 0000	

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Table 2: Raw data for 1592 (50.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (3965)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})									
				1	2	3	4	5	6	7	8	9	
test product	25.0%	clean conditions	0.5	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4303 4232	0300 3000	0000 0000	n.d.	
			1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
			2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
			5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
test product cytotoxicity	25.0%	clean conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3444 0333	0030 0000	0000 0000	0000 0000	
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3323 3440	0004 2000	0000 0000	0000 0000	

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1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 2: Raw data for 1592 (50.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (3965)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10}) 1	2	3	4	5	6	7	8	9
test product	10.0.%	clean conditions	0.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	4444 4444	4 1 4 1	4444 4444	4444 4444	4444 4444	1322 3333	0300 0000	0000 0000	n.d.
test product cytotoxicity	10.0%	clean conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3444 0333	0030 0000	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3323 3440	0004 2000	0000 0000	0000 0000

n.a. = not applicable
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0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Author JS Version 02 Test report no C15L0111A Date 10/09/2015 Product name 1592 Method EN 14476:2013*

Table 5: Raw data for formaldehyde solution (0.7 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (3965)

Product	Concentration	Interfering substance	(min)	Dilutions (log_{10}) 1	2	3	4	5	6	7	8	9
formaldehyde	0.7% (m/V)	PBS	5	tttt tttt	tttt tttt	4444 4444	4444 3443	4440 0343	0000 0000	0000 0000	0000 0000	n.d.
			15	tttt tttt	tttt tttt	2230 2232	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			30	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			60	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
formaldehyde cytotoxicity	0.7% (m/V)	PBS	n.a.	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	PBS	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3344 0223	0000 0302	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 6: Raw data for control of efficacy for suppression of disinfectant's activity (3965)

Product	Interfering substance	dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
test product	PBS	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	clean conditions	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4300 3423	0000 2230	0000 0000	n.d.
test product	dirty conditions	n.d.	n.d.	n.d.	n.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, 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 2015

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ZLG-AP-306.10.31

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Table 7: Raw data (adenovirus type 5) for cell sensitivity (3965)

Product	Dilution	Dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
PBS	-	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4423 3334	0000 1000	0000 0000	n.d.
test product	1:10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:100	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4334 2300	0300 3001	0000 0000	n.d.
test product	1:1,000	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013 ADENOVIRUS TYPE 5

Table 7: Raw data (adenovirus type 5) for cell sensitivity (3965)

Product	Concentration	Interfering substance	Level of cytotoxicity	$\log_{10}$ $TCID_{50}$/ml after ... min					> 4 $\log_{10}$ reduction after ... min
				0.5	1	2	30	60	
test product	80.0%	clean conditions	2.50	≤2.50±0.00	≤2.50±0.00	n.d.	n.d.	n.d.	0.5 (RF ≥ 5.13±0.41)
test product	50.0%	clean conditions	1.50	4.38±0.25	n.d.	n.d.	n.d.	n.d.	>0.5 (RF 3.25±0,48)
test product	25.0%	clean conditions	1.50	7.63±0.41	n.d.	n.d.	n.d.	n.d.	> 0.5
test product	10.0%	clean conditions	1.50	n.d.	n.d.	n.d.	7.63±0.25	n.d.	> 30

n.a. = not applicable n.d. = not done

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013 ADENOVIRUS TYPE 5

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

Author JS Version 02 Test report no C15L0111A Date 10/09/2015 Product name 1592 Method EN 14476:2013*

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Table 7: Raw data (adenovirus type 5) for cell sensitivity (3965)

Product	Concentration	Interfering substance	Level of cytotoxicity	$\log_{10}$ $TCID_{50}$/ml after ... min					> 4 $\log_{10}$ reduction after ... min
				0	5	15	30	60	
formaldehyde	0.7% (w/v)	PBS	3.50	n.d.	6.25±0.33	4.38±0.25	≤3.50±0.00	≤3.50±0.00	30 (RF ≥4.13±0.29)
virus contr.	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	7.63±0.41	n.a.
virus contr.	80.0%	clean conditions	n.a	7.50±0.35	n.d.	n.d.	n.d.	7.63±0.41	n.a.
suppression control	80.0%	clean conditions	2.50	n.d.	n.d.	n.d.	n.d.	7.63±0.41	n.a.
sens.control PBS	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	7.63±0.25	n.a.
sens. control test product	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	7.63±0.49	n.a.

n.a. = not applicable n.d. = not done sens. = sensitivity

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test repot 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 2015

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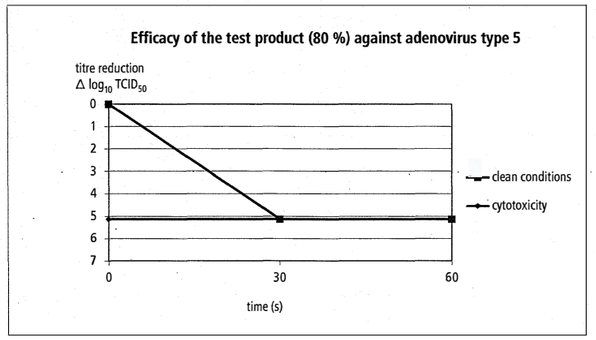
VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
ADENOVIRUS TYPE 5

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

Author JS Version 02 Test report no C15L0111A Date 10/09/2015
Product name 1592
Method EN 14476:2013*

Figure 1: Virus-inactivating properties of 1592 (80.0 %)



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saniswiss SAFE HYGIENE SOLUTIONS

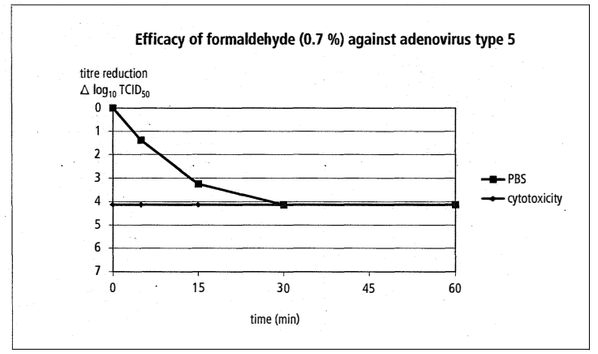
VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
ADENOVIRUS TYPE 5

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

Author JS Version 02 Test report no C15L0111A Date 10/09/2015
Product name 1592
Method EN 14476:2013*

Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)



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Certificate CH21/0060

The management system of

Saniswiss SA

Route de Frontenex 41A
CH - 1207 Genève

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Consulting in design and development of disinfectant for invasive and non-invasive medical devices
Distribution and sales of disinfectant for invasive and non-invasive medical devices

This certificate is valid from 11 January 2021 until 10 January 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 15 December 2023
Issue 1. Certified since January 2021

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 **f** +44 (0)151 350-6600 www.sgs.com

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Certificate CH21/0075

The management system of

Saniswiss SA

Route de Frontenex 41A
CH-1207 Geneva

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, development, manufacturing, sales and distribution of hygiene and disinfectant products.

This certificate is valid from 19 January 2021 until 18 January 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due 60 days prior to expiry date.
Issue 1. Certified since January 2021.

Authorised by

SGS Société Générale de Surveillance SA
Technoparkstrasse 1 8005 Zurich Switzerland
t +41 (0)44 445-16-80 f +41 (0)44 445-16-88 www.sgs.com

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Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Notification authority for chemicals

CH-3003 Bern, FOPH **A-Priority**

SANISWISS SA
Route de Frontenex 41A
1207 Genève

Reference: **562028-68**
Your Ref.:
Our Ref.: BLO / LEI
Bern, March 21, 2022

Certificate of Registration in Switzerland

We confirm that the following biocidal product is authorised in Switzerland

Name of product	CPID Number	Authorisation Number
Saniswiss Sanitizer Hands H1	562028-68	CHZN4503

This biocidal product is allowed to be placed on the Swiss market by **SANISWISS SA**, **Genève**, pursuant to article 7 paragraph 1 letter c and article 13 of the Swiss Ordinance on Biocidal Products (OBP; SR 813.12).

Kind regards

Notification Authority for Chemicals
Scientific assistant

Dr. Olivier Blaser

FEDERAL OFFICE OF PUBLIC HEALTH

Federal Office of Public Health
Notification authority for chemicals
Schwarzenburgstrasse 157, CH-3003 Bern
Tel. +41 58 462 73 05
cheminfo@bag.admin.ch
www.notificationauthority.admin.ch

SANISWISS SANITIZER HANDS H1

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Review date: 26/10/2021 Supersedes: 27/02/2014

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. PRODUCT IDENTIFIER

Product form : Mixture
Product name : Saniswiss SANITIZER HANDS H1
Product code : 132117, 132072, 132073, 132127, 132081, 132167, 132074, 132151

Product group : Mixture

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

1.2.1. Relevant identified uses

Main use category : Professional use
Description/Application : hydroalcoholic gel

1.2.2. Uses advised against

No additional information available

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Saniswiss SA
Route de Frontenex 41A
1207 Genève - Switzerland
t 41 22 718 75 75 - f 41 22 718 75 76 (during business hours Monday – Friday)
info@saniswiss.ch

1.4. EMERGENCY TELEPHONE NUMBER

Country	Organisation/Company	Address	Emergency number
Switzerland	Tox Info Suisse	Freiestrasse 16 8032 Zürich	+41 44 251 51 51

SECTION 2: HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flam. Liq. 2 H225

Eye Irrit. 2 H319

Aquatic Chronic 3 H412

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. LABEL ELEMENTS

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS02

GHS07

CLP Signal word : Danger
Hazard statements (CLP) : H225 - Highly flammable liquid and vapour
H319 - Causes serious eye irritation
H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, open flames, sparks. - No smoking
P273 - Avoid release to the environment
P280 - Wear eye protection

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 - If eye irritation persists: Get medical advice/attention
P403+P235 - Store in a well-ventilated place. Keep cool

2.3. OTHER HAZARDS

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. SUBSTANCE

Not applicable

3.2. MIXTURE

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ethanol	(CAS-no) 64-17-5 (Einecs nr) 200-578-6 (EG annex nr) 603-002-00-5 (REACH-no) 01-2119457610-43	50 - 80	F; R11
tetradecanol	(CAS-no) 112-72-1 (Einecs nr) 204-000-3 (REACH-no) 01-2119485910-33	< 1	Xi; R36

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol	(CAS-no) 64-17-5 (Einecs nr) 200-578-6 (EG annex nr) 603-002-00-5 (REACH-no) 01-2119457610-43	50 - 80	Flam. Liq. 2, H225 Eye Irrit. 2, H319
tetradecanol	(CAS-no) 112-72-1 (Einecs nr) 204-000-3 (REACH-no) 01-2119485910-33	< 1	Eye Irrit. 2, H319 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

General advice : In case of doubt or persistent symptoms, consult always a physician. For symptom description, see item 11.

Inhalation : Move to fresh air.

Skin contact : Rinse with water.

Eye contact : Wash with plenty of water and if necessary take medical advice.

Ingestion : Rinse mouth. Do not induce vomiting. Ask for medical advice.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Acute effects inhalation : No data available.

Acute effects skin : No data available.

Acute effects eyes : Causes serious eye irritation.

Acute effects oral route : No data available.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No additional information available

SECTION 5: FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media : Foam, powder, carbon dioxide (CO2), water spray.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

No additional information available

5.3. ADVICE FOR FIREFIGHTERS

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

6.1.1. For non-emergency personnel

Protective equipment : Concerning personal protective equipment to use, see section 8.

6.1.2. For emergency responders

No additional information available

6.2. ENVIRONMENTAL PRECAUTIONS

Prevent liquid from entering sewers, watercourses, underground or low areas.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Methods for cleaning up : Wash away remainder with plenty of water.

6.4. REFERENCE TO OTHER SECTIONS

No additional information available

SECTION 7: HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling : Do not eat, drink or smoke when using this product. Shower, eyes shower and water point in proximity.

Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage conditions : Store in original container. Protect from heat and direct sunlight.

Storage temperature : 5 - 30 °C

Material(s) to avoid : Not determined.

Storage area : Store in a cool area. Keep container in a well-ventilated place.

7.3. SPECIFIC END USE(S)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

Ethanol (64-17-5)		
France	VLE (mg/m³)	9500 mg/m³
France	VLE (ppm)	5000 ppm
France	VME (mg/m³)	1900 mg/m³
France	VME (ppm)	1000 ppm
Switzerland	VLE (mg/m³)	1920 mg/m³
Switzerland	VLE (ppm)	1000 ppm
Switzerland	VME (mg/m³)	960 mg/m³
Switzerland	VME (ppm)	500 ppm
Switzerland	Remark (CH)	4x15

Ethanol (64-17-5)	
DNEL/DMEL (Workers)	
Acute - systemic effects, inhalation	1900 mg/m³
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	950 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	87 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	114 mg/m³
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.96 mg/l
PNEC aqua (marine water)	0.79 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3.6 mg/kg dwt

Ethanol (64-17-5)	
PNEC sediment (marine water)	2.9 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.63 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.72 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	580 mg/l

8.2. EXPOSURE CONTROLS

Hand protection : No.
Eye protection : safety goggles (EN 166).
Protective equipment : No special required clothing.
Respiratory protection : No.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Liquid
Physical state/form : viscous liquid.
Colour : Colourless.
Odour : alcohol odour.
Odour threshold : No data available
pH : 7.5 - 8.5
Relative evaporation rate (butylacetate=1) : No data available
Melting point/range : No data available
Freezing point : No data available
Boiling point/Boiling range : > 35 °C
Flash point : = 20 °C
Autoignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : 0.863 - 0.873 (20°C)
Solubility : Water: 100 % 20°C
Log Pow : No data available
Log Kow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. OTHER INFORMATION

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY

No additional information available

10.2. CHEMICAL STABILITY

Stable in use and storage conditions as recommended in item 7.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

No additional information available

10.4. CONDITIONS TO AVOID

Heat. Direct sunlight.

10.5. INCOMPATIBLE MATERIALS

Do not mix with other products. Strong oxidizing agents.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide. nitrogen oxides (NOx).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity : Not classified

Ethanol (64-17-5)	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg

Skin corrosion/irritation : Not classified
pH: 7.5 - 8.5

Serious eye damage/irritation : Causes serious eye irritation.
pH: 7.5 - 8.5

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1. TOXICITY

Ecology - general : Harmful to aquatic life with long lasting effects.

tetradecanol (112-72-1)	
NOEC (chronic)	> 0.001 (≤ 0.01) mg/l

Ethanol (64-17-5)	
LC50 fish 1	11200 mg/l
LC50 other aquatic organisms 1	> 10000 mg/l
ErC50 (algae)	275 mg/l

12.2. PERSISTENCE AND DEGRADABILITY

Ethanol (64-17-5)	
Biochemical oxygen demand (BOD)	0.1 g O_2 /g substance
Chemical oxygen demand (COD)	1.9 g O_2 /g substance

12.3. BIOACCUMULATIVE POTENTIAL

Ethanol (64-17-5)	
Log Kow	-0.3

12.4. MOBILITY IN SOIL

No additional information available

12.5. RESULTS OF PBT AND VPVB ASSESSMENT

Ethanol (64-17-5)
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. OTHER ADVERSE EFFECTS

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Regional legislation (waste)	:	Follow the local regulation.
Waste treatment methods	:	Dispose of in accordance with relevant local regulations.
Waste / unused products	:	Do not discharge into drains or the environment.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN NUMBER

UN-No. (ADR)	:	1993

14.2. UN PROPER SHIPPING NAME

Proper shipping name	:	Flammable liquid, N.S.A contains ethanol
Transport document description (ADR)	:	UN 1993 Flammable liquid, N.S.A contains ethanol, 3, III, (D/E)

14.3. TRANSPORT HAZARD CLASS(ES)

Class (ADR)	:	3
Danger labels (ADR)	:	3

14.4. PACKING GROUP

Packing group (ADR)	:	III

14.5. ENVIRONMENTAL HAZARDS

Other information	:	No supplementary information available.

14.6. SPECIAL PRECAUTIONS FOR USER

14.6.1. Overland transport

Classification code (ADR)	:	F1
Transport category (ADR)		3
Tunnel code	:	D/E
Limited quantities (ADR)		5l
LQ	:	LQ07
Excepted quantities (ADR)	:	E1

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Other information, restriction and prohibition regulations	:	Not affected by the conditions of restriction _ ANNEXE XVII.

15.1.2. National regulations

No additional information available

15.2. CHEMICAL SAFETY ASSESSMENT

No additional information available

SECTION 16: OTHER INFORMATION

Indication of changes:				
	2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	
	2.2	Label elements	Modified	
	8		Modified	
	11		Modified	
	12.		Modified	
	15		Modified	
	16		Modified	

Other information : It is recommended to pass the information of this safety data sheet, eventually in an appropriated form, to the users. Such information is actually to be best of our knowledge and believes accurate as reliable. This information relates to the specific material designated and may not be valid in combination with other product(s). EC Regulation 1272/2008 and its amendments.

Full text of R-, H- and EUH-statements:		
	Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
	Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
	Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
	Flam. Liq. 2	Flammable liquids, Category 2
	H225	Highly flammable liquid and vapour
	H319	Causes serious eye irritation
	H410	Very toxic to aquatic life with long lasting effects
	H412	Harmful to aquatic life with long lasting effects

It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product

saniswiss

sanitizer HANDS H1

SAFE™

VIRUCIDE 1 2 3 4 5 6 7 8 9 10

BIO ETHANOL

sanitizer HANDS H1

HAND SANITIZER, DÉSINFECTANT MAINS, HANDDESINFEKTIONSMITTEL, DEZINFECTANT PENTRU MÂINI

GEL

Efficacy Bactericidal: EN 1500, EN 12791 (Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Enterococcus hirae). Yeasticidal: EN 13727 (Candida albicans). Fungicidal: EN 13624 (Aspergillus brasiliensis). Mycobactericidal: EN 14348 (Mycobacterium avium, Mycobacterium terrae). Virucidal: EN 14476 (Norovirus, Poliovirus, Vaccinia virus, Adenovirus).
Composition Ethanol (CAS n° 64-17-5: 720mg/g), moisturizing agents and superfatting agents perfume-free, colorants-free. Made in France.

EN **Direction for use** For professional users, use on a dry, clean and healthy skin. Do not rinse. Hygienic disinfection: rub with a min. of 3 ml, a hollow of hand, during 30 sec. Surgical disinfection: rub with a min. of 2 x 3 ml, a hollow of hand, during 2 x 45 sec. **Precaution** The packaging must be eliminated as hazardous waste under the full responsibility of the holder of this waste. Do not empty residues into drains and watercourses. DANGER H225 - Highly flammable liquid and vapour. H319 - Causes serious eye irritation. H412 - Harmful to aquatic life with long lasting effects.

FR **Mode d'emploi** Usage réservé aux professionnels, employé pur sur une peau saine, propre et sèche. Ne pas rincer. Désinfection hygiénique : frictionner avec au min. 3 ml, un creux de main, durant 30 sec. Désinfection chirurgicale : frictionner avec au min. 2 x 3 ml, un creux de main, durant 2 x 45 sec. **Précautions** L'emballage doit être éliminé en tant que déchet dangereux sous l'entière responsabilité du détenteur de ce déchet. Ne pas jeter les résidus dans les égouts et les cours d'eau. **DANGER** H225 - Liquide et vapeurs très inflammables. H319 - Provoque une sévère irritation des yeux. H412 - Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme. Centre antipoisons BE : (+32) 070 245 245

DE **Anwendung** Für professionelle Nutzer, auf trockener, sauberer und gesunder Haut anwenden. Nicht spülen. Hygienische Desinfektion: Reiben Sie mit min. 3 ml, eine Handkuhle voll, während 30 Sek. Chirurgische Desinfektion: Reiben Sie mit min. 2 x 3 ml, eine Handkuhle voll, während 2 x 45 sec. **Hinweise** Die Verpackung muss als gefährlicher Abfall unter der vollen Verantwortung des Anwenders beseitigt werden. Die Rückstände nicht in die Kanalisation oder Wasserläufe entleeren. **GEFAHR** H225 - Flüssigkeit und Dampf leicht entzündbar. H319 - Verursacht schwere Augenreizung. H412 - Schädlich für Wasserorganismen, mit langfristiger Wirkung. Giftkontrollzentrum BE : (+32) 070 245 245

RO **Mod de utilizare** Numai pentru uz profesional, se utilizează pe o piele uscată, curată și sănătoasă. Nu clătiți. Dezinfecție igienică: aplicați minim 3 ml de produs și frecați mâinile timp de 30 de secunde. Dezinfecție chirurgicală: aplicați minim 2 x 3 ml de produs și frecați mâinile timp de 2 x 45 sec. **Atenție!** Ambalajul trebuie eliminat ca deșeu periculos pe răspunderea deplină a deținătorului acestui deșeu. Nu goliți reziduurile în canalizare și în cursurile de apă. **Pericol** H225 - Foarte periculos lichid și vapori extreme de inflamabili. H319 - Provoacă o iritație gravă a ochilor.

SAFE™

perfume-free, colorants-free, quats-free, aldehyde-free

REF 132167

LOT For LOT & EXP see bottle

1000 ml

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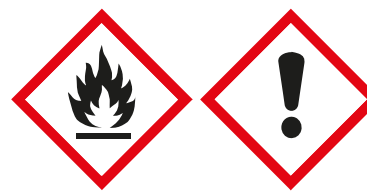

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saniswiss

sanitizer HANDS H1

SAFE™

VIRUCIDE
1 2 3 4 5 6 7 8 9 10

BIO ETHANOL

biosanitizer H1

SANITIZER

GEL

Spectrum Bactericide: EN 1500 (2013), EN 1040 (2006), EN 12791 (2016), EN 13727+A2 (2015). Yeasticide: EN 1275 (2006) *C. albicans*, EN 1650 (2008) *C. albicans*. Fongicide: EN 13624 (2013). Mycobactericide: EN 14348 (2005). Virucide: EN 14476+A1(2015) poliovirus, adenovirus, norovius. Activity complies with standard EN 14476 (2013) rotavirus, vaccinia virus, BVDV, influenza A / H1N1, influenza A / H5N1, HBV, HIV, HCV, coronavirus (incl. RSV), herpes virus.
Composition Ethanol (CAS n° 64-17-5 72% w/w), moisturizing agents and superfatting agents perfume-free, fragrance-free. Made in France.
Direction for use For professional users, use on a dry, clean and healthy skin. Do not rinse. Hygienic disinfection: rub with a min. of 3 ml, a hollow of hand, during 30 sec. Surgical disinfection: rub with a min. of 2 x 3 ml, a hollow of hand, during 2 x 45 sec.
Caution The packaging must be eliminated as hazardous waste under the full responsibility of the holder of this waste. Do not empty residues into drains and water-ways. Danger H225 - Highly flammable liquid and vapour. H319 - Causes serious eye irritation.

FR **Mode d'emploi** Usage réservé aux professionnels, employé pur sur une peau saine, propre et sèche. Ne pas rincer. Désinfection hygiénique: frictionner avec au min. 3 ml, un creux de main, durant 30 sec. Désinfection chirurgicale: frictionner avec au min. 2 x 3 ml, un creux de main, durant 2 x 45 sec.
Précautions L'emballage doit être éliminé en tant que déchet dangereux sous l'entière responsabilité du détenteur de ce déchet. Ne pas jeter les résidus dans les égouts et les cours d'eau. Danger H225 - Liquide et vapeurs très inflammables. H319 - Provoque une sévère irritation des yeux.

DE **Anwendung** Für professionelle Nutzer, auf trockener, sauberer und gesunden Haut anwenden. Nicht spülen. Hygienische Desinfektion: Reiben Sie mit min. 3 ml, eine Handkuhle voll, während 30 Sek. Chirurgische Desinfektion: Reiben Sie mit min. 2 x 3 ml, eine Handkuhle voll, während 2 x 45 Sek.
Hinweise Die Verpackung muss als gefährlicher Abfall unter der vollen Verantwortung des Anwenders beseitigt werden. Die Rückstände nicht in die Kanalisation oder Wasser-wege entleeren. Gefahr H225 - Flüssigkeit und Dampf leicht entzündbar. H319 - Verursacht schwere Augenreizung.

NL **Gebruiksaanwijzing** Voor professionele gebruikers, gebruik rechtstreeks op een droge, propere en gezonde huid. Niet spoelen. Hygiënische handontsmetting: inwrijven met een handpalm vol, min. 3 ml, gedurende 30 sec. Chirurgische handontsmetting: 2x inwrijven met een handpalm vol, min. 3 ml, gedurende 45 sec.
Voorzorgsmaatregelen De verpakking moet worden verwijderd als gevaarlijk afval onder de volledige verantwoordelijkheid van een specifieke afvalophaler. Gooi resten niet weg in de afvoeren en/of waterwegen. Gevaar H225 - Licht ontvlambare vloeistof en damp. H319 - Veroorzaakt ernstige oogirritatie.

SAFE™

perfume-free, colorants-free, quats-free, aldehyde-free, respectful to human health and environment

1000 ml

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biocide PT1 code 132167
sh1nl/1000 -102020

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S263-1/2018

DETERMINATION OF BACTERICIDAL (EN 13727:2012+A2:2015)
ACTIVITY OF THE PRODUCT **1592 (Saniswiss biosanitizer H1)**

Sample ID: S263/2018
Sample name: **1592 (Saniswiss biosanitizer H1)**
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva, Switzerland
Producer: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva, Switzerland
Sampling point: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva, Switzerland

Page: 1
From pages: 10

Incoming date:
10.10.2018

Delivery date:
14.2.2019

Hodonín, 14.2.2019

-2-
Chemila, spol. s.r.o.
Za Dráhou 4386/3
695 01 Hodonín
CZ
č. 1273

Ing. Jana Šlivová, Head of Laboratory

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BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 2

Subject of testing:
Determination of bactericidal of the product.

Identification of the sample:

Name of the product:	**1592**
Batch number:	1028413
Date of manufacture:	01.08.2018
Expiry date:	01/08/21
Manufacturer:	Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva
Incoming date:	10.10.2018
Storage conditions:	5 – 30 °C
Active compounds and concentrations:	CAS 64-17-5 Ethanol 50-80%

Experimental conditions: **Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method**
SOP-M-19-00 (EN 13727:2012+A2:2015)

Period of analysis:	30.10. – 31.10.2018	
Test temperature:	20 °C ± 1 °C	
Test method:	dilution neutralization method	
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062	
Appearance of the product:	colourless gel	
Test concentration:	100% (concentrated) *	
Contact time:	30 s	
Interfering substances:	0.3 g/l BSA (clean conditions)	
Test organisms:	*Pseudomonas aeruginosa*	ATCC 15442
	Staphylococcus aureus	ATCC 6538
	Enterococcus hirae	ATCC 10541
	Escherichia coli K12	NCTC 10538
Incubation conditions:	37 °C ± 1 °C, 24 hours	

Test procedure:
1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least a 5 lg reduction (10^5).
$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$
* The product can only be tested at a concentration of 97% (RTU product, used modified method) or less, as some dilution is always produced by adding the inoculum and interfering substance.

The standard:
EN 13727:2012+A2:2015 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) October 2015

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA 1208 Geneva
Client: Saniswiss SA 19, Chemin des Tulipiers, Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 3

The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **1592** on *Pseudomonas aeruginosa* ATCC 15442

Tab No. 1.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	62	Φ_{Nvo}= 57.5	V_{c1}	50	Φ_A = 52.5	V_{c1}	50	Φ_B = 56	V_{c1}	43	Φ_C = 48
V_{c2}	53		V_{c2}	55		V_{c2}	62		V_{c2}	53	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})		V_{c1} 60		V_{c2} 54	Φ_{NVB} 57	$30 \leq \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160					
						x	yes	no			

Tab No. 1.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
Φ = 45.5 x 10^8 = lg 9.66	10^{-7}	>330	>330	lg N_0 = lg N/100 = lg 7.66
9.17 ≤ lg N ≤ 9.70	10^{-8}	49	42	7.17 ≤ lg N_0 ≤ 7.70
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **1592** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration (%)*/contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a = lg (Φ_a x 10)	**lg R (lg N_0 = lg 7.66)**
100/30/clean	10^0	<14	<14	< 2.15	**≥ 5.51**

2. Testing the efficacy of chemical disinfectant **1592** on *Staphylococcus aureus* ATCC 6538

Tab No. 2.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	51	Φ_{Nvo}= 60	V_{c1}	37	Φ_A = 45.5	V_{c1}	46	Φ_B = 41	V_{c1}	51	Φ_C = 59
V_{c2}	69		V_{c2}	54		V_{c2}	36		V_{c2}	67	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})		V_{c1} 72		V_{c2} 57	Φ_{NVB} 64.5	$30 \leq \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160					
						x	yes	no			

Tab No. 2.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
Φ = 49 x 10^8 = lg 9.69	10^{-7}	>330	>330	lg N_0 = lg N/100 = lg 7.69
9.17 ≤ lg N ≤ 9.70	10^{-8}	56	42	7.17 ≤ lg N_0 ≤ 7.70
				x yes no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **1592** on *Staphylococcus aureus* ATCC 6538

Test concentration (%)*/contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a = lg (Φ_a x 10)	**lg R (lg N_0 = lg 7.69)**
100/30/clean	10^0	<14	<14	< 2.15	**≥ 5.54**

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BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 4

3. Testing the efficacy of chemical disinfectant **1592** on *Enterococcus hirae* ATCC 10541

Tab No. 3.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	28	Φ_{Nvo}= 34	V_{c1}	24	Φ_A = 28.5	V_{c1}	30	Φ_B = 34	V_{c1}	28	Φ_C = 33.5
V_{c2}	40		V_{c2}	33		V_{c2}	38		V_{c2}	39	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})		V_{c1} 34		V_{c2} 37	Φ_{NVB} 35.5	$30 \leq \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160					
						x	yes	no			

Tab No. 3.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
Φ = 34.5 x 10^8 = lg 9.54	10^{-7}	>330	>330	lg N_0 = lg N/100 = lg 7.54
9.17 ≤ lg N ≤ 9.70	10^{-8}	30	39	7.17 ≤ lg N_0 ≤ 7.70
				x yes no

Tab No. 3.3 Testing the efficacy of chemical disinfectant **1592** on *Enterococcus hirae* ATCC 10541

Test concentration (%)*/contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a = lg (Φ_a x 10)	**lg R (lg N_0 = lg 7.54)**
100/30/clean	10^0	<14	<14	< 2.15	**≥ 5.39**

4. Testing the efficacy of chemical disinfectant **1592** on *Escherichia coli K12* NCTC 10538

Tab No. 4.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	48	Φ_{Nvo}= 49	V_{c1}	44	Φ_A = 45	V_{c1}	30	Φ_B = 40.5	V_{c1}	47	Φ_C = 47.5
V_{c2}	50		V_{c2}	46		V_{c2}	51		V_{c2}	48	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})		V_{c1} 49		V_{c2} 50	Φ_{NVB} 49.5	$30 \leq \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160					
						x	yes	no			

Tab No. 4.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
Φ = 47.5 x 10^8 = lg 9.68	10^{-7}	>330	>330	lg N_0 = lg N/100 = lg 7.68
9.17 ≤ lg N ≤ 9.70	10^{-8}	47	48	7.17 ≤ lg N_0 ≤ 7.70
				x yes no

Tab No. 4.3 Testing the efficacy of chemical disinfectant **1592** on *Escherichia coli K12* NCTC 10538

Test concentration (%)*/contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a = lg (Φ_a x 10)	**lg R (lg N_0 = lg 7.68)**
100/30/clean	10^0	<14	<14	< 2.15	**≥ 5.53**

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 5

5. Evaluation of bactericidal activity of the product **1592**

Tab No. 5.1 The efficacy of chemical disinfectant **1592** on test strains – bactericidal activity

Bactericidal activity of the product (EN 13727:2012+A2:2015)						
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 13727:2012 +A2:2015	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	30	100	clean	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	30	100	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	30	100	clean	≥ 5	**> 5**
Escherichia coli K12 NCTC 10538	20	30	100	clean	≥ 5	**> 5**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0/ N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$
* The product can only be tested at a concentration of 97% (RTU product, used modified method) or less, as some dilution is always produced by adding the inoculum and interfering substance.

Prepared by: Ing. Barbora Stoklásková, Lab Technician

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 6

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method
SOP-M-19-00 (EN 13727:2012+A2:2015)

Period of analysis:	6.11. – 7.11.2018
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	distilled water
Appearance of the product:	colourless gel
Test concentration:	20%, 40%, 100% (concentrated)**
Contact time:	30 s
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli K12* NCTC 10538
Incubation conditions:	37 °C ± 1 °C, 24 hours

Test procedure:
1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least a 5 lg reduction (10^5).
$R = N_0/ N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$
** Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:
EN 13727:2012+A2:2015 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) October 2015

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BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 7

6. Testing the efficacy of chemical disinfectant **1592** on *Pseudomonas aeruginosa* ATCC 15442

Tab No. 6.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%**		
V_{c1}	53	Φ_{Nvo}= 51	V_{c1}	33	Φ_A = 44	V_{c1}	49	Φ_B = 44.5	V_{c1}	43	Φ_C = 40.5
V_{c2}	42		V_{c2}	55		V_{c2}	40		V_{c2}	38	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x yes		no	x Yes		no	x yes		no	x yes		no

Validation of suspension (N_{VB})	V_{c1}	44	V_{c2}	49	Φ_{NVB}	46.5	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x yes		no

Tab No. 6.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 47 \times 10^7 = \lg 8.67$	10^{-6}	>330	>330	$\lg N_0 = \lg N/10 = \lg 7.67$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	50	44	$7.17 \leq \lg N_0 \leq 7.70$
				x yes No

Tab No. 6.3 Testing the efficacy of chemical disinfectant **1592** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration (%) /contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.67$)**
20 / 30 / clean	10^{-4}	81	39	6.78	**0.89**
40 / 30 / clean	10^{0}	66	69	2.83	**4.84**
100** / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.52**

7. Testing the efficacy of chemical disinfectant **1592** on *Staphylococcus aureus* ATCC 6538

Tab No. 7.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%**		
V_{c1}	42	Φ_{Nvo}= 46	V_{c1}	46	Φ_A = 42.5	V_{c1}	46	Φ_B = 43	V_{c1}	40	Φ_C = 43.5
V_{c2}	50		V_{c2}	39		V_{c2}	40		V_{c2}	47	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x yes		no	x Yes		no	x yes		no	x yes		no

Validation of suspension (N_{VB})	V_{c1}	45	V_{c2}	43	Φ_{NVB}	44	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x yes		no

Tab No. 7.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 166 \times 10^6 = \lg 8.22$	10^{-6}	164	168	$\lg N_0 = \lg N/10 = \lg 7.22$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	19	15	$7.17 \leq \lg N_0 \leq 7.70$
				x yes No

Tab No. 7.3 Testing the efficacy of chemical disinfectant **1592** on *Staphylococcus aureus* ATCC 6538

Test concentration (%) /contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.22$)**
20 / 30 / clean	10^{-4}	48	50	6.69	**0.53**
40 / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.07**
100** / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.07**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0/N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

** Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

saniswiss SAFE HYGIENE SOLUTIONS

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 8

8. Testing the efficacy of chemical disinfectant **1592** on *Enterococcus hirae* ATCC 10541

Tab No. 8.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%**		
V_{c1}	43	Φ_{Nvo}= 45	V_{c1}	46	Φ_A = 43	V_{c1}	46	Φ_B = 42	V_{c1}	44	Φ_C = 44
V_{c2}	47		V_{c2}	40		V_{c2}	38		V_{c2}	44	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x yes		no	x Yes		no	x yes		no	x yes		no

Validation of suspension (N_{VB})	V_{c1}	45	V_{c2}	43	Φ_{NVB}	44	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x yes		no

Tab No. 8.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 168 \times 10^6 = \lg 8.23$	10^{-6}	164	171	$\lg N_0 = \lg N/10 = \lg 7.23$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	21	14	$7.17 \leq \lg N_0 \leq 7.70$
				x yes No

Tab No. 8.3 Testing the efficacy of chemical disinfectant **1592** on *Enterococcus hirae* ATCC 10541

Test concentration (%) /contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.23$)**
20 / 30 / clean	10^{-4}	44	56	6.70	**0.53**
40 / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.08**
100** / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.08**

9. Testing the efficacy of chemical disinfectant **1592** on *Escherichia coli K12* NCTC 10538

Tab No. 9.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%**		
V_{c1}	40	Φ_{Nvo}= 46	V_{c1}	38	Φ_A = 43.5	V_{c1}	33	Φ_B = 41.5	V_{c1}	51	Φ_C = 43.5
V_{c2}	52		V_{c2}	49		V_{c2}	50		V_{c2}	36	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x yes		no	x Yes		no	x yes		no	x yes		no

Validation of suspension (N_{VB})	V_{c1}	45	V_{c2}	50	Φ_{NVB}	47.5	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x yes		no

Tab No. 9.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 47 \times 10^7 = \lg 8.67$	10^{-6}	>330	>330	$\lg N_0 = \lg N/10 = \lg 7.67$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	43	51	$7.17 \leq \lg N_0 \leq 7.70$
				x yes No

Tab No. 9.3 Testing the efficacy of chemical disinfectant **1592** on *Escherichia coli K12* NCTC 10538

Test concentration (%) /contact time (s)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.67$)**
20 / 30 / clean	10^{-4}	146	166	7.20	**0.47**
	10^{-5}	20	17		
40 / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.52**
100** / 30 / clean	10^{0}	<14	<14	< 2.15	**≥ 5.52**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0/N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

** Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 1 9, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 9

10. Evaluation of bactericidal activity of the product **1592**

Tab No. 10.1 The efficacy of chemical disinfectant **1592** on test strains – bactericidal activity

Bactericidal activity of the product (EN 13727:2012+A2:2015)						
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations [%]	Interfering substances - conditions	lg R EN 13727:2012 +A2:2015	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	30	20	clean	≥ 5	**< 5**
Staphylococcus aureus ATCC 6538	20	30	20	clean	≥ 5	**< 5**
Enterococcus hirae ATCC 10541	20	30	20	clean	≥ 5	**< 5**
Escherichia coli K12 NCTC 10538	20	30	20	clean	≥ 5	**< 5**
Pseudomonas aeruginosa ATCC 15442	20	30	40	clean	≥ 5	**< 5**
Staphylococcus aureus ATCC 6538	20	30	40	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	30	40	clean	≥ 5	**> 5**
Escherichia coli K12 NCTC 10538	20	30	40	clean	≥ 5	**> 5**
Pseudomonas aeruginosa ATCC 15442	20	30	100**	clean	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	30	100**	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	30	100**	clean	≥ 5	**> 5**
Escherichia coli K12 NCTC 10538	20	30	100**	clean	≥ 5	**> 5**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0/ N_a = the reduction in viability, or lg R = lg N_0 – lg N_a
** Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Ing. Barbora Stoklásková, Lab Technician

saniswiss SAFE HYGIENE SOLUTIONS

BACTERICIDAL

STUDY OF THE BACTERICIDAL ACTIVITY COMPLYING WITH EN 13727 : 2012 + A2 :2015

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S263/2018
Rep No: 156
Sample name: **1592**
Sampled: by client
Sampling point: Saniswiss SA, 1208 Geneva
Client: Saniswiss SA, 19, Chemin des Tulipiers, 1208 Geneva

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 30.10. – 7.11.2018
Delivered amount: 1 l
Batch No: 1028413
Page: 10

Interpretation:
Results of tests are in Tabs.
According to EN 13727:2012+A2:2015 the tested concentrated* product **1592,** batch No. 1028413, in the contact time 30 s under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli K12* NCTC 10538 by at least a 5 lg reduction.

* The product can only be tested at a concentration of 97% (RTU product, used modified method) or less, as some dilution is always produced by adding the inoculum and interfering substance.

According to EN 13727:2012+A2:2015 the tested concentrated** product **1592,** batch No. 1028413, in the contact time 30 s under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli K12* NCTC 10538 by at least a 5 lg reduction.

** Product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

Conclusion:
The product **1592** is capable of reducing the number of viable bacterial cells of the relevant organisms under defined conditions to the declared values, and consequently may be called bactericidal.

14.2.2019, Hodonín

Chemila, spol. s.r.o.
Za Drsthou 4386/3
695 01 Hodonín
CZ
č. 1273

Ing. Eva Kremlová, Leader of Study

LEVURICIDAL

STUDY OF THE BACTERICIDAL AND LEVURICIDAL ACTIVITY COMPLYING WITH EN 1500 : 2013

Dr. Torsten Koburger-Janssen
c/o Hygiene Nord GmbH
Walther-Rathenau-Str.49a
D-17489 Greifswald

DR. T. KOBURGER-JANSSEN W.-RATHENAU-STR. 49 A. D-17489 GREIFSWALD

Saniswiss sa
ch. des tulipiers 19
1208 Genève
Switzerland

DATE I DATUM
July 07,2017 / 07.07 .2077

GUTACHTERLICHE STELLUNGNAHME / *EXPERT ' S REPORT*
- BIOSANITIZER H I -

Das vorliegende Gutachten stellt eine Umschreibung dar. Säimtliche Testungen erfolgten mil dem unter dem Namen 1592 gefuhrten Prüfmuster. Beruhend auf der Bestotigung der Rezepturidentitat durch den Hersteller konnen die Werle und Konzentration Zeit-Relationen des Produktes 1592 (Gutachterliche Stellungnahme von Dipl. Biol. T. Koburger **vom 08.03.2016) auf das Produkt Biosanitizer H1 Obertragen warden. Vo diesem Hintergrund wird hier die Produktbezeichnung Biosanitizer H1 verwnedet.**

This expert's report represents a transcription of the original expert's report (dated March 08, 2016) to the product brand name Biosanitizer H1. ***All tests mentioned below were conducted using product samples under the name 1592. Due to*** *the manufactuer's* ***confirmation of the identity*** *of the* ***formulations, all results and recommendations of the original*** *expert's report can therefore be transcribed to Biosanilizer H1. Consequently, this product name is now used in this expert's report and in the* ***corresponding test report.***

Im Marz 2015 und im Januar und Februar 2016 wurden durch die Hygiene NordGmbH mit dem Prufmuster, einem Mittel zur **Biosanitizer H 1** Händedesinfektion der Firma Saniswiss SA, Genf, Schweiz, folgende Untersuchunegn auf Basis der EN 1500 (2013) und der "ANFORDERUNGEN UND METHODEN zur VAH - Zertifiezierung „chemischer Desinfektionsverfahren" (2015) durchgeführt:

The efficacy of ***Biosanitizer H 1*** *as a hygienichandrub (manufadured by Saniswiss SA, Geneva, Switzerland) was evaluated by the testing laboratory Hygiene Nord GmbH, Greifswald, Germany. The following tests were performed in the month of March, 2015 and during the months of January and February 2016 in accordance with the EN 1500 (2013) and the "REQUIREMENTS AND TEST METHODS for the VAH-certification of chemical disinfedants" (2015):*

1. Bestimmung der **bakteriostatischen** und **levurostatischen Wirksamkeit** sowie geeigneter **Neutralisationsmittel.** Die Versuchsdurchfuhrung und die Ergebnisse sind im Prufbericht A 15263-1 der Hygiène Nord GmbH vom 04.03.2016 enthalten.

   Determination of a suitable ***neutralizer*** *and analysis of the bacteriostatc and fungistatic activity. Results are presented in the Hygiene Nord GmbH test report A 15263-1 (March 04, 2016).*

LEVURICIDAL

STUDY OF THE BACTERICIDAL AND LEVURICIDAL ACTIVITY COMPLYING WITH EN 1500 : 2013

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2. Im **quantitativen Suspensionsversuch** wurde die bakterizide und levurozide Wirksamkeit des Prüfmusters **Biosanitizer H 1** unter hoher organischer Belastung bestimmt (0,3 % Albumin + 0,3 % Schaferythrozyten) untersucht. Die Versuchsdurchführung und die Ergebnisse sind im Prüfbericht A 15263-1 der Hygiene Nord GmbH vom 04.03.2016 enthalten.

   The bactericidal and yeasticidal activity of ***Biosanitzer H 1*** *was evaluated by* ***quantitative suspension tests*** *under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes). Results are presented in the Hygiene Nord GmbH test report A 15263-1 (March 04, 2016).*

3. Durch **praxisnahe Versuche zur hygienischen Händedesinfektion** wurde die Wirksamkeit des Prüfmusters **Biosanitizer H 1** unter Anwendungsbedingungen untersucht. Die Versuchsdurchführung und die Ergebnisse sind im Prüfbericht A 15086 der Hygiene Nord GmbH vom 08.03.2016 enthalten.

   The activity of ***Biosanitizer H 1 as a hygienic handrub*** *was evaluated under conditions simulating* ***practical conditions****. Results are presented in the Hygiene Nord GmbH test report A 15086 (March 08, 2016).*

ZUSAMMENFASSUNG / SUMMARY

Nach Bewertung der Ergebnisse kann festgestellt werden, dass das Prüfprodukt **Biosanitizer H 1** den „ANFORDERUNGEN UND METHODEN zur VAH-Zertifizierung chemischer Desinfektionsverfahren" (2015) genügt, da folgende Wirkungen beobachtet wurden:

Upon evaluation of the test results it can be concluded that **Biosanitizer H 1** *complies with the "REQUIREMENTS AND TEST METHODS for the VAH-certification of chemical disinfectants" (2015):*

- Bakterizide und levurozide Wirksamkeit in den *in vitro* - Tests:
  Im quantitativen Suspensionstest unter hoher Belastung wurden die Prüfspezies *P. aeruginosa, E. coli, P mirabilis, E. hirae, S. aureus* und *C. albicans* bei der Konzentration-Zeit-Relation 80 % / 15 s in einem ausreichenden Maße inaktiviert (log RF ≥ 5 bzw. log RF ≥ 4).

  Bactericidal and yeasticidal activity in the in vitro tests:
  In the quantitative suspension test under dirty conditions, the product possesses bactericidal (log RF ≥ 5) and yeasticidal (log RF ≥ 4) efficacy against the test organisms P. aeruginosa, E. coli, P. mirabilis, E. hirae, S. aureus and C. albicans within the contact time of 15 s at a product concentration of 80 %.

- Bestätigung der Wirksamkeit unter praxisnahen Bedingungen: Die Anforderungen an ein Produkt zur hygienischen Händedesinfektion wurden bei Feuchthalten der Hände mit einem Produktvolumen von 3 ml innerhalb einer Einwirkzeit von 30 s erfüllt.

  - Confirmation of that efficacy under conditions simulating practical conditions (hygienic handrub). The product fulfilled the requirements if the hands were kept moist with 3 ml of the product for a contact time of 30 s.

LEVURICIDAL

STUDY OF THE BACTERICIDAL AND LEVURICIDAL ACTIVITY COMPLYING WITH EN 1500 : 2013

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Für die Aufnahme in die Desinfektionsmittelliste des VAH können daher folgende Anwendungsempfehlung für **Biosanitizer H 1** gegeben werden:

It can therefore be recommended to include ***Biosanitizer H 1*** *in the VAH List of Disinfectants as follows:*

Biosanitizer H 1:

Hygienische Händedesinfektion / *Hygienic handrub*: **100 % (3 ml) / 30 s**

Greifswald, 07.07.2017 / *July 07,2017*

Dr. rer. med. (Dipl. Biol.) T. Koburger-Janssen

HYGIENE NORD GMBH
C/O BIOTECHNIKUM
WALTHER-RATHENAU-STRASSE 49 A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY

DAkkS Deutsche Akkreditierungsstelle
D-PL-18411-01-01
D-PL-18411-01-02

HYGIENE NORD GMBH

HYGIENE NORD GMBH, C/O BIOTECHNIKUM, W.-RATHENAU-STR. 49 A, D-17489 GREIFSWALD

Saniswiss SA
19 Chemin des Tulipiers
1208 Geneva
Switzerland

CUSTOMER NUMBER	DATE
815	March 27, 2015

REPORT A 15086
BIOSANITIZER H1
HYGIENIC HANDRUB (EN 1500)

Purpose

The activity of the hygienic handrub product **BIOSANITIZER H1** (Saniswiss SA, Geneva, Switzerland) should be evaluated by a test simulating practical conditions according to EN 1500 (2013).

HYGIENE NORD GMBH
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S.W.I.F.T./BIC: DEUTDEDBROS
GESCHÄFTSFÜHRER
DIPL. BIOL. TORSTEN KOBURGER
SITZ DER GESELLSCHAFT:
GREIFSWALD
HANDELSREGISTER:
AG STRALSUND HRB 5168
UST.-ID (VAT):
DE211580653

saniswiss SAFE HYGIENE SOLUTIONS

Test Description

Manufacturer:	Saniswiss SA, Geneva, Switzerland
Product:	BIOSANITIZER H1 Hygienic hand antiseptic
Sample number:	P 151168
Batch number:	PR195-F14
Manufacture date:	March 20, 2015
Best before:	not provided
Date of order:	March 23, 2015
Date of delivery:	March 23, 2015
Test date:	March 26, 2015 – March 27, 2015
Basis:	EN 1500 (2013): Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2)
Test organism:	*Escherichia coli* K 12 NCTC 10538
Test solutions:	100 %
Active ingredients in 100 g:	not provided
Odour:	alcoholic
Appearance:	colourless clear liquid
Appearance of dilution:	10 %: colourless clear liquid, white flocculation
pH – value (pH-meter)	100 %: 9.02 80 %: 8.42 10 %: 7.26 WSH: 7.20
pH – value (pH-stripes)	100 %: 5 -6 10 %: 6-7
Neutralizer:	4 % Tween 80 + 3 % Saponin + 0.4 % Lecithin + 0.25 % SDS (Neutralizer XXIV)
Test temperature:	20 ± 1 °C
Incubation temperature:	36 ± 1 °C

Method

Hygienic handrub - Evaluation of the activity of Biosanitizer H1 in a test simulating practical conditions in accordance with EN 1500 (2013)

The number of test organisms released from the fingertips of artificially contaminated hands is assessed before and after the hygienic handrub. A cross-over design was used for testing the activity of the test product in both parts of this study. The efficacy of the product formula **Biosanitizer H1** was analysed using the test organism *E. coli* K12. A sufficient amount of the test product was applied to keep the subjects' hands well moistened with a volume of 3 ml for a contact time of **30 s**

Contamination fluid: $4.80*10^8$ cfu / ml

Prevalues. Hands were prepared by washing for 1 min with soft soap to remove natural transients. After thoroughly drying the hands with paper towels they were immersed in the contamination fluid up to the mid-metacarpals for 5 seconds. Avoiding the formation of droplets, hands were allowed to dry in the air for 3 minutes. Immediately after drying, the fingertips were rubbed for 1 min on the base of a Petri dish containing 10 ml of TSB without neutralizer to assess the release of test organisms before treatment of the hands (prevalues). For each of the required dilutions (10^{-3} and 10^{-4}) of these sampling fluids 0.1 ml were spread on the surface of TSA plates.

Postvalues. Immediately after sampling for the prevalues, the hygienic handrub procedure was performed with 2 x 3 ml of the reference product propan-2-ol (60 %) in 2 x 30 s by the first group, and keeping hands moist with **3 ml** of the test product formulation **Biosanitizer H1** for **30 s** by the second group, respectively, and switching groups afterwards. The reference, as well as the test procedure was completed by a 5 s rinse of the fingers under running tap water. Excess water was shaken of, after that fingertips were rubbed for 1 min on the base of a Petri dish containing 10 ml of TSB with neutralizer for 1 min. Appropriate volumes and dilutions of those sampling fluids (1 ml of the 10^0, and 0.1 ml of the 10^0 and 10^{-1} dilutions) were spread on the surface of TSA plates.

Plates were incubated aerobically at 36 ± 1 °C for 18 to 24 hours. The number of colony forming units per plate and dilution step was recorded. The viable counts per millilitre sampling fluid were calculated and transformed to decimal logarithms. From the difference of the mean log prevalues and the mean log postvalues of both hands a log reduction factor is established for each subject. The arithmetic means of all individual log reduction factors are calculated and compared for both the reference and the test procedure.

For the test validation, conformance of the results to the following criteria is required:

1. All results of at least 18 subjects shall be available.
2. The overall mean of the log prevalues for the reference and test procedure shall be at least 5.00.
3. In each procedure, not more than three individual log reduction factors fewer than 3.00 shall occur.
4. The absolute difference of mean differences between log reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2.00.
5. The quotient of the cfu numbers of consecutive dilutions of the sampling fluids must not be < 5 or > 15, within the relevant range of 14 – 330 cfu.

- However, this criterion was only considered, if overall data indicated systematic errors or neutralization problems - as any other variations is taken care of by the weighted mean calculation already.

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Results

Detailed results are presented in table 2. The results are valid, because the followings requirements according EN 1500 were fulfilled:

- all results of at least 18 volunteers are available
- the overall mean of the log prevalues for reference and test procedure is ≥ 5.00
- in each procedure (reference and test product) less than three individual log reduction factors are smaller than 3.00
- the absolute difference of mean differences between log reductions of RP and PP of group RP → PP and group PP → RP is be less than 2.00
- no systematic errors were detected by the calculation of the quotients of cfu numbers of consecutive dilutions of the sampling fluids.

For the test organism *E. coli,* the overall mean values of the reference product are:

prevalue	**5.80**
postvalue	**1.30**
reduction factor (RF)	**4.49**

The overall mean values of the test product formulation **Biosanitizer H1** at a contact time of **30 s** are:

prevalue	**5.92**
postvalue	**1.62**
reduction factor (RF)	**4.30**

The mean log reduction (RF) for the test product **(Biosanitizer H1)** is smaller than that of the reference product. According to the EN 1500 (2013), the test product was considered non inferior to the reference product in the Hodges-Lehman statistical analysis (see Table 4; p = 0.025, agreed inferiority margin = 0.6; calculated value = 0.49).

The test product formulation **Biosanitizer H1** does therefore **correspond** to the requirements of the EN 1500 (2013) for the **hygienic handrub** when hands are kept moist with 3 ml of the product for a contact time of **30 s**.

Greifswald, March 27, 2015

Dr rer. med. (Dipl. Biol.) T. Koberger - General Manager -

Prof. Dr. med. A. Kramer - MD for Hygiene and Environmental Medicine -

Table 1: Neutralization–control and validation (EN 1500:2013)

Date:	March 27, 2015	**Order number:**	A 15086
Product:	Biasanitizer H1	**Sample number:**	P 151168
Test organism:	*E. coli*	**Batch number:**	PR195-F14
Interfering substance:	none		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Test suspension (N):	$4.80*10^8$ cfu / ml	**Incubation time:**	24 h – 48 h
Test suspension (Nv_0):	$1.25*10^5$ cfu / ml	**Test temperature**	20 ± 1 °C
Validation Suspension (N_v):	$1.58*10^3$ cfu / ml		

Neutralization – control and validation:

Validation suspension (Nv0)					Neutralizer control (control B)					Method validation (Control C) 80 %				
	cfu / Plate 1 & 2		V_c	$\bar{x}$ [cfu / ml]		cfu / Plate 1 & 2		V_c	$\bar{x}$ [cfu / ml]		cfu / Plate 1 & 2		V_c	$\bar{x}$ [cfu / ml]
V_{c1}	86	75	161	**158**	V_{c1}	69	76	145	**141.5**	V_{c1}	76	54	130	**132.5**
V_{c2}	72	83	155		V_{c2}	70	68	138		V_{c2}	72	63	135	
30 ≤ $\bar{x}$ of Nv_0 ≤ 160?					$\bar{x}$ of B is ≥ 0.0005* $\bar{x}$ of Nv_0?					$\bar{x}$ of C is ≥ 0.5* $\bar{x}$ of Nv_0?				
[X] Yes* [ ] No					[X] Yes [ ] No					[X] Yes [ ] No				

* OK with regard to the increased bacterial count of the test suspension

Method validation (Control C) 10 %			
	cfu / Plate 1 & 2	V_c	$\bar{x}$ [cfu / ml]
V_{c1}	95 80	175	**175**
V_{c2}	83 92	175	
$\bar{x}$ of C is ≥ 0.5* $\bar{x}$ of Nv_0?			
[X] Yes [ ] No			

Control of group of subjects (EN 1500:2013)

Group 1 (RP → PP) subjects 1 - 10			Group 2 (PP → RP) subjects 11 - 20			Absolute difference of mean differences
mean $\log_{10}$ RF		difference	mean $\log_{10}$ RF		difference	
RP	PP		RP	PP		**abs (0.00 - 0.38) = 0.39**
4.52	4.52	0.00	4.47	4.09	0.38	result < 2.00 ?
						[X] Yes [ ] No

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Table 2.1: Hygienic handrub – test results – reference product vs. test product

test date:	March 26, 2015 60	**order number:**	A 15086
reference:	% propan-2-ol	**batch number:**	093192228
test product:	Biosanitizer H1	**batch number:**	PR195-F14
neutralizer:	XXIV	**sample number:**	P 151168

subject	hand	reference product					test product				
		prevalue [cfu]		postvalue [cfu]			prevalue [cfu]		postvalue [cfu]		
		0.1 ml 10^{-3}	0.1 ml 10^{-4}	1 ml 10^{0}	0.1 ml 10^{0}	0.1 ml 10^{-1}	0.1 ml 10^{-3}	0.1 ml 10^{-4}	1 ml 10^{0}	0.1 ml 10^{0}	0.1 ml 10^{-1}
1	right	152	26	12	4	0	162	25	26	1	0
	left	187	28	78	4	0	151	19	> 330	33	4
2	right	28	6	16	1	0	41	4	28	1	0
	left	55	9	10	0	0	57	5	14	1	0
3	right	84	22	130	17	0	97	7	60	6	0
	left	23	5	38	6	1	60	8	4	0	0
4	right	16	1	216	24	4	8	0	180	7	0
	left	20	1	20	1	0	21	2	30	2	0
5	right	76	14	2	0	0	68	11	0	0	0
	left	58	8	6	1	0	65	6	2	0	0
6	right	174	43	0	0	0	> 330	42	0	0	0
	left	146	15	0	0	0	194	25	0	0	0
7	right	115	12	0	0	0	118	14	0	0	0
	left	105	23	0	0	0	89	10	0	0	0
8	right	97	5	74	6	0	139	20	26	3	0
	left	58	5	0	0	0	131	16	2	0	0
9	right	54	8	224	23	2	93	12	> 330	150	25
	left	72	6	26	1	0	85	11	> 330	171	33
10	right	12	1	> 330	62	4	50	4	> 330	168	33
	left	9	0	> 330	59	8	36	4	> 330	102	15
11	right	171	32	2	0	0	> 330	34	> 330	50	2
	left	127	21	22	1	0	> 330	32	> 330	36	0
12	right	65	10	8	0	0	82	16	100	11	0
	left	70	4	16	1	0	95	11	46	4	0
13	right	132	27	0	0	0	76	12	26	2	0
	left	120	22	12	0	0	63	10	12	0	0
14	right	64	10	26	6	0	92	12	10	1	0
	left	69	11	62	5	1	70	12	12	1	0
15	right	35	2	26	2	0	155	24	> 330	106	14
	left	51	4	8	1	0	155	24	30	4	0
16	right	50	8	10	2	0	49	12	26	5	0
	left	44	8	42	3	0	38	8	16	5	0
17	right	105	25	> 330	38	2	110	18	> 330	91	14
	left	133	8	> 330	129	21	144	16	> 330	> 330	38
18	right	> 330	40	92	11	0	170	31	> 330	36	0
	left	141	19	24	2	0	139	27	40	5	0
19	right	59	8	6	0	0	64	9	14	0	0
	left	45	5	2	0	0	57	7	2	0	0
20	right	20	1	140	18	1	32	6	76	11	1
	left	3	0	108	10	1	16	1	> 330	48	8

Table 2.2: Hygienic hand rub – test results (logarithms and reduction factors) reference product vs. test product

test product: Biosanitizer H1 sample number: P 151168
reference: 60 % propan-2-ol order number: A 15086

subject	hand	reference product					test product				
		prevalue log		postvalue log		reduc-tion-factors	prevalue log		postvalue log		reduc-tion-factors
		R/L	mean	R/L	mean		R/L	mean	R/L	mean	
1	R	6.21	6.25	1.08	1.49	**4.76**	6.23	6.21	1.41	1.97	**4.24**
	L	6.29		1.89			6..9		2.52		
2	R	5.45	5.59	1.20	1.10	**4.49**	5.61	5.68	1.45	1.30	**4.39**
	L	5.74		1.00			5.76		1.15		
3	R	5.98	5.67	2.13	1.85	**3.82**	5.99	5.88	1.78	1.19	**4.69**
	L	5.36		1.58			5.78		0.60		
4	R	5.20	5.25	2.34	1.82	**3.43**	4.90	5.11	2.26	1.87	**3.25**
	L	5.30		1.30			5.32		1.48		
5	R	5.91	5.84	0.30	0.54	**5.30**	5.83	5.82	0.00	0.15	**5.67**
	L	5.76		0.78			5.81		0.30		
6	R	6.30	6.23	0.00	0.00	**6.23**	6.62	6.46	0.00	0.00	**6.46**
	L	6.17		0.00			6.30		0.00		
7	R	6.06	6.06	0.00	0.00	**6.06**	6.08	6.01	0.00	0.00	**6.01**
	L	6.07		0.00			5.95		0.00		
8	R	5.99	5.88	1.87	0.93	**4.94**	6.16	6.14	1.41	0.86	**5.28**
	L	5.76		0.00			6.13		0.30		
9	R	5.73	5.79	2.35	1.88	**3.91**	5.97	5.95	3.20	3.23	**2.71**
	L	5.86		1.41			5.93		3.27		
10	R	5.08	5.02	2.79	2.78	**2.24**	5.70	5.63	3.26	3.14	**2.48**
	L	4.95		2.77			5.56		3.03		
11	R	6.27	6.20	0.30	0.82	**5.38**	6.53	6.52	2.70	2.63	**3.89**
	L	6.13		1.34			6.51		2.56		
12	R	5.81	5.83	0.90	1.05	**4.78**	5.95	5.96	2.00	1.83	**4.13**
	L	5.85		1.20			5.98		1.66		
13	R	6.16	6.14	0.00	0.54	**5.60**	5.88	5.84	1.41	1.25	**4.59**
	L	6.11		1.08			5.80		1.08		
14	R	5.81	5.82	1.41	1.60	**4.22**	5.96	5.90	1.00	1.04	**4.86**
	L	5.84		1.79			5.85		1.08		
15	R	5.54	5.63	1.41	1.16	**4.47**	6.21	6.21	3.04	2.26	**3.95**
	L	5.71		0.90			6.21		1.48		
16	R	5.70	5.67	1.00	1.31	**4.36**	5.69	5.63	1.41	1.31	**4.33**
	L	5.64		1.62			5.58		1.20		
17	R	6.07	6.10	2.58	2.86	**3.24**	6.07	6.11	2.98	3.28	**2.83**
	L	6.12		3.13			6.16		3.58		
18	R	6.60	6.38	1.96	1.67	**4.71**	6.26	6.22	2.56	2.08	**4.14**
	L	6.16		1.38			6.18		1.60		
19	R	5.77	5.71	0.78	0.54	**5.17**	5.81	5.78	1.15	0.72	**5.06**
	L	5.65		0.30			5.76		0.30		
20	R	5.30	4.89	2.16	2.10	**2.79**	5.51	5.35	1.88	2.28	**3.07**
	L	4.48		2.03			5.20		2.68		
arithm. mean		5.80		1.30	**4.49**		5.92		1.62	**4.30**	
absolute SD		0.40		0.80	1.04		0.34		1.02	1.09	
relative SD		6.88		61.09	23.14		5.80		62.78	25.30	

SD standard deviation R right L left

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Table 3: Hygienic handrub – used volumes for keeping hands moist during contact time reference product vs. test product

reference product: Propan-2-ol 60 vol. order number: A 15086
% test product: Biosanitizer H1 sample number: P 151168

subject	reference product [ml]	test product [ml]
1	6.0	3.0
2	6.0	3.0
3	6.0	3.0
4	6.0	3.0
5	6.0	3.0
6	6.0	3.0
7	6.0	3.0
8	6.0	3.0
9	6.0	3.0
10	6.0	3.0
11	6.0	3.0
12	6.0	3.0
13	6.0	3.0
14	6.0	3.0
15	6.0	3.0
16	6.0	3.0
17	6.0	3.0
18	6.0	3.0
19	6.0	3.0
20	6.0	3.0

Table 4: Sorting of individual differences and computation for Hodges-Lehmann 97.5 % upper confidence limits (EN 1500:2013)

Median of differences RP – PP: 0.11

Subject		Mean pairwise differences $(d_i+d_{ii})/2$ (no duplicates. only values ≥median)										
		11	9	13	12	18	1	15	17	4	19	2
	RP-PP	**1.49**	1.20	1.01	**0.65**	**0.57**	**0.52**	**0.52**	**0.41**	**0.18**	**0.11**	**0.10**
11	1.49	1.49										
9	1.20	1.35	1.20									
13	1.01	1.25	1.11	1.01								
12	0.65	1.07	0.93	0.83	0.65							
18	0.57	1.03	0.89	0.79	0.61	0.57						
1	0.52	1.01	0.86	0.77	0.59	0.55	0.52					
15	0.52	1.01	0.86	0.77	0.59	0.55	0.52	0.52				
17	0.41	0.95	0.81	0.71	0.53	**0.49**[53]	0.47	0.47	0.41			
4	0.18	0.84	0.69	0.60	0.42	0.38	0.35	0.35	0.30	0.18		
19	**0.11**	0.80	0.66	0.56	0.38	0.34	0.32	0.32	0.26	0.15	0.11	
2	**0.10**	0.80	0.65	0.56	0.38	0.34	0.31	0.31	0.26	0.14	0.11	
7	0.05	0.77	0.63	0.53	0.35	0.31	0.29	0.29	0.23	0.12		
16	0.03	0.76	0.62	0.52	0.34	0.30	0.28	0.28	0.22	0.11		
6	-0.23	0.63	0.49	0.39	0.21	0.17	0.15	0.15				
10	-0.24	0.63	0.48	0.39	0.21	0.17	0.14	0.14				
20	-0.28	0.61	0.46	0.37	0.19	0.15	0.12	0.12				
8	-0.34	0.58	0.43	0.34	0.16	0.12						
5	-0.37	0.56	0.42	0.32	0.14							
14	-0.64	0.43	0.28	0.19								
3	-0.87	0.31	0.17									

The tabulated value for the smaller sum of ranks for n = 20 in the Wilcoxon Signed Ranks Test is 52 at a significance level of p = 0.025 in the directional test (1-tailed). Therefore, the upper confidence limit (97.5 %) is determined by the mean pairwise difference of the differences RP-PP with the rank 53 (c = 52+1 = **53**). With **0.49**, this value is smaller than the agreed inferiority margin of 0.6. Therefore, the hypothesis of inferiority of the test product (PP) can be rejected and it can be concluded that the test preparation PP is not inferior to RP.

Legend:

MW	=	mean
x	=	mean
RF	=	Reduction factor
> 300	=	not countable
n.d.	=	not determined
WSH	=	hard water (water of standardized hardness)
DGHM	=	Deutsche Gesellschaft für Hygiene und Mikrobiologie
cfu	=	colony forming unit

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RAPPORT D'ESSAI N°3712-1

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Test d'efficacité mycobactéricide
selon la norme NF EN 14348 (Juin 2005)
Produit 1592
Essai partiel sur Mycobacterium avium DSM 44157
(Méthode par dilution/neutralisation)

DESTINATAIRE : SANISWISS SA

I- IDENTIFICATION DU DONNEUR D'ORDRE

SANISWISS SA
19 chemin des Tulipiers
1208 GENEVE
Suisse
Tél. +41-22-718-75-75 Fax. +41-22-718-75-76

II- IDENTIFICATION DE L'ECHANTILLON

- Nom du produit : **1592** (Saniswiss biosanitizer H1)
- Numéro de lot : PR288-F12
- Fabricant : Saniswiss SA
- Date de fabrication : 20/07/15
- Date de péremption : 20/07/18
- Date de réception au laboratoire : 28/07/15
- Aspect du produit : liquide visqueux limpide incolore
- Conditions de stockage : à température ambiante et à l'abri de la lumière
- Diluant du produit recommandé par le fabricant : non concerné
- Matière(s) active(s) : Non communiquées

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III- METHODE D'ESSAI

Norme NF EN 14348 (Juin 2005) : Essai quantitatif de suspension pour l'évaluation de l'activité mycobactéricide des désinfectants chimiques utilisés en médecine, y compris les désinfectants pour instrument.

Réduction logarithmique au moins égale à 4 log décimaux dans les conditions de l'essai.

IV- CONDITIONS EXPERIMENTALES

- Période d'analyse : du 17/09/15 au 08/10/15
- Analyse réalisée par : AF. GABILLET
- Diluant du produit utilisé au cours de l'essai : eau distillée
- Concentrations de produit testé (V/V) : 20-40 et 80%
- Technique d'essai : dilution/neutralisation
- Aspect des dilutions : opaques pour 20% et 40% et limpide pour 80%
- Stabilité du mélange substance interférente/dilutions du produit/suspension microbienne : absence de précipité au cours de l'essai
- Temps de contact : 30 secondes (+/-5 secondes)
- Température d'essai : 20°C (+/-1°C)
- Substance interférente : Albumine bovine 0,3 g/l (conditions de propreté)
- Température d'incubation : 37°C (+/-1°C)
- Identification de la souche utilisée :
  - Mycobacterium avium DSM 44157
- Neutralisant (m/V) : 3% Polysorbate 80 ; 3% Saponine ; 0,3% Lécithine d'œuf ; 0,1% L-histidine ; 0,5% Thiosulfate de sodium (stérilisé à 121°C pendant 20 minutes).

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V- RESULTATS D'ESSAI

Vc : nombre de colonies comptées sur les boîtes,
N: nombre d'UFC / ml dans la suspension microbienne d'essai,
N_0: nombre de cellules par ml dans le mélange d'essai au début du temps de contact, il représente un dixième de N,
Nv : Nombre de cellules par ml de la suspension microbienne de validation. Il est 10 fois supérieur aux dénombrements en termes de valeurs de Vc en raison de l'étape de dilution à 10^{-1},
Nv_0 : Nombre de cellules par ml dans les mélanges A, B et C au début du temps de contact. Il représente un dixième de Nv,
Na : Nombre de survivants par ml dans le mélange d'essai à l'issue du temps de contact et avant neutralisation ou filtration sur membrane,
A : nombre de survivants dans le témoin des conditions expérimentales,
B : nombre de survivants dans le témoin du neutralisant ou du témoin de filtration,
C : nombre de survivants dans le témoin de validation de la méthode,
R : réduction du nombre de cellules viables ($R=N_0/Na$ ou $LogR=LogN_0-LogNa$).

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Essai sur Mycobacterium avium DSM 44157

Souche testée	Suspension microbienne d'essai	Essai de validation			
		Suspension microbienne	Conditions expérimentales (A)	Témoin du neutralisant ou du témoin de filtration (B)	Inactivation par neutralisation ou par filtration sur membrane (C)
Mycobacterium avium DSM 44157 Lot 558	10^{-7} : Vc1 : 365 Vc2 : 340 10^{-8} : Vc1 : 64 Vc2 : 65 N= $3,8.10^9$ N_0= $3,8.10^8$ Log N_0 = 8,58	Vc1 : 100 Vc2 : 119 Nv= $1,1.10^3$ Nv_0= $1,1.10^2$	Vc1 : 146 Vc2 : 137 A= $1,4.10^2$	Vc1 : 138 Vc2 : 114 B= $1,3.10^2$	80% Vc1 : 104 Vc2 : 130 C = $1,2.10^2$
L'essai est validé si : N est compris entre $1,5.10^9$ et 5.10^9UFC/ml (9,17 ≤ lg ≤ 9,70) N_0 est compris entre $1,5.10^8$ et 5.10^8UFC/ml (8,17 ≤ lg ≤ 8,70) N_{v0} est compris entre 30 et 160 UFC/ml (N_v est compris entre 300 et 1600 UFC/ml) A, B, C est supérieur ou égal à 0,5xN_{v0} Le quotient des dénombrements obtenus par moyenne pondérée est compris entre 5 et 15					

Souche testée	Concentrations testées % (V/V)											
		20%				40%				80%			
		10^0	10^{-1}	10^{-2}	10^{-3}	10^0	10^{-1}	10^{-2}	10^{-3}	10^0	10^{-1}	10^{-2}	10^{-3}
Mycobacterium avium DSM 44157 Lot 558	Vc1	>660	>660	>660	>660	>660	>660	>660	336	365	85	16	3
	Vc2	>660	>660	>660	>660	>660	>660	>660	352	361	78	17	4
	Na	>6,6.10⁶				3,4.10⁶				4,0.10³			
	lg Na	>6,82				6,53				3,60			
	Lg R	<1,76				2,05				4,98			

MYCOBACTERICIDAL

STUDY OF THE MYCOBACTERICIDAL ACTIVITY COMPLYING WITH EN 14348 : 2005

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FM 064-18 A

RAPPORT D'ESSAI N°3712-1

Imprimé le : 13/10/15
Date de 1ère impression : 13/10/15
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VI- CONCLUSION

Selon la méthodologie de la norme NF EN 14348 (Juin 2005), le lot PR288-F12 du produit 1592 de la société SANISWISS SA, dans les conditions d'essai suivantes :

- en 30 secondes de temps de contact,
- à la température d'essai de 20°C,
- en présence d'albumine bovine à 0,3 g/l (conditions de propreté),

présente une activité mycobactéricide (réduction supérieure ou égale à 4 Log décimaux) lorsqu'il est dilué à 80% (V/V) vis-à-vis de la souche Mycobacterium avium DSM 44157.

La souche est conservée selon la norme NF EN 12353.
La souche d'essai a été soumise à essai une seule fois.

VII-SIGNATURES

Fait à DINARD,

Rédigé par	Validé par
AF. GABILLET Responsable d'essai	M.SESQUES Docteur en microbiologie Directeur technique p/o P. FOUTEL Responsable Qualité

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BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Test Report BS EN 14348: 2005 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants— Test method and requirements (phase 2, step 1)

Test Laboratory

BluTest Laboratories Ltd
Robertson Incubator (Level 4)
56 Dumbarton Road
Glasgow
G11 6NU-UK

Identification of sample

Name of the product	**SANISWISS BIOSANITIZER H1**
Client	SANISWISS SA, GENEVA, SWITZERLAND
Project	BT-PHA-04
Date of Delivery	16 February 2016
Storage conditions	Ambient and darkness
Active substances	Not known

Test Method and its validation

Method	Filtration-neutralization technique
Neutralizer	Lecithin 3g/l, Polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, phosphate buffer 0.0025mol/l, sterilized by autoclave

Experimental Conditions

Period of analysis	5 April to 25 April 2016
Product diluent used	Sterile hard water
Product test concentrations	20.0 % V/V; 40.0% V/V; 80.0% V/V
Appearance product dilutions	Colourless, clear product solution
Contact time	t = 30s +/- 2 s
Test temperature	20°C ± 1°C
Interfering substance	0.3 g/l bovine albumin
Stability of mixture	Precipitate absent throughout the test
Temperature of incubation	37°C ± 1°C + 5.0% CO_2
Identification of strain	*Mycobacterium terrae* ATCC 15755

Conclusion

Following the EN 14348 (2005) protocol, **BIOSANTIZER H1,** possesses tuberculocidal activity (6.02 log_{10} reduction) at a concentration of 80% V/V in 30 seconds at 20°C under **CLEAN** conditions (0.3 g/l bovine albumin) for reference strain *Mycobacterium terrae* ATCC 15755

Signed

Dr Chris Woodall, Director
BluTest Laboratories Limited
Glasgow, UK
29 April 2016

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Company Registration Number: SC364409 VAT Registration Number: GB 979 1131 96

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BluTest
GLOBAL MICROBIOLOGY EXPERTISE

RESULTS

TABLE 1

	Number of cells per ml in the mycobacterial suspensions	Number of cells per ml in the test mixtures at the beginning of the contact time (time 0)	Number of survivors per ml in the test mixtures at the end of the contact-time.
Test	N = 1.77 x 10^9	No = 1.77 x 10^8	Na (SEE TABLE 2)
Controls	Nv = 5.20 x 10^2	Nvo = 5.20 x 10^1	A = 4.10 x 10^1 B = 3.95 x 10^1 C = 4.70 x 10^1

a) *N* is between 1,5 x 10^9 cfu/ml and 5,0 x 10^9 cfu/ml (9,17 ≤ lg *N* ≤ 9,70) and N_0 is between 1,5 x 10^8 cfu/ml and 5,0 x 10^8 cfu/ml (8,17 ≤ lg N_0 ≤ 8,70)
b) N_{vo} is between 30 and 160 cfu/ml (3,0 x 10^1 and 1,6 x 10^2) and N_v is between 3.0 x 10^2 and 1,6 x 10^3 cfu/ml
c) *A,B,C* are equal to or greater than 0.5 x N_{vo}

TABLE 2

CONCENTRATION	Na	No/Na	Log Reduction (R)
80.0% W/V	1.68 X 10^2	1.05 x 10^6	6.02
40.0% W/V	>3.3 X 10^4	<5.36 x 10^3	<3.73
20.0% W/V	>3.3 X 10^4	<5.36 x 10^3	<3.73

DISCLAIMER

BluTest (BT) has performed the Testing detailed in this report using reasonable skill and care and that BT has used reasonable endeavours to carry out the Testing [in accordance with an EN 14348 protocol]. All forecasts, recommendations and results contained in any report to the Company shall be submitted in good faith. However, other than as expressly set out in this report, no warranty is given (i) in relation to the Testing or the use(s) to which any results or deliverables produced in the course of the Testing are or may be put by the Company or their fitness or suitability for any particular purpose or under any special conditions notwithstanding that any such purpose or conditions may have been made known to BT or (ii) that the intended results or deliverables from the Testing can be achieved or (iii) that the Company can freely make use of the results or the deliverables without infringing any third party intellectual property rights and the Company will be deemed to have satisfied itself in this regard. BT shall have no liability (which is hereby excluded to the fullest extent permissible by law) in respect of any loss, liability or damage, including without limitation any indirect and/or consequential loss such as loss of profit or loss of business, market or goodwill, that the Company may suffer directly or indirectly as a result of or in connection with: (i) the performance of the Testing, except for direct loss arising from a breach of the foregoing warranties; (ii) the use of any materials, samples or other information provided by the Company for use in the Testing; and (iii) the Company's reliance upon or use of any results or deliverables provided as part of the Testing. The total liability of BT shall not exceed the sums paid to BT for the performance of the Testing.

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Akkreditierte
Prüfstelle nach
ÖNORM EN ISO 17025

Saniswiss SA
19 Chemin des Tulipiers
CH - 1208 Geneva
Switzerland

Bischofshofen, 2019-05-13

Prüfbericht / *test report* B 20234 – Neuausfertigung / *revised version*

Labor-Nr. / *Identification of the test laboratory:*	B 20234
Prüfprodukt / *Test product*:	1592 (Saniswiss biosanitizer H1)
Chargen-Bez. / *Batch number*:	LOT: PR195-F5
Hersteller / *Manufacturer*:	Saniswiss SA
Auftragsdatum / *Date of order*:	2016-04-25
Materialeingang / *Date of delivery*:	2016-05-02
Lagerbedingungen / *storage conditions*:	gemäß Herstellerangaben / *those of the manufacturer*
Vom Hersteller empfohlenes Verdünnungsmittel / *product diluent recommended by the manufacturer for use*:	konzentrierte Anwendung / *concentrated application*
Aussehen / *Appearance*:	klare, farblose, viskose Flüssigkeit / *clear colourless viscous liquid*
Geruch / *Odour*:	alkoholisch / *alcoholic*
Methodik / *Method*:	EN 12791 (2016) Chirurgische Händedesinfektion – Prüfverfahren und Anforderungen (Phase 2. Stufe 2) / *EN 12791 (2016) Surgical hand disinfection – Test method and requirements (phase2. step2)* SOP 02-054

Geschäftsführer Prof. Dr. med. Heinz-Peter Werner | Margarita Gilowsky, MBA | Landesgericht Salzburg | Firmenbuchnummer: FN 180657 y | UID-Nr.: ATU 46628403
Oberbank AG: IBAN AT42 1509 2001 4103 1948 | BIC OBKLAT2L

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pH-Werte / *pH-values*:	100%: 8.20
Neutralisationsmittel / *Neutralizer*:	3,0 % Tween 80 + 3,0 % Saponin + 0,1 % Histidin + 0,1 % Cystein / *3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine*
Prüfzeitraum / *Period of analysis*:	2016-06-01 to 2016-07-06
Wirkstoff(e) laut Herstellerangabe / *Active ingredient(s)*:	in 100ml: Not declared

Prüfung der Eignung für die Chirurgische Händedesinfektion nach EN 12791
Testing of Surgical hand rub product - EN 12791

Prüfdatum / *Date of test*: 2016-06-01; 2016-06-08; 2016-06-15; 2016-06-22; 2016-06-29; 2016-07-06

Referenzverfahren / Reference procedure:

Portionsweise 3 ml 60% (v/v) Propan-1-ol während 3 Minuten auf den Händen verreiben
Aliquots of 3 ml 60% (v/v) Propan-1-ol rubbed on the hand during 3 minutes.

Prüfverfahren / *Test procedure*:

3 ml- Portionen des Produktes 1592 auf den Händen verreiben, so dass die Hände während 2 x 45 Sekunden (90 Sekunden) nass bleiben.
Rub portions of 3 ml of product 1592 on the hands to keep them wet for 2 x 45 seconds (90 seconds).

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Ergebnisse der Validierung der Neutralisation / *Results of validation of neutralisation*

Testdatum / *Date of test*:	2016-06-01	B 20234
Konzentration / *Concentration*:	80% (v/v) Endkonzentration / *end concentration*	
Belastung / *load:*	0,3 g/l Rinderalbumin (niedrige Belastung) / *0.3 g/l bovine albumin (clean conditions)*	
Aussehen der Produktverdünnung / *Appearance of product dilutions*:	klar / clear	
Einwirkungszeit / *Contact time*:	90 Sekunden / *seconds*	

Testkeim / *Test strain*: S. aureus

Validierungs-suspension / *validation suspension* (Nv & Nv_0)	Kontrolle / *control* (Nv_B) x1000	Kontrolle / *control* (B)	Kontrolle / *control* (C)	Kontrolle / *control* (A)
Vc: 49 56	Vc: 57 53	Vc: 39 40	Vc: 28 25	Vc: 57 56
Nv_0: 52.5	NvB: 55	B: 39.5	C: 26.5	C: 56.5
Nv: 525				
Ergebnis gültig / *result valid*: **ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**

Testkeim / *Test strain*: E. hirae

Validierungs-suspension / *validation suspension* (Nv & Nv_0)	Kontrolle / *control* (Nv_B) x1000	Kontrolle / *control* (B)	Kontrolle / *control* (C)	Kontrolle / *control* (A)
Vc: 60 53	Vc: 47 52	Vc: 34 42	Vc: 48 52	Vc: 65 55
Nv_0: 56.5	NvB: 49.5	B: 38	C: 49	C: 60
Nv: 565				
Ergebnis gültig / *result valid*: **ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**

Testkeim / *Test strain*: E. coli

Validierungs-suspension / *validation suspension* (Nv & Nv_0)	Kontrolle / *control* (Nv_B) x1000	Kontrolle / *control* (B)	Kontrolle / *control* (C)	Kontrolle / *control* (A)
Vc: 53 58	Vc: 38 37	Vc: 33 38	Vc: 58 59	Vc: 66 62
Nv_0: 55.5	NvB: 37.5	B: 35.5	C: 58.5	C: 64
Nv: 555				
Ergebnis gültig / *result valid*: **ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**	**ja / yes**

Testkeim / *Test strain*: P. aeruginosa

Validierungs-suspension / *validation suspension* (Nv & Nv_0)	Kontrolle / *control* (Nv_B) x1000	Kontrolle / *control* (B)	Kontrolle / *control* (C)	Kontrolle / *control* (A)
Vc: 52 44	Vc: 53 51	Vc: 46 42	Vc: 52 45	Vc: 51 45
Nv_0: 48	NvB: 52	B: 44	C: 48.5	C: 48
Nv: 480				
Ergebnis gültig / *result valid*: ja / yes	ja / yes	ja / yes	ja / yes	ja / yes

Testkeim / *Test strain*: C. albicans

Validierungs-suspension / *validation suspension* (Nv & Nv_0)	Kontrolle / *control* (Nv_B) x1000	Kontrolle / *control* (B)	Kontrolle / *control* (C)	Kontrolle / *control* (A)
Vc: 44 38	Vc: 56 53	Vc: 36 42	Vc: 42 34	Vc: 35 43
Nv_0: 41	NvB: 54.5	B: 39	C: 38	C: 39
Nv: 410				
Ergebnis gültig / *result valid*: ja / yes	ja / yes	ja / yes	ja / yes	ja / yes

Verifizierung / *Verification*

Nv ist zwischen / *is between* 3 x 10^2 and 1.6 x 10^3

Nv_0 ist zwischen / *is between* 30 and 160 (3 x 10^1 and 1.6 x 10^2)

A, B,C ist gleich oder größer als / *is equal to or greater than* 0.5 mal / *times* N_{v0}

Nv_B ist zwischen / *is between* 3 x 10^4 and 1.6 x 10^5

Legende / *Legend*

Vc = Lebendkeimzahl / *viable count*

Nv = Anzahl der KBE/ml in der Validierungsuspension / *number of cfu/ml in the validation suspension*

N_{v0}, N_{vB} = Anzahl der KBE/ml in den Prüfgemischen B und C zu Beginn der Einwirkzeit / *number of cfu/ml in the mixtures B and C at the beginning of the contact time*
Im Falle der Neutralisationskontrolle B (Verdünnungs-Neutralisation) die Anzahl der KBE/ml nach 100- facher Verdünnung. Nv_0 ist 1/10 im Bezug auf die Validierungssuspension Nv, im Falle von Nv_B 1/1000. / *In the case of neutralizer control B (dilution neutralisation method) it is the number of cells per ml after 100 fold dilution. Nv_0 is one-tenth of the mean of the Vc values of validationsuspension Nv taken into account, in case of Nv_B it is one thousandth.*

A = Anzahl der überlebenden Zellen in der Kontrolle der Prüfbedingungen am Ende der Einwirkzeit. Sie entspricht dem Mittelwert der berücksichtigten Vc- Werte des Gemisches. / *Number of survivors of the experimental conditions control at the end of the contact time. It corresponds of the mean of the Vc-values of the mixture taken into account.*

B = Anzahl der überlebenden Zellen in der Kontrolle der Neutralisation in der definierten Zeit von 5 Minuten (im Falle von Produkten mit einer Einwirkzeit von ≤ 10 min nur 10 Sekunden) oder der Kontrolle der Filtration / *number of survivors in the neutralizer control at the defined times 5 minutes (in the case of products with a contact time of ≤ 10 min only 10 seconds) or the filtration control*

C = Anzahl der überlebenden Zellen in der Methodenvalidierung in der definierten Zeit von 30 Minuten / *number of survivors in the method validation at the defined times 30 minutes*

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Prüfung der Eignung für die Chirurgische Händedesinfektion nach EN 12791
Reference surgical hand disinfection procedure – Experimental results - EN 12791

Versuchsdaten / *dates of experiments*: 2016-06-01; 2016-06-08; 2016-06-15; 2016-06-22; 2016-06-29; 2016-07-06
Anwendung / *application*: 3 min. Einreiben / 3 *min rub*
Nx: 4/4/3/4/3/3/4/3/3/4/3/3/3/3/3/3/5/3/3/4/3/3/3

Proband / subject		Anzahl KBE je Platte aus Verdünnung $10^{(x)}$ - Referenz / *Number of cfu per plate from dilution $10^{(x)}$ - Reference*								
Nr./ no.	Hand / hand	Vorwert / *pre-count*			Nachwert / *post-count*					
					Sofortwirkung / *immediate*			3-Stundenwirkung / *3-hours*		
		-1	-2	-3	0	-1	-2	0	-1	-2
1	links / left	>330	>330	137	>330	162	17			
	rechts / right	>330	>330	296				>330	>330	53
2	links / left	>330	>330	228	51	5	0			
	rechts / right	>330	>330	85				49	4	0
3	links / left	>330	>330	33	>330	63	6			
	rechts / right	>330	197	20				>330	>330	84
4	links / left	>330	>330	272				>330	>330	66
	rechts / right	>330	>330	59	>330	73	7			
5	links / left	>330	>330	128	>330	83	8			
	rechts / right	>330	>330	70				>330	213	21
6	links / left	>330	>330	265				>330	>330	104
	rechts / right	>330	>330	229	>330	49	4			
7	links / left	>330	>330	219	>330	>330	120			
	rechts / right	>330	>330	149				>330	>330	89
8	links / left	>330	>330	259				>330	>330	70
	rechts / right	>330	>330	237	>330	>330	142			
9	links / left	>330	170	17	>330	81	8			
	rechts / right	>330	>330	84				>330	>330	58
10	links / left	>330	>330	77				>330	>330	49
	rechts / right	>330	>330	61	>330	116	11			
11	links / left	>330	>330	166				>330	>330	69
	rechts / right	>330	>330	159	144	15	1			
12	links / left	>330	>330	292	>330	112	12			
	rechts / right	>330	>330	289				92	9	0
13	links / left	>330	>330	59				>330	44	4
	rechts / right	>330	>330	95	185	18	1			
14	links / left	>330	>330	68	273	28	2			
	rechts / right	>330	>330	55				23	2	0
15	links / left	>330	161	16				>330	>330	68
	rechts / right	>330	230	23	75	8	1			
16	links / left	320	243	24	4	0	0			
	rechts / right	>330	223	23				88	9	1
17	links / left	>330	>330	53				89	9	1
	rechts / right	>330	>330	37	121	12	1			
18	links / left	>330	>330	84	>330	>330	106			
	rechts / right	>330	>330	119				>330	>330	266

19	links / left	>330	>330	280	>330	>330	58			
	rechts / right	>330	>330	269				>330	258	25
20	links / left	>330	>330	276				>330	81	8
	rechts / right	>330	>330	284	>330	>330	96			
21	links / left	>330	203	20	>330	166	17			
	rechts / right	>330	130	13				>330	>330	33
22	links / left	>330	>330	64				>330	>330	149
	rechts / right	>330	>330	48	>330	>330	208			
23	links / left	178	18	1	13	1	0			
	rechts / right	>330	>330	143				>330	91	9
24	links / left	>330	>330	97				271	27	2
	rechts / right	>330	>330	136	271	27	3			

Nx = Anzahl der 3ml- Portionen pro Proband / *3 ml portions used during procedure per subject*
__ = zur weiteren Berechnung verwendete Werte / *count used for further computation*

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Chirurgische Händedesinfektion mit 1592 – Versuchsergebnisse
Surgical hand disinfection procedure with 1592 – Experimental results

Produkt / *product*: 1592

Versuchsdaten / *dates of experiments*: 2016-06-01; 2016-06-08; 2016-06-15; 2016-06-22; 2016-06-29; 2016-07-06

Anwendung / *application*: 3 ml- Portionen des Produktes 1592 auf den Händen verreiben, so dass die Hände während 2 x 45 Sekunden (90 Sekunden) nass bleiben.
Rub portions of 3 ml of product 1592 on the hands to keep them wet for 2 x 45 seconds (90 seconds).

2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/

Proband / subject		Anzahl KBE je Platte aus Verdünnung 10 (x) - Prüfprodukt / *Number of cfu per plate from dilution 10 (x) - Test product*								
Nr./ no.	Hand / hand	Vorwert / *pre-count*			Nachwert / *post-count*					
					Sofortwirkung / *immediate*			3-Stundenwirkung / *3-hours*		
		-1	-2	-3	0	-1	-2	0	-1	-2
1	links / left	>330	>330	87				>330	>330	48
	rechts / right	>330	>330	107	>330	>330	34			
2	links / left	>330	>330	67	23	2	0			
	rechts / right	>330	287	29				36	3	0
3	links / left	>330	>330	138				>330	108	10
	rechts / right	>330	>330	96	>330	>330	50			
4	links / left	>330	>330	283	>330	70	7			
	rechts / right	>330	>330	272				>330	34	3
5	links / left	>330	155	15				153	15	1
	rechts / right	>330	294	31	>330	34	3			
6	links / left	>330	>330	124	>330	34	3			
	rechts / right	>330	>330	77				>330	32	3
7	links / left	>330	>330	282				n z	75	7
	rechts / right	>330	>330	297	>330	>330	79			
8	links / left	>330	>330	251	>330	>330	81			
	rechts / right	>330	>330	257				>330	>330	60
9	links / left	>330	136	14				>330	71	7
	rechts / right	>330	128	13	64	6	0			
10	links / left	>330	>330	74	>330	35	3			
	rechts / right	>330	>330	63				>330	>330	32
11	links / left	>330	>330	168	70	7	0			
	rechts / right	>330	>330	80				>330	38	3
12	links / left	>330	>330	247				67	6	0
	rechts / right	>330	>330	272	37	3	0			
13	links / left	>330	>330	59	99	10	1			
	rechts / right	>330	>330	65				89	8	0
14	links / left	>330	>330	103				25	2	0
	rechts / right	>330	>330	138	224	22	2			
15	links / left	>330	100	9	47	4	0			
	rechts / right	>330	142	14				>330	81	8
16	links / left	>330	>330	151				68	6	0
	rechts / right	>330	>330	100	3	0	0			
17	links / left	>330	116	11	52	5	0			
	rechts / right	>330	>330	96				47	4	0

18	links / left	>330	169	17				>330	>330	37
	rechts / right	>330	133	14	24	2	0			
19	links / left	>330	>330	262				>330	85	8
	rechts / right	>330	>330	231	>330	67	6			
20	links / left	>330	>330	225	>330	120	12			
	rechts / right	>330	>330	224				>330	46	4
21[1)]	links / left	>330	>330	39				>330	154	15
	rechts / right	>330	80	58	11	1	0			
22[1)]	links / left	>330	>330	177	>330	33	3			
	rechts / right	>330	>330	164				>330	105	10
23[1)]	links / left	>330	82	8				>330	58	6
	rechts / right	>330	53	5	10	1	0			
24[1)]	links / left	>330	>330	102	16	1	0			
	rechts / right	>330	>330	124				81	8	0

__ = zur weiteren Berechnung verwendete Werte / *count used for further computation*

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Liste der berechneten log-Werte und log-Reduktionsfaktoren
Referenzverfahren (RP)
List of computed lg values and lg reduction factors
Reference procedure (RP)

Produkt / product: Propan-1-ol mit einer Volumenkonz. von 60% /
propan-1-ol 60% volume concentration

Proband / *subject* No.	Sofortwirkung / *immediate effect*			3-Stunden-Wirkung / *3-hours effect*		
	lg x	lg y	lg z	lg x	lg y	lg z
1	5.14	3.21	1.93	5.47	3.72	1.75
2	5.36	1.71	3.65	4.93	1.69	3.24
3	4.52	2.80	1.72	4.30	3.92	0.38
4	4.77	2.86	1.91	5.43	3.82	1.61
5	5.11	2.92	2.19	4.85	3.33	1.52
6	5.36	2.69	2.67	5.42	4.02	1.40
7	5.34	4.08	1.26	5.17	3.95	1.22
8	5.37	4.15	1.22	5.41	3.85	1.56
9	4.23	2.91	1.32	4.92	3.76	1.16
10	4.79	3.06	1.73	4.89	3.69	1.20
11	5.20	2.16	3.04	5.22	3.84	1.38
12	5.47	3.05	2.42	5.46	1.96	3.50
13	4.98	2.27	2.71	4.77	2.64	2.13
14	4.83	2.44	2.39	4.74	1.36	3.38
15	4.36	1.88	2.48	4.21	3.83	0.38
16	3.71	0.60	3.11	4.35	1.94	2.41
17	4.57	2.08	2.49	4.72	1.95	2.77
18	4.92	4.03	0.89	5.08	4.42	0.66
19	5.45	3.76	1.69	5.43	3.41	2.02
20	5.45	3.98	1.47	5.44	2.91	2.53
21	4.31	3.22	1.09	4.11	3.52	0.59
22	4.68	4.32	0.36	4.81	4.17	0.64
23	3.25	1.11	2.14	5.16	2.96	2.20
24	5.13	2.43	2.70	4.99	2.43	2.56
$\bar{x}$	4.85	2.82	2.02	4.97	3.21	1.76
s	0.57	0.96	0.79	0.42	0.89	0.93
N	24	24	24	24	24	24

lg x — lg Vorwert / *lg prevalue*
lg y — lg Nachwert / *lg postvalue*
lg z — lg Reduktionsfaktor / *lg reduction factor*
$\bar{x}$ — Gesamtmittelwert von lg x. lg y und lg z / *overall mean of lg x. lg y and lg z*
s — Standardabweichung / *standard deviation*
N — Anzahl der Werte (Probanden) in jeder Spalte / *number of values (=subjects) in each column*

Liste der berechneten log-Werte und log-Reduktionsfaktoren 1592 (PP)

List of computed lg values and lg reduction factors 1592 (PP)

Produkt / product: 1592

Proband / *subject* No.	Sofortwirkung / *immediate effect*			3-Stunden-Wirkung / *3-hours effect*		
	lg x	lg y	lg z	lg x	lg y	lg z
1	5.03	3.53	1.50	4.94	3.68	1.26
2	4.83	1.36	3.47	4.46	1.56	2.90
3	4.98	3.70	1.28	5.14	3.03	2.11
4	5.45	2.85	2.60	5.43	2.53	2.90
5	4.47	2.53	1.94	4.19	2.18	2.01
6	5.09	2.53	2.56	4.89	2.51	2.38
7	5.47	3.90	1.57	5.45	2.88	2.57
8	5.40	3.91	1.49	5.41	3.78	1.63
9	4.11	1.81	2.30	4.13	2.85	1.28
10	4.87	2.54	2.33	4.80	3.51	1.29
11	5.23	1.85	3.38	4.90	2.58	2.32
12	5.43	1.57	3.86	5.39	1.83	3.56
13	4.77	2.00	2.77	4.81	1.95	2.86
14	5.14	2.35	2.79	5.01	1.40	3.61
15	4.00	1.67	2.33	4.15	2.91	1.24
16	5.00	0.48	4.52	5.18	1.83	3.35
17	4.06	1.72	2.34	4.98	1.67	3.31
18	4.13	1.38	2.75	4.23	3.57	0.66
19	5.36	2.83	2.53	5.42	2.93	2.49
20	5.35	3.08	2.27	5.35	2.66	2.69
21	4.10	1.04	3.06	4.59	3.19	1.40
22	5.25	2.52	2.73	5.21	3.02	2.19
23	3.72	1.00	2.72	3.91	2.76	1.15
24	5.01	1.20	3.81	5.09	1.91	3.18
$\bar{x}$	4.84	2.22	2.62	4.88	2.61	2.26
s	0.55	0.96	0.79	0.48	0.69	0.86
N	24	24	24	24	24	24

lg x	lg Vorwert / *lg prevalue*
lg y	lg Nachwert / *lg postvalue*
lg z	lg Reduktionsfaktor / *lg reduction factor*
$\bar{x}$	Gesamtmittelwert von lg x. lg y und lg z / *overall mean of lg x. lg y and lg z*
s	Standardabweichung / *standard deviation*
N	Anzahl der Werte (Probanden) in jeder Spalte / *number of values (=subjects) in each column*

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Test auf Effekte der Reihenfolge / *Test for sequence effects*

Sofortwirkung / *Immediate effect*

Prozedur / *Procedure*	Reihenfolge / *Sequence*						Absolute Differenz / *Absolute Difference*
	RP -> PP			PP -> RP			
	Mittelwert / Mean	s	NN	Mittelwert / Mean	s	NN	
„RP“ (Propan-1-ol 60% v/v)	1.95	0.71	12	2.10	0.88	12	
„PP“ (1592)	2.13	0.61	12	3.11	0.65	12	
Differenz der Mittelwerte / *Difference of Means*							
RP - PP	-0.18			-1.01			0.83

3-Stunden Wirkung / *3-hour effect*

Prozedur / *Procedure*	Reihenfolge / *Sequence*						Absolute Differenz / *Absolute Difference*
	RP -> PP			PP -> RP			
	Mittelwert / Mean	s	NN	Mittelwert / Mean	s	NN	
„RP“ (Propan-1-ol 60% v/v)	1.73	0.80	12	1.79	1.08	12	
„PP“(1592)	2.16	0.68	12	2.37	1.03	12	
Differenz der Mittelwerte / *Difference of Means*							
RP - PP	-0.43			-0.58			0.15

lg R	Dezimale log Reduktion / *decimal lg reduction*
RP -> PP	Reihenfolge zuerst RP dann PP / *sequence first RP. second PP*
PP -> RP	Reihenfolge zuerst PP dann RP / *sequence first PP. second RP*
s	Standardabweichung / *standard deviation*
NN	Anzahl der Werte (Probanden) / *number of values (volunteers)*

Individuelle Differenzen der log Reduktionen zwischen RP und PP für die Sofort- und 3h Wirkung /

Individual differences of lg reductions between RP and PP for immediate and 3-hour effects

Proband / *Volunteer*	Chronologische Reihenfolge / *Chronological sequence*	log R Sofortwirkung / *lg R immediate effect*			log R 3h Wirkung / *lg R 3-hour effect*		
		RP	PP	Differenz / *Difference* RP-PP	RP	PP	Differenz / *Difference* RP-PP
1	RP => PP	1.93	1.50	0.43	1.75	1.26	0.49
2	RP => PP	3.65	3.47	0.18	3.24	2.90	0.34
3	RP => PP	1.72	1.28	0.44	0.38	2.11	-1.73
4	PP => RP	1.91	2.60	-0.69	1.61	2.90	-1.29
5	RP => PP	2.19	1.94	0.25	1.52	2.01	-0.49
6	RP => PP	2.67	2.56	0.11	1.40	2.38	-0.98
7	RP => PP	1.26	1.57	-0.31	1.22	2.57	-1.35
8	RP => PP	1.22	1.49	-0.27	1.56	1.63	-0.07
9	RP => PP	1.32	2.30	-0.98	1.16	1.28	-0.12
10	RP => PP	1.73	2.33	-0.60	1.20	1.29	-0.09
11	PP => RP	3.04	3.38	-0.34	1.38	2.32	-0.94
12	PP => RP	2.42	3.86	-1.44	3.50	3.56	-0.06
13	PP => RP	2.71	2.77	-0.06	2.13	2.86	-0.73
14	PP => RP	2.39	2.79	-0.40	3.38	3.61	-0.23
15	PP => RP	2.48	2.33	0.15	0.38	1.24	-0.86
16	PP => RP	3.11	4.52	-1.41	2.41	3.35	-0.94
17	RP => PP	2.49	2.34	0.15	2.77	3.31	-0.54
18	PP => RP	0.89	2.75	-1.86	0.66	0.66	0.00
19	RP => PP	1.69	2.53	-0.84	2.02	2.49	-0.47
20	RP => PP	1.47	2.27	-0.80	2.53	2.69	-0.16
21	PP => RP	1.09	3.06	-1.97	0.59	1.40	-0.81
22	PP => RP	0.36	2.73	-2.37	0.64	2.19	-1.55
23	PP => RP	2.14	2.72	-0.58	2.20	1.15	1.05
24	PP => RP	2.70	3.81	-1.11	2.56	3.18	-0.62

lg R	Dezimale log Reduktion / *decimal lg reduction*
RP -> PP	Reihenfolge zuerst RP dann PP / *sequence first RP. second PP*
PP -> RP	Reihenfolge zuerst PP dann RP / *sequence first PP. second RP*

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Akzeptanzkriterien für die Testergebnisse nach EN12791 5.7.1. a) bis d) / *Acceptance criteria for test results according to EN12791 5.7.1. a) to d)*

a)	Vollständige Versuchsdaten sind vorhanden / *complete set of results available:* von 24 Personen */ from 24 volunteers*	Somit mehr als das Minimum von 23 / *hence. more than the minimum of 23*
b)	Die mittleren lg der Vorwerte des RP (Sofortwirkung / 3-h Wirkung) / *Mean of lg prevalues for RP (immediate / 3-h effect)* = 4.85 / 4.84 und für PP (Sofortwirkung / 3-h Wirkung) / *and for PP (immediate / 3-h effect)* = 4.85 / 4.84	Somit alle min. 3.5 / *hence all min. 3.5*
c)	Die absolute Differenz der mittleren Differenzen zwischen RP und PP / *Absolute difference of mean differences between RP and PP* d1) zwischen den Gruppen RP => PP und PP => RP (Sofortwirkung) / between the groups RP => PP and PP => RP *(immediate effect)*: 0.83 d2) zwischen den Gruppen RP => PP und PP => RP (3-h Wirkung) / between the groups RP => PP and PP => RP *(3-h effect)*: 0.15	Somit < 2 / *hence < 2* Somit < 2 / *hence < 2*
d)	Alle Resultate in den Tabellen Seite 6-9 welche zur Berechnung des gewichteten Mittelwertes verwendet wurden. haben einen Quotienten im Bereich 5 bis 15 / *Results in tables page 6-9 which were used for weighted mean counts; all quotions of weighted mean counts between 5 and 15.*	

Alle Akzeptanz- Kriterien erfüllt / *All acceptance criteria are fulfilled*

Legende:

RF	=	Reduktionsfaktor / *reduction factor*
RP	=	Referenzprodukt / *reference product*
PP	=	Prüfprodukt / *test product*
lg	=	$\log_{10}$ / lg_{10}

Sortierung der einzelnen Differenzen und Berechnung der oberen 97.5% Vertrauensgrenzen nach Hodges-Lehmann /
Sorting of individual differences and computation of the Hodges-Lehmann 97.5% upper confidence limit

Sofortwirkung / *immediate effect*

Sortierte Differenzen von / *Sorted differences* of RP-PP	Mittlere paarweise Differenzen / *Mean pairwise differences* ($d_i + d_{ij}$) /2																							
	0.44		0.43		0.25		0.18		0.15		0.15		0.11		-0.06		-0.27		-0.31		-0.34			
0.44	0.44	1																						
0.43	0.43	2	0.43	2																				
0.25	0.34	4	0.34	4	0.25	14																		
0.18	0.31	6	0.30	7	0.21	15	0.18	19																
0.15	0.29	8	0.29	8	0.20	16	0.16	22	0.15	24														
0.15	0.29	8	0.29	8	0.20	16	0.16	22	0.15	24	0.15	24												
0.11	0.27	12	0.27	12	0.18	19	0.14	27	0.13	28	0.13	28	0.11	30										
-0.06	0.19	18	0.18	19	0.09	31	0.06	34	0.04	38	0.04	38	0.02	41	-0.06	48								
-0.27	0.08	32	0.08	32	-0.01	44	-0.04	46	-0.06	48	-0.06	48	-0.08	55	-0.16	71	-0.27							
-0.31	0.06	34	0.06	34	-0.03	45	-0.06	48	-0.08	55	-0.08	55	-0.10	63	-0.18	74	-0.29		-0.31					
-0.34	0.05	37	0.04	38	-0.04	46	-0.08	55	-0.09	61	-0.09	61	-0.11	64	-0.20	77	-0.30		-0.32		-0.34			
-0.40	0.02	41	0.01	43	-0.07	52	-0.11	64	-0.12	66	-0.12	66	-0.14	70	-0.23		-0.33		-0.35		-0.37			
-0.58	-0.07	52	-0.07	52	-0.16	71	-0.20	77	**-0.21**	**82**	-0.21		-0.23		-0.32		-0.42		-0.44		-0.46			
-0.60	-0.08	55	-0.08	55	-0.17	73	-0.21	81	-0.22		-0.22		-0.24		-0.33		-0.43		-0.45		-0.47			
-0.69	-0.12	66	-0.13	69	-0.22		-0.25		-0.27		-0.27		-0.29		-0.37		-0.48							
-0.80	-0.18	74	-0.18	74	-0.27		-0.31		-0.32		-0.32		-0.34		-0.43									
-0.84	-0.20	77	-0.20	77	-0.29		-0.33		-0.34		-0.34		-0.36		-0.45									
-0.98	-0.27		-0.27		-0.36		-0.40		-0.41		-0.41		-0.43											
-1.11	-0.33		-0.34		-0.43		-0.46		-0.48		-0.48													
-1.41	-0.48		-0.49																					
-1.44																								
-1.86																								
-1.97																								
-2.37																								

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Vorzeichenrangtest für gepaarte Stichproben nach Wilcoxon /
Wilcoxon`s matched-pairs signed-ranks test

Sofortwirkung / *immediate effect*

Anzahl der Paare / *Number of pairs*	Signifikanzniveau / *Significance level*		
	p = 0.025 einseitig / *one sided*	p = 0.01 einseitig / *one sided*	p = 0.01 zweiseitig / *two sided*
23	73	62	54
24	81	69	61
25	89	76	68

Der Medianwert liegt zwischen dem 12. und 13. Wert: [-0,40+(-0,58)]/2 = -0,49. Die kleineren Exponenten geben die Ränge an.

Die mittleren paarweisen Differenzen, die den Medianwert (hier -0.49) nicht überschreiten, werden berechnet. Aus den kritischen Werten für Vorzeichenrangtests für gepaarte Stichproben nach Wilcoxon ergibt sich bei einem Eingangswert von n=24 und einem einseitigen Signifikanzniveau von 0.025 ein kritischer Wert von 81. **Folglich ist c=81+1=82**. Die paarweisen Differenzen werden in absteigender Reihenfolge sortiert. **Der 82. Wert ist -0.21.** Folglich ist die nach Hodges-Lehmann einseitige obere 97.5%-Vertrauensgrenze für die Differenz der log R zwischen RP und PP -0.21, was geringer ist als die vereinbarte Grenze für Unterlegenheit von 0.75.

Deshalb wird die Hypothese der Unterlegenheit von PP verworfen und es kann die Schlussfolgerung gezogen werden, dass das Prüfprodukt PP dem Referenzprodukt RP nicht unterlegen ist.

The median is between the 10th and 11th value: [-0.40+(-0.58)]/2 = -0.49. The small exponents represent the ranks.

The mean pair wise differences, that do not exceed the median (here: -0.49) are computed. From the critical values for Wilcoxon`s matched-pairs signed-ranks test the entry for n=24 and a one-sided 0.025 level of significance the critical value of 81 is found. ***Hence c=81+1=82****. In the body of the table the pair wise differences are sorted in descending order.* ***There the 82rd value is -0.21****. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg R between RP and PP is -0.21, which is less than the agreed inferiority margin of 0.75.*

Therefore the hypothesis of inferiority of the immediate effect of PP versus RP can be rejected and it can be concluded that the test preparation PP is non- inferior to RP.

Sortierung der einzelnen Differenzen und Berechnung der oberen 97.5% Vertrauensgrenzen nach Hodges-Lehmann /
Sorting of individual differences and computation of the Hodges-Lehmann 97.5% upper confidence limit

3h- Wirkung / *3h- effect*

Sortierte Differenzen von / *Sorted differences of* RP-PP	**Mittlere paarweise Differenzen / *Mean pairwise differences* ($d_i + d_{ii}$) /2**																							
	1.05		**0.49**		**0.34**		**0.00**		**-0.06**		**-0.07**		**-0.09**		**-0.12**		**-0.16**		**-0.23**		**-0.47**			
1.05	1.05	1																						
0.49	0.77	2	0.49	5																				
0.34	0.69	3	0.41	11	0.34	13																		
0.00	0.52	4	0.24	17	0.17	23	0.00	39																
-0.06	0.49	5	0.21	18	0.14	26	-0.03	42	-0.06	45														
-0.07	0.49	5	0.21	18	0.13	27	-0.03	42	-0.06	45	-0.07	50												
-0.09	0.48	8	0.20	21	0.12	29	-0.04	44	-0.07	50	-0.08	53	-0.09	55										
-0.12	0.46	9	0.18	22	0.11	31	-0.06	45	-0.09	55	-0.09	55	-0.10	58	-0.12	63								
-0.16	0.44	10	0.16	24	0.09	32	-0.08	53	-0.11	60	-0.11	60	-0.12	63	-0.14	67	-0.16	72						
-0.23	0.41	11	0.13	27	0.05	34	-0.11	60	-0.14	67	-0.15	70	-0.16	72	-0.17	75	-0.19	77	-0.23					
-0.47	0.29	14	0.01	38	-0.06	45	**-0.23**	**82**	-0.26		-0.27		-0.28		-0.29		-0.31		-0.35		-0.47			
-0.49	0.28	15	0.00	39	-0.07	50	-0.24		-0.27		-0.28		-0.29		-0.30		-0.32		-0.36		-0.48			
-0.54	0.25	16	-0.02	41	-0.10	58	-0.27		-0.30		-0.30		-0.31		-0.33		-0.35		-0.38		-0.50			
-0.62	0.21	18	-0.06	45	-0.14	67	-0.31		-0.34		-0.34		-0.35		-0.37		-0.39		-0.42		-0.48			
-0.73	0.16	24	-0.12	63	-0.19	77	-0.36		-0.39		-0.40		-0.41		-0.42		-0.44		-0.48		-0.51			
-0.81	0.12	29	-0.16	72	-0.23	81	-0.40		-0.43		-0.44		-0.45		-0.46		-0.48		-0.51					
-0.86	0.09	32	-0.18	76	-0.26		-0.43		-0.46		-0.46		-0.47		-0.49		-0.51							
-0.94	0.05	34	-0.22	79	-0.30		-0.47		-0.50		-0.50		-0.51											
-0.94	0.05	34	-0.22	79	-0.30		-0.47		-0.50		-0.50		-0.51											
-0.98	0.03	37	-0.24		-0.32		-0.49																	
-1.29	-0.12	63	-0.40		-0.47																			
-1.35	-0.15	70	-0.43		-0.50																			
-1.55	-0.25																							
-1.73	-0.34																							

Vorzeichenrangtest für gepaarte Stichproben nach Wilcoxon /
Wilcoxon`s matched-pairs signed-ranks test

3h- Wirkung / 3h- effect

Anzahl der Paare / *Number of pairs*	**Signifikanzniveau / *Significance level***		
	p = 0.025 einseitig / *one sided*	**p = 0.01 einseitig / *one sided***	**p = 0.01 zweiseitig / *two sided***
23	73	62	54
24	81	69	61
25	89	76	68

Der Medianwert liegt zwischen dem 12. und 13. Wert: [-0,49+(-0,54)]/2 = -0,515. Die kleineren Exponenten geben die Ränge an.

Die mittleren paarweisen Differenzen, die den Medianwert (hier -0.515) nicht überschreiten, werden berechnet. Aus den kritischen Werten für Vorzeichenrangtests für gepaarte Stichproben nach Wilcoxon ergibt sich bei einem Eingangswert von n=24 und einem einseitigen Signifikanzniveau von 0.025 ein kritischer Wert von 81. **Folglich ist c=81+1=82**. Die paarweisen Differenzen werden in absteigender Reihenfolge sortiert. **Der 82. Wert ist -0.23.** Folglich ist die nach Hodges-Lehmann einseitige obere 97.5%-Vertrauensgrenze für die Differenz der log R zwischen RP und PP -0.23, was geringer ist als die vereinbarte Grenze für Unterlegenheit von 0.85.

Deshalb wird die Hypothese der Unterlegenheit von PP verworfen und es kann die Schlussfolgerung gezogen werden, dass das Prüfprodukt PP dem Referenzprodukt RP nicht unterlegen ist.

The median is between the 10th and 11th value: [-0.49+(-0.54)]/2 = -0.515. The small exponents represent the ranks.

The mean pair wise differences, that do not exceed the median (here: -0.515) are computed. From the critical values for Wilcoxon`s matched-pairs signed-ranks test the entry for n=24 and a one-sided 0.025 level of significance the critical value of 81 is found. ***Hence c=81+1=82****. In the body of the table the pair wise differences are sorted in descending order.* ***There the 82rd value is -0.23****. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg R between RP and PP is -0.23, which is less than the agreed inferiority margin of 0.85.*

Therefore the hypothesis of inferiority of the immediate effect of PP versus RP can be rejected and it can be concluded that the test preparation PP is non- inferior to RP.

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Statistischer paariger Vergleich der im Referenzverfahren und Prüfverfahren erhobenen Werte
Statistical comparison of values as obtained with R and P

(Vorzeichen-Rangtest für Paardifferenzen nach WILCOXON)
(WILCOXON matched-pairs signed-rank test)

3-Stunden-Wirkung - Langzeitwirkung / *3-hours effect - sustained effect*

Proband / *subject* Nr. / *no.*	lg RF von / *lg RF derived from* R	P	Differenz / *Difference* R-P	Rang der Differenz / *Rank of Difference* ohne VZ / *without sign*	mit VZ / *with sign*
1	1.75	1.26	0.49	9.5	9.5
2	3.24	2.90	0.34	7	7
3	0.38	2.11	-1.73	23	-23
4	1.61	2.90	-1.29	20	-20
5	1.52	2.01	-0.49	9.5	-9.5
6	1.40	2.38	-0.98	18	-18
7	1.22	2.57	-1.35	21	-21
8	1.56	1.63	-0.07	2	-2
9	1.16	1.28	-0.12	4	-4
10	1.20	1.29	-0.09	3	-3
11	1.38	2.32	-0.94	16.5	-16.5
12	3.50	3.56	-0.06	1	-1
13	2.13	2.86	-0.73	13	-13
14	3.38	3.61	-0.23	6	-6
15	0.38	1.24	-0.86	15	-15
16	2.41	3.35	-0.94	16.5	-16.5
17	2.77	3.31	-0.54	11	-11
18	0.66	0.66	0.00		
19	2.02	2.49	-0.47	8	-8
20	2.53	2.69	-0.16	5	-5
21	0.59	1.40	-0.81	14	-14
22	0.64	2.19	-1.55	22	-22
23	2.20	1.15	1.05	19	19
24	2.56	3.18	-0.62	12	-12

RF = Reduktionsfaktor / reduction factor
VZ = Vorzeichen / sign

R = Referenzverfahren / reference
P = Prüfprodukt / test product
Rangsumme / rank sum (+): 35.5
Rangsumme / rank sum (-): 240.5

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Vorzeichen-Rangtest für gepaarte Stichproben nach WILCOXON /
WILCOXON matched-pairs signed-rank test

Kritische Werte für die untere der beiden Rangsummen mit (+) oder (-) Vorzeichen bei unterschiedlichen Signifikanzniveaus. /
Critical values for the lower of both sums of rank with (+) or (-) sign at different significance levels.

n Anzahl der Paare mit einer Differenz ≠ 0 / *number of pairs with difference = 0*	Signifikanzniveau / *level of significance* 0.025 einseitig / *one sided*	0.01 einseitig / *one sided*	0.01 zweiseitig / *two sided*
23	73	62	54
24	81	69	61
25	89	76	68
26	98	84	75

Bewertung von / *Evaluation of* 1592

Vergleich der durch das Prüfprodukt (PP) und das Referenzprodukt (RP) ermittelten mittleren Reduktionsfaktoren (log) / *Comparison of the mean lg reduction factors (RF) as obtained with product (PP) and reference (RP)*

Bewertete Wirkung / *assessed effects*	Mittelwert lg RF / *mean lg RF* P	R	Signifikanz der Differenz / *Significance of difference*
Sofortwirkung / *immediate*	2.62	2.02	
3-Stunden-Wirkung - Langzeitwirkung / *3-hours effect - sustained effect*	2.26	1.76	s (P ≤ 0.01)

s = signifikant / *significant*
ns = nicht signifikant / *not significant*

SURGICAL HANDRUB

STUDY OF THE SURGICAL HANDRUB COMPLYING WITH EN 12791

Schlussfolgerung / *Conclusion:*

Das Prüfverfahren mit **1592** resultiert jeweils in einem mittleren Reduktionsfaktor sowohl in der Sofortwirkung, als auch in der 3-Stunden-Wirkung gegenüber dem Referenzverfahren nicht unterlegen.

Das Produkt wurde auch auf eine Langzeitwirkung hin untersucht. Die Prüfergebnisse, im Vergleich mit Propan-1-ol, haben gezeigt, dass das Produkt **1592** eine Langzeitwirkung aufweist.

Demzufolge ist in Übereinstimmung mit EN 12791 das Produkt **1592** geeignet als chirurgisches Händedesinfektionsmittel mit Langzeitwirkung für die folgende Anwendung:

3 ml- Portionen des Produktes 1592 auf den Händen verreiben, so dass die Hände während 2 x 45 Sekunden (90 Sekunden) nass bleiben.

*The testing procedure with **1592** showed in each mean value, in both the immediate effect and the 3-hours effect non- inferior compared to the reference procedure.*

*The product was also tested for a 3-hours effect. The test results, in comparison with propan-1-ol, have shown that the product **1592** showed a 3-hours effect.*

*According to EN 12791 the product **1592** is suitable for surgical hand disinfection with a 3-hours effect by the following application:*

Rub portions of 3 ml of product 1592 on the hands to keep them wet for 2 x 45 seconds (90 seconds).

Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch das Prüflabor
The test results in this test report relate only to the items tested. This test report shall not be reproduced except in complete text without the written approval of the testing laboratory.

Nach Aussendung des Prüfberichtes B 20234 - Neuausfertigung vom 29.04.2019 wurden Modifikationen vorgenommen.

Dieser Prüfbericht ersetzt somit den Prüfbericht B 20234 - Neuausfertigung vom 29.04.2019.

Modifications were performed after dispatch of Test Report B 20234 - revised version dated 2019-04-29.

This Test Report thus supersedes the Test Report B 20234 - revised version of 2019-04-29.

Prof. Dr. med. H.-P. Werner
technischer Leiter / *technical manager*

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CHELAB SILLIKER
a Mérieux NutriSciences Company

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 0051

TEST REPORT N. 15/000189203

date of issue 08/09/2015

Customer ID 0067822

Messrs
SANISWISS SA
Chemin des Tulipiers 19
1208 Ginevra
Svizzera

Sample information

Acceptance number	15.024129.0001
Delivered by	The Courier on 20/04/2015
Receiving Date	20/04/2015
Place of origin	SANISWISS SA chemin des Tulipirs 19 1208 Ginevra Svizzera
Sample Description	1592 LOT PR195-F10 08/04/15

Sampling information

Sampled by Customer

ANALYTICAL RESULTS

	Value/Uncertain	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units	Line
ON SAMPLE AS IT IS							1
VIRUCIDAL ACTIVITY:SUSPENSION TEST Met.: UNI EN 14476:2013	view attached report				23/04/2015--05/06/2015	09	2

Operative units

Unit 09 : Via Fratta Resana PHARMA (TV)

Responsabile prove biologiche	Direttore laboratorio
Dott.ssa Federica Cattapan Ordine nazionale dei biologi Albo professionale n.045961 sez.A	Dott. Sébastien Moulard

- The line marked by a star (*) is not accredited by Accredia, member of MLA. - If not otherwise specified, the uncertainty is extended and has been calculated with a recovery factor k=2 corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probabilty interval of about 99%. - LoQ is the limit of quantification."n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - Registration with the number 7 of the Regional List of the laboratories of the Regione Veneto which perform analyses as regards the procedures for the food safety in food industries, as reported in Annex A of DDR n°73 of 16th January 2008 - If not differently specified the quantitative microbiological tests (excluded MPN) are performed on single repetition and two consecutive dilutions in accordance to ISO 7218:2007/Amd1:2013.

Report digitally signed according to the law in force.
The results contained in this Test Report refer only to the analyzed sample. This Test Report can not be copied, even partially, without Chelab's written permission.

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Attached to the test report number: 15/000189203

CHELAB SILLIKER
a Mérieux NutriSciences Company

EVALUATION OF VIRUCIDAL ACTIVITY ACCORDING TO UNI EN 14476:2013 QUANTITATIVE SUSPENSION TEST ON NOROVIRUS

Documento con firma digitale avanzata ai sensi della normativa vigente.
I risultati contenuti nel presente Rapporto di prova si riferiscono esclusivamente al campione oggetto di analisi. Il presente Rapporto di prova non può essere riprodotto parzialmente, salvo autorizzazione scritta di Chelab srl..

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476: 2013 NOROVIRUS

Attached to the test report number: 15/000189203

CHELAB SILLIKER
a Mérieux NutriSciences Company

Sponsor:	SANISWISS SA Chemin des Tulipiers 19 1208 Ginevra Svizzera
Contract Laboratory:	CHELAB-SILLIKER SRL
Analysts:	Dr. Francesca Squizzato Dr. Giulio Zilio Dr. Luna Ravasio
Analysis requested:	Quantitative suspension test for the evaluation of virucidal activity on norovirus according to UNI EN 14476:2013

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476: 2013 NOROVIRUS

Attached to the test report number: 15/000189203

CHELAB SILLIKER
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a) Sample Identification:
   - Product Name: 1592 – Saniswiss biosanitizer H1 LOT PR195-F10 08/04/15
   - Laboratory Number: 15.024129.0001
   - Storage conditions: room temperature protected from light
   - Appearance of the product: clear colourless liquid

b) Method used: UNI EN 14476:2013 evaluation of virucidal activity on norovirus. Neutralization by filtration.

c) Experimental Conditions:
   - Cell lines: RAW 264.7 on murine norovirus
   - Test viruses: Murine norovirus, strain S99 Berlin
   - Product test concentrations: 97%, 50% and 10% (50% and 10% prepared in distilled water
   - Interfering substance: Albumine Bovine 0,3 g/L (clean conditions)
   - Contact time: 30 seconds ± 10 seconds
   - Test temperature: 20 °C ± 1°C
   - Plates incubation temperature: 37°C ± 1°C, 5% CO_2 for 3-4 days
   - Growth medium: MEM 10% FCS
   - Manteinance medium: MEM 2% FCS

d) Test Results: see table n° 1-2.

e) Conclusions:

According to UNI EN 14476:2013, the test product when used at concentrations
- 97%

Has virucidal activity (R ≥ 4) under the following test conditions:

Contact time: 30 seconds ± 10 seconds

Temperature: 20°C ± 1°C

Interfering substance: Albumine Bovine 0,3 g/L (clean conditions)

Test Virus: Murine norovirus, strain S99 Berlin

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VIRUCIDAL

STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476: 2013
NOROVIRUS

Attached to the test report number: 15/000189203

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Table 1 – Results of the test UNI EN 14476:2013 on Murine norovirus

VIRUS	TEST	SAMPLE	VIRUS TITRATION $logTCID_{50}$	ACCEPTANCE CRITERIA	RESULT
NOROVIRUS	TITRATION OF VIRUS CONTROL	0 MINUTES	6.75	/	/
		30 SECONDS	6.75	/	/
	PRELIMINARY CYTOTOXICITY EFFECT	DONE			
	CELL SUSCEPTIBILITY	CONTROL	6.875	Control–sample < 1	R = 0.125
		0.5% *	7.0		PASS
	EFFICIENCY FOR SUP-PRESSION OF DISINFEC-TANT ACTIVITY	50%	6.75	≤ 0.5	R = 0 PASS
		10%	6.75	≤ 0.5	R = 0 PASS
	VIRUCIDAL ACTIVITY	50%	4.375	R ≥ 4	R = 2.375 NOT ACTIVE
		10%	6.625	R ≥ 4	R = 0.125 NOT ACTIVE
	REFERENCE VIRUS INACTIVATION TEST	30 MINUTES	4.5	N.A.	R = 2.25
		60 MINUTES	3.625	N.A.	R = 3.125

* lowest apparently non cytotoxic dilution
N.A. = not available in UNI EN 14476:2013

Table 2: Results of the test UNI EN 14476 on Murine norovirus: Modified test procedure for 97% (sample as it is)

VIRUS	TEST	SAMPLE	VIRUS TITRATION $logTCID_{50}$	ACCEPTANCE CRITERIA	RESULT
NOROVIRUS	TITRATION OF VIRUS CONTROL	0 MINUTES	6.875	/	/
		30 SECONDS	6.875	/	/
	PRELIMINARY CYTOTOXICITY EFFECT	DONE			
	CELL SUSCEPTIBILITY	CONTROL	6.875	Control–sample < 1	R = 0.125
		0.5% *	7.0		PASS
	EFFICIENCY FOR SUP-PRESSION OF DISINFEC-TANT ACTIVITY	97%	6.625	≤ 0.5	R = 0.25 PASS
	VIRUCIDAL ACTIVITY	97%	2.75	R ≥ 4	R = 4.125 ACTIVE

* lowest apparently non cytotoxic dilution

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saniswiss

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

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

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-306.10.31

18.06.2015

Test report C15L0111Po

Evaluation of the effectiveness of Saniswiss biosanitizer H1
1592

TEST REPORT

Test virus: poliovirus type 1 strain LSc-2ab

Method: EN 14476:2013

quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine

Sponsor:
Saniswiss SA
Chemin des Tulipiers 19
CH – 1208 Geneva

Norderoog 2, D - 28259 Bremen
Tel.: +49 421-27819102, Fax: +49 421-2760283
info@brillhygiene.com, http://www.brillhygiene.com

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1. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, D - 28259 Bremen

2. Identification of sample

Manufacturer	Saniswiss SA
Name of product	1592
Product diluent recommended by the manufacturer	-
Batch number	PR195-F10
Application	-
Production date	02.03.2015
Expiry date	-
Active compound (s) (100 g)	72 % (w/w) ethanol
Appearance, odour	clear, colorless liquid alcoholic
pH-values (in WSH)	not applicable
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	09.03.2015

3. Materials

3.1 Culture medium and reagents

- Dulbecco`s Modified Eagle`s Medium (DMEM, Biozym Scientific GmbH, catalogue no. 880021)
- fetal calf serum (Biochrom AG, article no. S 0115)
- 1.4 % formaldehyde solution
- Aqua bidest. (Fresenius Kabi Deutschland, article no. P2N 1636071)
- PBS (Invitrogen, article no. 18912-014)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153).

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, 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 2015

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3.2 Virus and cells

The poliovirus type 1 strain LSc-2ab (Chiron-Behring) was obtained from PD Dr. Olaf Thraenhart, Eurovir, D-14943 Luckenwalde.

BGM cells (*buffalo green monkey* = permanent monkey kidney cell line; supplied by Prof. Dr. Lindl, Institut für angewandte Zellkultur, D-81669 München, Germany) were cultivated in a 175 cm^2 flask with Dulbecco`s Modified Eagle`s Medium (DMEM) and 10 % fetal calf serum (FCS).

The cells (passage 15) were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

3.3 Apparatus, glassware and small items of equipment

- CO_2 incubator, Nunc GmbH & Co. KG, model QWJ 350
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)
- Polysterol 96-well microtitre plate (Nunc GmbH & Co. KG, Wiesbaden)
- Cell culture flask (Nunc GmbH & Co. KG, Wiesbaden)
- Sealed test tubes (Sarstedt AG & Co., Nümbrecht).

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, 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 2015

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4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	undiluted (97.0 % and 80.0 %) and as 50.0 %, 25.0 % and 10.0 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	30 and 60 seconds and 30 minutes
Interfering substance	0.3 g/l bovine serum albumin (BSA, clean conditions EN 14476:2013)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water (50.0 %, 25.0 % and 10.0 % solutions)
Stability of product in the mix with virus and interfering substance (97.0 % and 80.0 % solutions)	no flocculation, no precipitation
Virus strain	poliovirus type 1 strain LSc-2ab (Chiron-Behring)
Date of testing	09.03.2015 – 18.06.2015
End of testing	18.06.2015

5. Methods

5.1 Preparation of test virus suspension

For preparation of test virus suspension according to EN 5.4.1 *BGM cells* were infected with a multiplicity of infection of 0.1 at 37 °C. After cells showed a cytopathic effect, they were subjected to a threefold freeze/thaw procedure followed by a low speed centrifugation in order to sediment cell debris. After aliquotation of the supernatant, test virus suspension was stored at -80 °C.

5.2 Preparation of disinfectant (dilutions)

The test product was evaluated undiluted. Due to the addition of test virus suspension and interfering substance an 80.0 % solution resulted. Additionally, the test product was examined as 97.0 % solution (0.1 parts virus suspension + 0.2 parts interfering substance (5-fold) + 9.7 parts disinfectant).

Furthermore, the product was evaluated as 50.0 % and 10.0 % solutions (demonstration of non-active range). These solutions were prepared with water immediately before the inactivation tests.

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 421. 27819102, Telefax +49. 421. 2760283, 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 2015

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5.3 Infectivity assay

Infectivity was determined as endpoint titration according to EN 5.5 transferring 0.1 ml of each dilution into eight wells of a microtitre plate to 0.1 ml of freshly trypsinised *BGM cells* (10-15 x 10^3 cells per well), beginning with the highest dilution. Microtitre plates were incubated at 37 °C in a 5 % CO_2 atmosphere. The cytopathic effect was read by using an inverted microscope after seven days. Calculation of the infective dose $TCID_{50}$/ml was calculated with the method of Spearman (2) and Kärber (3) with the following formula:

$$- \log_{10}TCID_{50} = X_0 - 0.5 + \sum r/n$$

meaning

X_0 = $\log_{10}$ of the lowest dilution with 100 % positive reaction

r = number of pos. determinations of lowest dilution step with 100 % positive and all higher positive dilution steps

n = number of determinations for each dilution step.

5.4 Calculation and verification of virucidal activity

The virucidal activity of the test disinfectant was evaluated by calculating the decrease in titre in comparison with the control titration without disinfectant. The difference is given as reduction factor (RF).

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by four $\log_{10}$ steps within the recommended exposure period. This corresponds to an inactivation of ≥ 99.99 %.

5.5 Inactivation assay

Determination of virucidal activity has been carried out in accordance to EN 5.5. The test product was examined undiluted (97.0 % and 80.0 %) and as 50.0 %, 25.0 % and 10.0 % (demonstration of non-active range) solutions in water at 20 °C according to EN 14476:2013. 30 and 60 seconds and 30 minutes were chosen as contact times.

Immediately at the end of a chosen contact time, activity of the disinfectant was stopped by dilution to 10^{-8}.

Titrations of the virus control were performed after the longest exposure time (EN 5.5.7).

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Furthermore, a cell control (only addition of medium) was incorporated.

Inactivation tests were carried out in sealed test tubes in a water bath at 20 °C ± 1.0 °C. Aliquots were retained after appropriate exposure times, and residual infectivity was determined.

5.6 Determination of cytotoxicity

Determination of cytotoxicity was performed according to EN 5.5.4.1.

5.7 Cell sensitivity to virus

For the control of cell sensitivity to virus 0.3 parts by volume hard water were mixed with 9.7 parts by volume of the lowest apparently non-cytotoxic dilution of the product. This mixture or PBS as control was added to a volume of double concentrated cell suspension. After 1 h at 37 °C the cells were centrifuged and re-suspended in cell culture medium (EN 5.5.4.2b).

Finally, a comparative titration of the test virus suspension was performed on the pre-treated (disinfectant) and non-pre-treated (PBS) cells as described above.

5.8 Control of efficacy for suppression of disinfectant's activity

Furthermore, a control of efficiency for suppression of disinfectant's activity was included (EN 5.5.5).

5.9 Reference virus inactivation test

As reference for test validation a 0.7 % formaldehyde solution according to EN 5.5.6 was included. 5, 15, 30 and 60 minutes were chosen as contact times. In addition, cytotoxicity of formaldehyde test solution was determined following EN 5.5.6.2 with dilutions up to 10^{-5}.

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6. Verification of the methodology

The following criteria as mentioned in EN 5.7 were fulfilled:

a) The titre of the test virus suspension allowed the determination of a ≥ 4 log_{10} reduction (maximal virus reduction ≥ 4.25 ± 0.23).

b) The difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test (see 6.6.7) was 1.63 ± 0.57 (between 0.5 - 2.5) after 30 min and 2.38 ± 0.37 (between 2.0 - 4.5) after 60 min for poliovirus type 1.

c) The test product (97.0 %) showed cytotoxicity in the 1:10 dilutions thus allowing the detection of a 4 log_{10} reduction of virus titre.

d) The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) *BGM cells* showed no significant difference (< 1 log_{10}; EN 5.7) of virus titre: 6.75 ± 0.33 (PBS) versus 6.75 ± 0.33 (1:100 dilutions of disinfectant, 97.0 %) $log_{10}TCID_{50}$/ml.

e) The control of efficacy for suppression of disinfectant's activity (97.0 %) showed no decrease (< 0.5 log_{10}; EN 5.5.5.1) in virus titre (6.75 ± 0.35 versus 6.75 ± 0.33 $log_{10}TCID_{50}$/ml).

f) One concentration demonstrated a 4 log_{10} reduction and (at least) one concentration demonstrated a log_{10} reduction of less than 4.

Since all criteria according EN 5.7 were fulfilled, examination with poliovirus type 1 according to EN 14476:2013 is valid.

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7. Results

Results of examination are shown in tables 1 to 10. Tables 1 to 9 demonstrate the raw data, whereas table 10 (a+b) gives a summary of results.

The undiluted test product (97.0 % assay) was able to inactivate poliovirus type 1 after 30 seconds in this quantitative suspension test (Tables 1 and 2). The reduction factors were ≥ 4.25 ± 0.23 and ≥ 4.25 ± 0.23 at this time point (mean value ≥ 4.25 ± 0.16). This corresponded to an inactivation of ≥ 99.99 %.

The test product in an 80.0 % assay was not able to inactivate poliovirus type 1 after 30 seconds in this quantitative suspension test (Table 3).

Tested as 50.0 % and 25.0 % solutions, the test product was not active within 30 seconds of exposure time (Tables 4 and 5).

Tested as 10.0 % solution, the test product was not active within 30 minutes of exposure time (Table 6).

8. Conclusion

The disinfectant 1592 tested undiluted demonstrated effectiveness against poliovirus type 1 after an exposure time of 30 seconds under clean conditions.
Therefore, the disinfectant 1592 can be declared as active against poliovirus type 1 as follows:

undiluted 30 seconds

Bremen, 18.06.2015

- Dr. Jochen Steinmann -
Scientific Director

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9. Quality control

The Quality Assurance of the results was maintained by performing the determination of the virus-inactivating properties of the disinfectant in accordance with Good Laboratory Practice regulations:

1) Chemicals Act of Germany, Appendix 1, dating of 01.08 1994 (BGBI. I, 1994, page 1703). Appendix revised at 14. 05. 1997 (BGBI. I, 1997, page 1060).
2) OECD Principles of Good Laboratory Practice (revised 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. Environment Directorate, Organization for Economic Co-operation and Development, Paris 1998.

The plausibility of the results was additionally confirmed by controls incorporated in the inactivation assays.

10. Records to be maintained

All testing data, protocol, protocol modifications, the final report, and correspondence between Dr. Brill + Partner GmbH and the sponsor will be stored in the archives at Dr. Brill + Partner GmbH.

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The test results in this test report relate only to the items examined.

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11. Literature

1. EN 14476:2013: Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemicals disinfectants and antiseptics in human medicine test - Test method and requirements (phase 2, step 1)

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Arch Exp Path Pharmak; 162, 1931, 480-487

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Appendix:

Legend to the Tables

Table 1: Raw data for 1592 (97.0 %) tested against poliovirus type 1 (1st assay)

Table 2: Raw data for 1592 (97.0 %) tested against poliovirus type 1 (2nd assay)

Table 3: Raw data for 1592 (80.0 %) tested against poliovirus type 1

Table 4: Raw data for 1592 (50.0 %) tested against poliovirus type 1

Table 5: Raw data for 1592 (25.0 %) tested against poliovirus type 1

Table 6: Raw data for 1592 (10.0 %) tested against poliovirus type 1

Table 7: Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1

Table 8: Raw data for control of efficacy for suppression of disinfectant's activity (97.0 %)

Table 9: Raw data (poliovirus type 1) for cell sensitivity (97.0 %)

Table 10 (a+b): Summary of results with 1592 and poliovirus type 1

Legend to the Figures

Figure 1: Virus-inactivating properties of 1592 (97.0 %)

Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)

VIRUCIDAL
STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
POLIOVIRUS TYPE 1

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

Author JS Version 02 Test report no C15L0111Po Date 18/06/2015 Product name: 1592 Method EN 14476:2013*

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Table 1: Raw data for 1592 (97.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3852) (1st assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	97.0%	clean conditions	0.5	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			1.0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			1.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	97.0%	clean conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4334	0000 0033	0000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 2: Raw data for 1592 (97.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945) (2nd assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	97.0%	clean conditions	0.5	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			1.0	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			1.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	97.0%	clean conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0444	0000 0000	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0040 0400	0000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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VIRUCIDAL
STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
POLIOVIRUS TYPE 1

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

Table 3: Raw data for 1592 (80.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	80.0%	clean conditions	0.5	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4440	0040 0040	0000 0000	n.d.	n.d.
			1.0	tttt tttt	4444 4444	4444 4444	0003 0040	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			1.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	80.0%	clean conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4404	4000 4000	0000 4000	4000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 4: Raw data for 1592 (50.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	50.0%	clean conditions	0.5	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0000 4040	0000 0000	n.d.
			1.0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			1.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	50.0%	clean conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4404	4000 4000	0000 4000	4000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 5: Raw data for 1592 (25.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	25.0%	clean conditions	0.5	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0444 4444	0000 4004	0000 0000	n.d.
			1.0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			1.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	25.0%	clean conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4404	4000 4000	0000 4000	4000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 6: Raw data for 1592 (10.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	10.0%	clean conditions	0.5	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4004 0440	0000 0000	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	10.0%	clean conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	clean conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4404	4000 4000	0000 4000	4000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 7: Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (3945)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
formaldehyde	0.7% (m/V)	PBS	5	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	4440 4444	0400 0000	n.d.	n.d.
			15	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	0000 0440	4400 0000	n.d.	n.d.
			30	tttt tttt	tttt tttt	4444 4444	4444 4444	4004 4044	0004 0000	0000 0000	n.d.	n.d.
			60	tttt tttt	tttt tttt	4444 4444	4444 4444	0000 0000	0000 0000	0000 0000	n.d.	n.d.
formaldehyde cytotoxicity	0.7% (m/V)	PBS	n.a.	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	PBS	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3000 4040	0000 0000	0000 0000

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 8: Raw data for control of efficacy for suppression of disinfectant's activity (97.0 %) (3945)

Product	Interfering substance	dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
test product	PBS	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	clean conditions	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	0040 0000	4000 0000	0000 0000	n.d.
test product	dirty conditions	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable 0 = no virus present; t = cytotoxic
n.d. = not done 1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 9: Raw data (poliovirus type 1) for cell sensitivity (97.0 %) (3945)

Product	Dilution	Dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
PBS	-	4444 4444	4444 4444	4444 4444	4444 4444	4433 4444	0040 0040	0000 0000	0000 0000	n.d.
test product	1:10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:100	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0004	0000 0000	0000 0000	n.d.
test product	1:1,000	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable 0 = no virus present; t = cytotoxic
n.d. = not done 1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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Table 10a: Summary of results with 1592 and poliovirus type 1

Product	Con-centration	Interfering substance	Level of cytotoxicity	log_{10} $TCID_{50}$/ml after ....min					> 4 log_{10} reduction after … min
				0.5	1	1.5	30	60	
test product	97.0%	clean conditions	2.50	≤ 2.50±0.00	n.d.	n.d.	n.d.	n.d.	0.5 (RF ≥ 4.25±0.23)
test product	97.0%	clean conditions	2.50	≤ 2.50±0.00	≤ 2.50±0.00	n.d.	n.d.	n.d.	0.5 (RF ≥ 4.25±0.23)
test product	80.0 %	clean conditions	2.50	6.63±0.41	4.75±0.33	n.d.	n.d.	n.d.	> 0.5
test product	50.0%	clean conditions	2.50	7.75±0.33	n.d.	n.d.	n.d.	n.d.	> 0.5
test product	50.0%	clean conditions	1.50	7.63±0.41	n.d.	n.d.	n.d.	n.d.	> 0.5
test product	10.0%	clean conditions	1.50	n.d.	n.d.	n.d.	8.00±0.38	n.d.	> 30

n.a. = not applicable n.d. = not done

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Table 10b: Summary of results with 1592 and poliovirus type 1

Product	Con-centration	Interfering substance	Level of cytotoxicity	log_{10} $TCID_{50}$/ml after ....min					> 4 log_{10} reduction after … min
				0	5	15	30	60	
formaldehyde	0.7% (w/v)	PBS	3.50	n.d.	7.50±0.35	7.00±0.46	6.25±0.44	5.50±0.00	> 60
virus control	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	7.88±0.37	n.a.
virus control 1	97.0%	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	6.75±0.33	n.a.
virus control 2	97.0%	clean conditions	n.a.	7.00±0.38	n.d.	n.d.	n.d.	6.75±0.33	n.a.
virus control	80.0%	clean conditions	n.a.	7.88±0.54	n.d.	n.d.	n.d.	7.63±0.25	n.a.
suppression control	97.0%	clean conditions	2.50	n.d.	n.d.	n.d.	6.75±0.35	n.d.	n.a.
sens.control PBS	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	6.75±0.33	n.a.
sens. control test product	97.0% → 1:100	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	6.75±0.33	n.a.

n.a. = not applicable n.d. = not done sens. = sensitivity

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VIRUCIDAL
STUDY OF THE VIRUCIDAL ACTIVITY COMPLYING WITH EN 14476 : 2013
POLIOVIRUS TYPE 1

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

Figure 1: Virus-inactivating properties of 1592 (97.0 %)

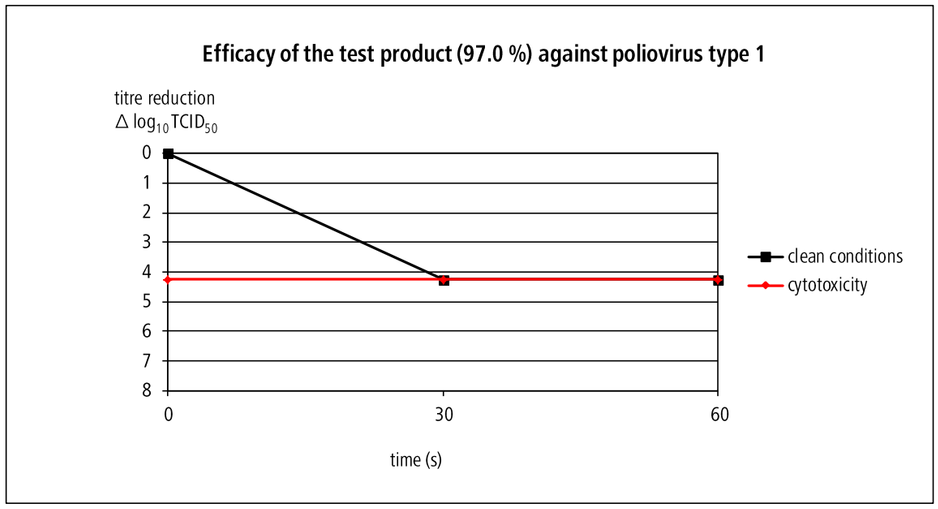

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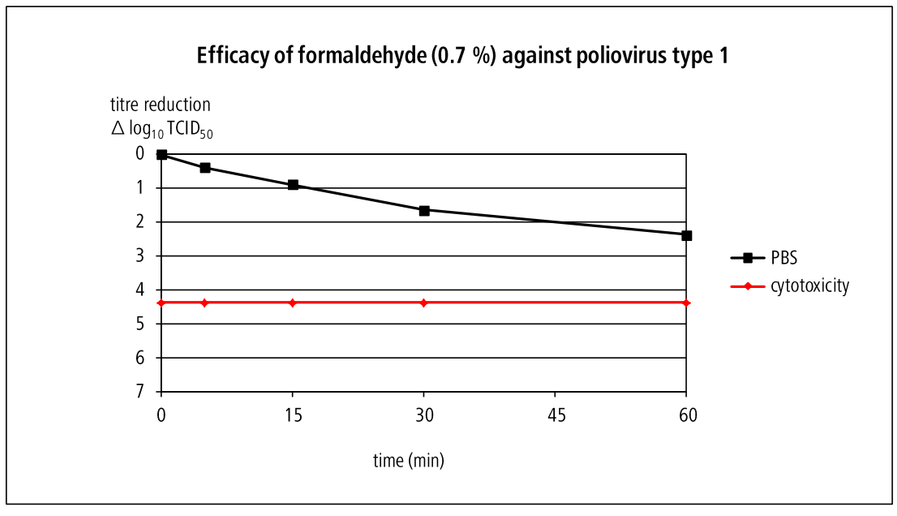
Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)



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