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

Sterisept Ready to Use / Sterisept Wipes

Evaluation of virucidal efficacy

Test report no.	L23/00149MV.2
Method	DIN EN 16777:2019-03
Endpoint	modified vaccinia virus, strain Ankara (MVA) (ATCC-VR-1508)
Client	Chemi-Pharm AS, Tänassilma tee 11, Tänassilma küla, Saku, EST - HARJU MAAKOND 76406
Laboratory	Dr. Brill + Partner GmbH, Institute for Hygiene and Microbiology Norderoog 2, DE-28259 Bremen

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

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Chemi-Pharm AS
Tänassilma tee 11, Tänassilma küla, Saku
EST - HARJU MAAKOND 76406

Bremen, 17 May 2023

Expert opinion

Activity of **Sterisept Ready to Use / Sterisept Wipes** against modified vaccinia virus, strain Ankara (MVA) (ATCC-VR-1508) in the quantitative non-porous surface test without mechanical action according to DIN EN 16777:2019-03 under dirty conditions

The surface disinfectant **Sterisept Ready to Use / Sterisept Wipes** was tested and evaluated according to DIN EN 16777:2019-03 "Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2); German version EN 16777:2018".

According to this norm a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

According to the test report L23/00149MV.2 dated 17/05/2023, the surface disinfectant **Sterisept Ready to Use / Sterisept Wipes** was examined undiluted at room temperature (18 to 25 °C ± 1 °C) and dirty conditions. 1 and 2 minutes were chosen as exposure times. In summary, a virucidal activity against MVA in a test simulating practical conditions was measured as follows:

undiluted 2 minutes dirty conditions (3.0 g/L bovine albumine + 3.0 mL/L sheep erythrocytes)

Dipl.-Biol. Dr. rer. nat. Florian H. H. Brill

Test report no L23/00149MV.2

Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of **Sterisept Ready to Use / Sterisept Wipes** in the medical area (DIN EN 16777:2019-03)

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1 General Information and Material

1.1 Client

Client ..... Chemi-Pharm AS, Tänassilma tee 11, Tänassilma küla, Saku, EST - HARJU MAAKOND 76406

Date of order 06/04/2023

Confirmation no. 231027

1.2 Identification of Test Laboratory

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

Study manager ..... Dr. Britta Becker

Scientific assistant ..... Dr. Dajana Paulmann

Laboratory technicians ..... Ursel Köster, Janina Rickers

1.3 Identification of Sample

Name of product ..... Sterisept Ready to Use / Sterisept Wipes

Internal product identifier 23/00233-001

Formulation code ..... not specified

Batch no. 14151022

Production date 15/03/2023

Expiry date ..... not specified

Manufacturer ..... Chemi-Pharm AS, Tänassilma tee 11, Tänassilma küla, Saku, EST - HARJU MAAKOND 76406

Date of delivery 20/03/2023

Storage conditions ..... room temperature and darkness

Appearance of product ..... clear, colorless liquid

Odour ..... characteristic

Product type ..... surface disinfectant

Area of accreditation ..... DAkkS D-PL-13412-01-02

Recommended diluent ..... not specified

pH value, undiluted (Manufacturer's data) ..... not specified

Active agents (Manufacturer's data)	Didecyl-Dimethyl-Ammonium Chloride (DDAC) 0,45g; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0,45g

1.4 Identification of Reference Product Stock Solution

Name of product	Glutaraldehyde
Batch no.	BCCH6306
Manufacturer	SIGMA - ALDRICH®
Storage conditions	at 5 °C and darkness

1.5 Experimental Conditions

Test period	27/04/2023 - 02/05/2023
Concentration of test product	100.0 + 50.0 + 10.0 %
Appearance of product dilutions	no precipitation
Exposure time(s)	1 and 2 minutes
Test temperature (range given in the norm)	room temperature (18 to 25 °C ± 1 °C)
Test temperature (measured during test)	19.1 °C
Incubation temperature	36.5 °C – 37.1 °C
Diluent used	Aqua dest.
Organic load	dirty conditions (3.0 g/L bovine albumine + 3.0 mL/L sheep erythrocytes)
Procedure to stop action of disinfectant	immediate dilution in cell culture medium
Virus Strain	modified vaccinia virus, strain Ankara (MVA) (ATCC-VR-1508)
Origin of Virus	LGC Standards GmbH, Wesel, Germany
Passage of Virus	4
Cells name	BHK 21-cells (baby hamster kidney cells)
Origin of Cells	Leibniz Institute, DSMZ-German Collection of Microorganisms and Cell Cultures GmbH, Braunschweig, Germany
Passage of Cells	28
Cell culture medium	Dulbecco`s Modified Eagle`s Medium (DMEM), biowest, catalogue no L0064-500

2 Methods

2.1 Preparation of test virus suspension

For preparation of test virus suspension, 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 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.

2.2 Determination of pH values and/or active concentrations

The following pH values and concentrations of active substances were measured.

Product-conc. [%]	100.0	50.0	10.0
pH in diluent	11.13	10.86	10.45
Active conc.	n.a.	n.a.	n.a.

2.3 Preparation of disinfectant (dilutions)

The test product was tested undiluted. Furthermore, the product was evaluated as 50.0 % and 10.0 % solutions (demonstrating of non-active range). These solutions were prepared immediately before the inactivation tests.

2.4 Preparation of the stainless steel discs

Prior to use the discs ((2 cm diameter discs) with Grade 2 B finish on both sides (article no. 4174-3000, GK Formblech GmbH, Berlin, Germany)) shall be placed in a container with an appropriate quantity of 5 % (v/v) Decon 90® for 60 minutes. Subsequently, the discs were rinsed with running freshly demineralised water for 2 x 10 s, dipped in a bath containing 70 % (v/v) propan-2-ol for 15 min and rinsed again with distilled water for at least 3 x 10 seconds. Finally, the discs were sterilised by autoclaving (steam sterilisation) according to 16777, section 5.3.3.

2.5 Preparation of the virus inoculum

Nine volumes of test virus suspension were mixed with one volume of interfering substance solution (EN 16777, section 5.2.2.8).

2.6 Inactivation assay and controls

Determination of virucidal activity has been carried out according to DIN EN 16777 at room temperature. For each test 2 discs per concentration and exposure time plus control discs were prepared.

Test discs were placed aseptically in a Petri dish and inoculated with 50 µl of the virus inoculum (EN 16777, section 5.5.2). After drying, the dried inoculum was covered with 100 µl of the test solution. For the virus control, 100 µl of hard water were placed on the carrier instead of the disinfectant (EN 16777, section 5.5.6). After the appropriate

contact time, action of the product was stopped by immediate dilution with 9.9 ml ice-cold medium (1:100 dilution) in a separate container (25 ml with cap). Container was vortexed for 60 seconds to re-suspend the virus. Directly after elution, series of ten-fold dilutions of the eluate in ice-cold maintenance medium were prepared and inoculated on cell culture (see EN 16777, section 5.5.2).

Titrations of the virus controls were performed before drying, directly after drying (VCt0) and after drying at the respective contact time(s).

In addition, a control of efficiency for suppression of disinfectant's activity was included (EN 16777, section 5.5.4).

For the control of cell susceptibility (EN 16777, section 5.5.3.2) one volume of the lowest apparently non-cytotoxic dilution of the product (or PBS as control) was added to one volume of double concentrated cell suspension. After 1 h at 37 °C the cells were centrifuged and re-suspended in cell culture medium. Finally, a comparative titration of the test virus suspension with the virus inoculums was performed on the pre-treated (disinfectant) and non-pre-treated (PBS) cells as described above.

Determination of cytotoxicity was performed as described in EN 16777, section 5.5.3.1. Stainless steel discs were inoculated with 45 µl cell culture medium (with FCS) and 5 µl interfering substance instead of the virus inoculum.

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

Determination of cytotoxicity was performed.

As reference for test validation according to EN 16777, section 5.5.5 glutaraldehyde was included. 5 minutes were chosen as contact time.

2.7 Determination of infectivity

Infectivity was determined as endpoint titration transferring 0.1 ml of each dilution into eight wells of a microtitre plate containing 0.1 ml of cell suspension. Microtitre plates were incubated at 37 °C in a 5 % CO_2-atmosphere. The cytopathic effect was read by using an inverted microscope. The infective dose $TCID_{50}$/ml was calculated with the method of Spearman (2) and Kärber (3).

Since it was not possible to test the test product due to cytotoxicity with the end point dilution method, in parallel to the end point dilution method the large volume plating method (LVP) was introduced. Following the large volume plating method (EN 16777, section B.3) the inactivation assays were further diluted 1:1,000 in cell culture medium. The total volume was added (without any further dilution) to the permissive cells. By introducing such a huge dilution, it is possible to eliminate cytotoxicity of the test product in order to demonstrate a 4 log_{10} reduction of virus titre. Calculation of virus titre follows formula of Taylor or Poisson (EN 16777, section B.3).

2.8 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 EN 16777, section 5.8.2, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by 4 $\log_{10}$ steps within the recommended exposure period. This corresponds to an inactivation of ≥ 99.99 %.

3 Results

3.1 Verification of results and pass criteria

Because following criteria were fulfilled, examination according to DIN EN 16777:2019-03 section 5.7 is valid:

a. The titre of the test virus suspension allowed the determination of a ≥ 4 $\log_{10}$ reduction.

b. The detectable reduction of the titre is at least 4 $\log_{10}$.

c. The difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test with glutaraldehyde (EN 16777) was in the range of the values specified in the EN 16777 (section 5.7, table 3) for MVA (< 3 log).

d. The cytotoxicity of the product solution does not affect cell morphology and cell growth or the susceptibility of the test organism in the dilutions of the test product used for demonstration of a 4 $\log_{10}$ reduction.

e. The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) cells showed no significant difference of virus titre (< 1 $\log_{10}$; norm section 5.5.3.2).

f. The control of efficacy for suppression of disinfectant's activity showed no decrease in virus titre (≤ 0.5 $\log_{10}$; norm section 5.5.4).

3.2 Results of Efficacy testing according to DIN EN 16777:2019-03

Results of examination are shown in tables 1 to 6. Tables 1 and 2 demonstrate a summary of results, whereas tables 3 to 6 represent the raw data.

Tested as 50.0 % and 10.0 % solution, the test product was not active within 2 minutes of exposure time (tables 1 and 4).

Since it was not possible to test the undiluted test product due to cytotoxicity with the end point dilution method, in parallel to the end point dilution method the large volume plating method (LVP) was introduced with 1 and 2 minutes of exposure time. The eluates of the assays were diluted 1:100 in the large volume plating assay (meaning a total dilution of 1:1,000). The mean virus titre of the controls was $\log_{10}$ $TCID_{50}$/ml = 6.31 ± 0.37 after 1 minute and 6.38 ± 0.44 after 2 minutes (tables 1 and 3).

The undiluted test product was active after 2 minutes of exposure time (tables 1 and 3). Since no residual virus was found in 288 cell culture units on both carriers at this time point, the result according to the formula of Poisson was

≤ 2.16 $\log_{10}$ $TCID_{50}$, respectively. The mean value was ≤ 2.16 $\log_{10}$ $TCID_{50}$. The reduction factor was therefore ≥ 4.22 ± 0.44 (6.38 ± 0.44 $\log_{10}$ $TCID_{50}$ minus ≤ 2.16 $\log_{10}$ $TCID_{50}$). This corresponded to an inactivation of ≥ 99.99 %.

3.3 Conclusion

The surface disinfectant Sterisept Ready to Use / Sterisept Wipes tested undiluted demonstrated activity against MVA after an exposure time of 2 minutes under dirty conditions. Therefore, the surface disinfectant Sterisept Ready to Use / Sterisept Wipes can be declared as active against MVA in the test simulating practical conditions (EN 16777) as follows:

undiluted	**2 minutes**	**dirty conditions**

4 Signature page

Bremen, 17/05/2023

Dipl.-Biol. Dr. rer. nat. Britta Becker
Director of Laboratory - Virology

Dipl.-Biol. Dr. rer. nat. Dajana Paulmann
Deputy Head of Laboratory - Virology

Table 1: Summary of results

Product name:	**Sterisept Ready to Use / Sterisept Wipes**	Batch:	14151022
Test organism:	MVA	Temperature:	room temperature (18 to 25 °C ± 1 °C)
Organic load:	dirty conditions		

test product conc.	Exposure time [min]	Cytotox./ LLOQ [log]	log_{10} $TCID_{50}$/ml with 95% CI *before* drying		log_{10} $TCID_{50}$/ml with 95 % CI *after* drying					
					carrier 1	carrier 2	carrier 3	carrier 4	MV	RF
100.0	1	2,16	n.a.	n.a.	3,44	3,64	n.d.	n.d.	3,54	2,77
										± 0,37
100.0	2	2,16	n.a.	n.a.	≤ 2,16	≤ 2,16	n.d.	n.d.	≤ 2,16	≥ 4,22
										± 0,40
50.0	1	3,50	n.a.	n.a.	4,75	4,63	n.d.	n.d.	4,69	1,63
					± 0,33	± 0,25			± 0,29	± 0,47
50.0	2	3,50	n.a.	n.a.	4,63	4,25	n.d.	n.d.	4,44	1,94
					± 0,25	± 0,33			± 0,29	± 0,49
10.0	1	2,50	n.a.	n.a.	5,50	5,88	n.d.	n.d.	5,69	0,63
					± 0,00	± 0,37			± 0,26	± 0,45
10.0	2	2,50	n.a.	n.a.	6,00	6,25	n.d.	n.d.	6,13	0,25
					± 0,38	± 0,33			± 0,36	± 0,53
Virus controls										
		Cytotox. [log]	log_{10} $TCID_{50}$/ml with 95% CI *before* drying		log_{10} $TCID_{50}$/ml with 95 % CI *after* drying					
					carrier 1	carrier 2	carrier 3	carrier 4	MV	RF
VC (virus inoculum)		n.a.	6,75		n.a.	n.a.	n.a.	n.a.	6,75	n.a.
			± 0,33						± 0,33	
VCt0		n.a.	n.a.	n.a.	6,50	6,75	n.d.	n.d.	6,63	0,13
					± 0,46	± 0,44			± 0,45	± 0,56
VCt1		n.a.	n.a.	n.a.	6,25	6,38	n.d.	n.d.	6,31	0,44
					± 0,33	± 0,41			± 0,37	± 0,50
VCt2		n.a.	n.a.	n.a.	6,50	6,25	n.d.	n.d.	6,38	0,38
					± 0,35	± 0,44			± 0,40	± 0,52

n.a. = not applicable CI = confidence interval RF = reduction factor Cytotox = cytotoxicity conc = concentration
n.d. = not detected MV = mean value VC = virus control LLOQ = lower limit of quantification

Table 2: Summary of results (controls)

Product name: **Sterisept Ready to Use / Sterisept Wipes** Batch: 14151022

Test organism: MVA Temperature: room temperature (18 to 25 °C ± 1 °C)

Organic load: dirty conditions

Controls	Cytotox./ LLOQ [log]	log_{10} $TCID_{50}$/ml with 95% CI *before* drying		log_{10} $TCID_{50}$/ml with 95 % CI *after* drying				MV	RF
				carrier 1	carrier 2	carrier 3	carrier 4		
Suppression control									
test product 100.0 %	3,50	6,63 ± 0,25	n.a.	n.a.	n.a.	n.a.	n.a.	6,63 ± 0,25	0,13 ± 0,41
Virus control for suppression									
VC (virus inoculum)	n.a.	6,75 ± 0,33	n.a.	n.a.	n.a.	n.a.	n.a.	6,75 ± 0,33	n.a.
Sensitivity control									
PBS control	n.a.	6,50 ± 0,00	n.a.	n.a.	n.a.	n.a.	n.a.	6,50 ± 0,00	n.a.
test product 100.0 %	n.a.	6,50 ± 0,35	n.a.	n.a.	n.a.	n.a.	n.a.	6,50 ± 0,35	0,00 ± 0,35
Reference control									
50 ppm GDA t5 min	1,50	n.a.	n.a.	5,13 ± 0,45	4,88 ± 0,37	n.d.	n.d.	5,00 ± 0,41	1,38 ± 0,53
Virus control for reference									
VCt5	n.a.	n.a.	n.a.	6,25 ± 0,33	6,50 ± 0,35	n.d.	n.d.	6,38 ± 0,34	0,38 ± 0,47

n.a. = not applicable CI = confidence interval RF = reduction factor Cytotox = cytotoxicity
n.d. = not detected MV = mean value VC = virus control LLOQ = lower limit of quantification

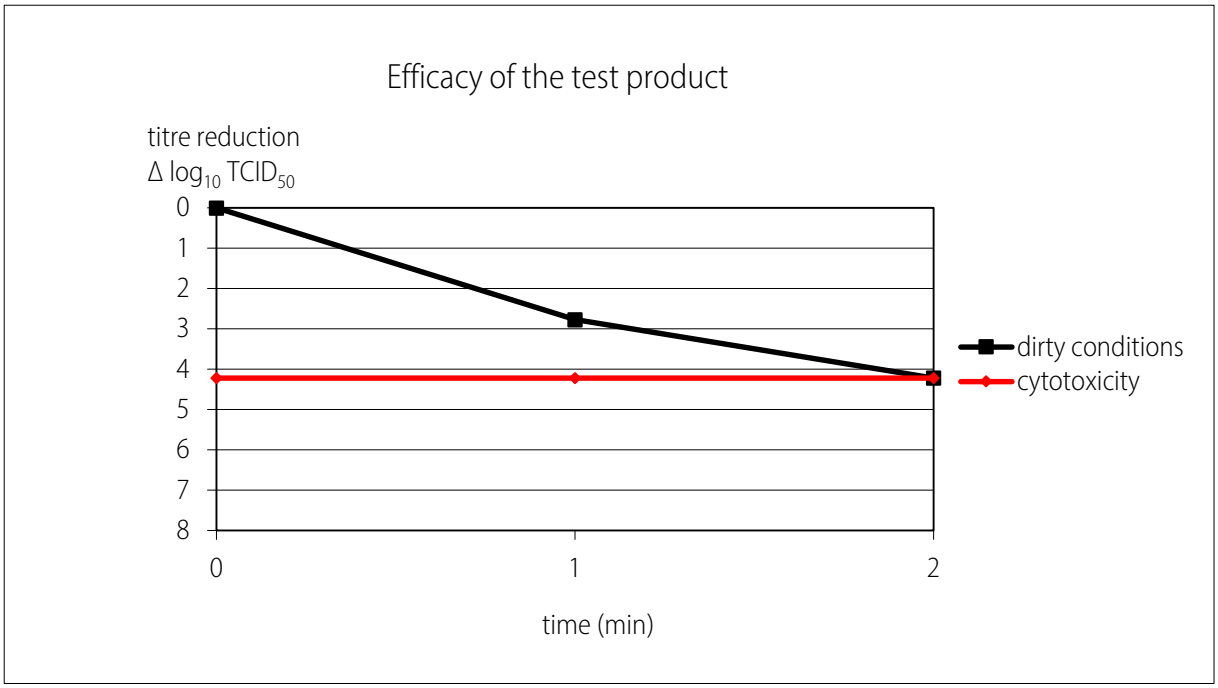

Figure 1: Virus-inactivating properties of Sterisept Ready to Use / Sterisept Wipes (100.0 %) against MVA

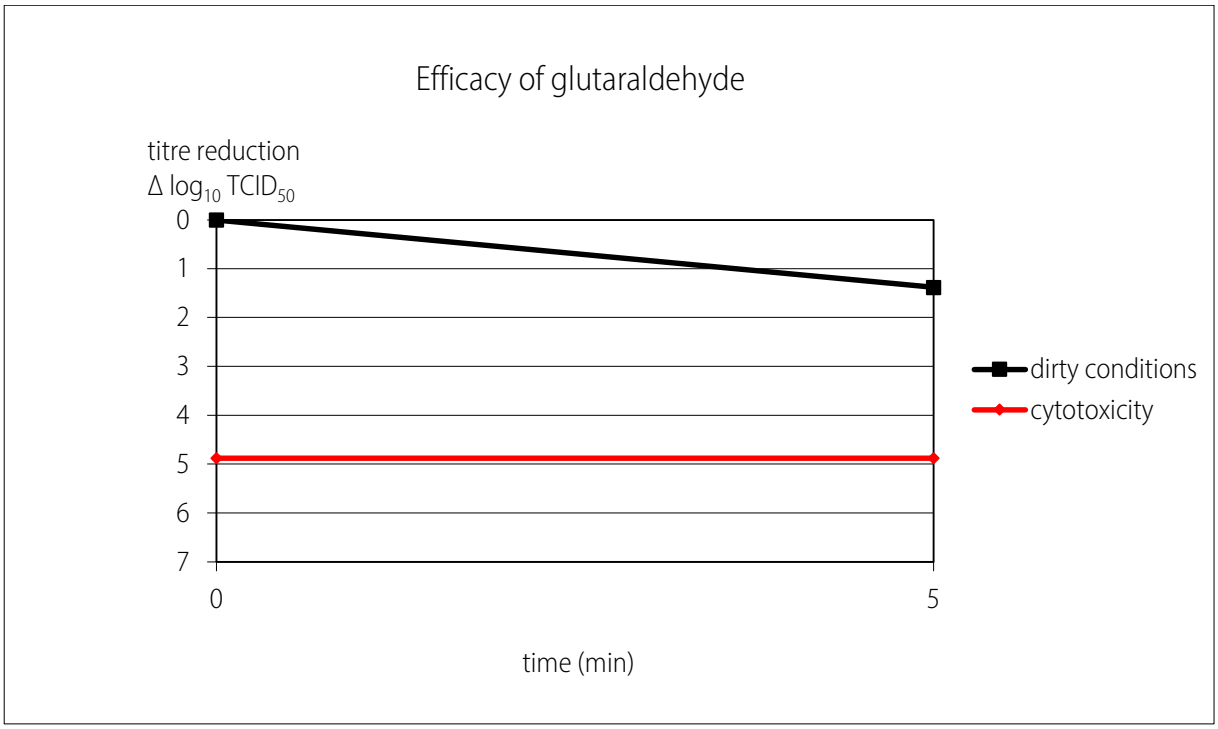

Figure 2: Virus-inactivating properties of the glutaraldehyde (50 ppm) against MVA

Table 3: Raw data for efficacy test following LVP

Product name:	**Sterisept Ready to Use / Sterisept Wipes**	Batch:	14151022
Test organism:	MVA	Temperature:	room temperature (18 to 25 °C ± 1 °C)
Organic load:	dirty conditions	Test Run:	1st assay
No. of assay:	#8486		

Conc. [%]: 100.0		Dilution: 1:1,000							Contact time [min]: 1				
		Row											
Carrier	Plate	1	2	3	4	5	6	7	8	9	10	11	12
1	1	0400 0000	0000 0404	0400 0040	4004 0000	0000 0000	0000 0040	0400 4000	0000 4040	0000 0000	4440 4000	0000 4000	0040 0400
	2	0040 0000	0000 4004	4000 0000	0040 0000	0000 4000	0000 0400	4400 0004	0000 0004	0000 4000	0040 0000	0400 0040	0004 0000
	3	0040 4000	0000 0000	4000 4004	0000 0000	0000 4000	4000 0004	0040 0000	0004 4000	0400 0440	0000 0000	0004 0000	0400 0040
2	1	0404 0000	0000 0440	0400 0004	0004 0400	0044 4000	0000 0004	4000 4000	0000 0000	4040 0004	0004 0404	0000 0400	0404 0000
	2	0044 0000	4400 0040	0004 4000	0000 4044	0040 0000	4000 0040	0404 0000	0000 4400	0400 4404	4040 0000	0000 4040	0404 0000
	3	0044 0000	0000 4004	4400 0004	0004 4040	0000 0040	0440 0400	0000 0000	4044 0044	0000 0400	0004 0400	4000 4000	0400 4040

Conc. [%]: 100.0		Dilution: 1:1,000							Contact time [min]: 2				
		Row											
Carrier	Plate	1	2	3	4	5	6	7	8	9	10	11	12
1	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	2	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	3	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
2	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	2	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	3	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000

	Contact time [min]	Carrier	Dilutions [log_{10}]								
			1	2	3	4	5	6	7	8	9
Virus control											
before drying	n.a.	0	n.d.	n.d.	4444 4444	4444 4444	2234 3444	2003 0000	0000 0000	0000 0000	n.d.
after drying (VCt0)	0	1	n.d.	4444 4444	4444 4444	4444 4444	4302 3403	0300 0020	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	3420 3244	0300 0340	0000 0000	n.d.	n.d.
after drying (VCt1)	1	1	n.d.	4444 4444	4444 4444	4444 4444	4303 0432	0000 0000	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	0134 3102	3000 0000	0000 0000	n.d.	n.d.
after drying (VCt2)	2	1	n.d.	4444 4444	4444 4444	4444 4444	3403 4432	0000 0200	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	4230 0012	0000 0300	0000 0000	n.d.	n.d.

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

Table 4: Raw data for efficacy test

Product name:	**Sterisept Ready to Use / Sterisept Wipes**	Batch:	14151022
Test organism:	MVA	Temperature:	room temperature (18 to 25 °C ± 1 °C)
Organic load:	dirty conditions	Test Run:	1st assay
No. of assay:	#8486		

Conc. [%]	Contact time [min]	Carrier	Dilutions [log_{10}]								
			1	2	3	4	5	6	7	8	9
50.0	1	1	tttt tttt	tttt tttt	3421 3432	0004 0400	0000 0000	0000 0000	n.d.	n.d.	n.d.
		2	tttt tttt	tttt tttt	3443 2334	0200 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.
	2	1	tttt tttt	tttt tttt	4334 2344	0003 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.
		2	tttt tttt	tttt tttt	3044 2230	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.
10.0	1	1	tttt tttt	4444 4444	4444 4444	4444 4444	0000 0000	0000 0000	n.d.	n.d.	n.d.
		2	tttt tttt	4444 4444	4444 4444	4444 4444	3020 3000	0000 0000	n.d.	n.d.	n.d.
	2	1	tttt tttt	4444 4444	4444 4444	4344 3234	4032 0020	0000 0000	n.d.	n.d.	n.d.
		2	tttt tttt	4444 4444	4444 4444	4343 3234	4322 0102	0000 0000	n.d.	n.d.	n.d.
Virus control											
Before drying	n.a.	n.a.	n.d.	n.d.	4444 4444	4444 4444	2234 3444	2003 0000	0000 0000	0000 0000	n.d.
VCt0	0	1	n.d.	4444 4444	4444 4444	4444 4444	4302 3403	0300 0020	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	3420 3244	0300 0340	0000 0000	n.d.	n.d.
VCt1	1	1	n.d.	4444 4444	4444 4444	4444 4444	4303 0432	0000 0000	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	0134 3102	3000 0000	0000 0000	n.d.	n.d.
VCt2	2	1	n.d.	4444 4444	4444 4444	4444 4444	3403 4432	0000 0200	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	4230 0012	0000 0300	0000 0000	n.d.	n.d.
Cytotoxicity control											
100.0	1	1	tttt tttt	tttt tttt	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	n.d.
50.0	1	1	tttt tttt	tttt tttt	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	n.d.
10.0	1	1	tttt tttt	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	n.d.

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

Table 5: Raw data for controls

Product name:	**Sterisept Ready to Use / Sterisept Wipes**	Batch:	14151022
Test organism:	MVA	Temperature:	room temperature (18 to 25 °C ± 1 °C)
Organic load:	dirty conditions	Test Run:	1st assay
No. of assay:	#8486		

Conc. [%]	Disinfectant dilution	Dilutions [log_{10}]								
		1	2	3	4	5	6	7	8	9
Suppression control										
100.0	1:100	n.d.	4444 4444	4444 4444	4444 4444	4123 4434	0300 0000	0000 0000	n.d.	n.d.
Virus control for suppression										
n.a.	n.a.	n.d.	n.d.	4444 4444	4444 4444	2234 3444	2003 0000	0000 0000	0000 0000	n.d.
Sensitivity control										
100.0	1:1,000	n.d.	n.d.	4444 4444	4444 4444	4304 4434	0003 0000	0000 0000	0000 0000	n.d.
PBS	n.a.	n.d.	n.d.	4444 4444	4444 4444	4323 4324	0000 0000	0000 0000	0000 0000	n.d.

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

Table 6: Raw data for reference test

Reference:	Glutaraldehyde	Batch:	BCCH6306
Test organism:	MVA	Temperature:	room temperature (18 to 25 °C ± 1 °C)
Organic load:	dirty conditions	Test Run:	1st assay
No. of assay:	#8486		

Conc. [ppm]	Contact time [min]	Carrier	Dilutions [log_{10}]								
			1	2	3	4	5	6	7	8	9
50	5	1	4444 4444	4444 4444	3443 4434	0020 3204	0000 0200	0000 0000	n.d.	n.d.	n.d.
		2	4444 4444	4444 4444	4344 4344	0001 2200	0000 0000	0000 0000	n.d.	n.d.	n.d.
Virus control											
VCt5	5	1	n.d.	4444 4444	4444 4444	4444 4444	0320 2343	0000 0000	0000 0000	n.d.	n.d.
		2	n.d.	4444 4444	4444 4444	4444 4444	4343 0323	0030 0000	0000 0000	n.d.	n.d.
Cytotoxicity control											
50	5	1	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.	n.d.

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

5 Appendix

5.1 Version history

Previous versions are replaced by most recent version.

Version	Date	Reason of change and changelog	Author
01	03/05/2023	-	IW
02	17/05/2023	Correction of the product name according to customer specifications	BBi

5.2 Accreditation and certificates

DIN EN 16777:2019-03 is included in our accreditation according to DIN EN ISO/IEC 17025.

5.3 Terms of use

No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results exclusively apply to the tested samples. Information on measurement uncertainty and Version history on request.

5.4 Literature

1 DIN EN 16777:2019-03 "Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2); German version EN 16777:2018"
2 Spearman, C.: The method of "right or wrong cases" (constant stimuli) without Gauss's formulae. Brit J Psychol; 2 1908, 227-242
3 Kärber, G.: Beitrag zur kollektiven Behandlung pharmakologischer Reihenversuche. Arch Exp Path Pharmak; 162, 1931, 480-487

5.5 List of Abbreviations

DIN	=	Norm by German institute for normation (German: Deutsches Institut für Normung)
EN	=	European norm (issued by European Committee for Standardization – CEN)
IEC	=	International Electrotechnical Commission
ISO	=	International Organization for Standardization
$TCID_{50}$	=	Tissue Culture Infectious Dose 50
PBS	=	Phosphate buffered saline (see norm section 5.2.2.3 for recipe)
n.d.	=	Not detected
n.a.	=	Not applicable