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Bremen, 14/08/2018

Expert opinion

Activity of NERTA OMNIKYLL against poliovirus type 1 in a quantitative suspension test according to the EN 14476:2013+A1:2015 under clean conditions

This expert opinion is based on the test report L18/0256Po.3 dating 14/08/2018.

The virus-inactivating properties of the surface disinfectant NERTA OMNIKYLL of Advanced Precision Laboratories BVBA against poliovirus type 1 were investigated by a quantitative suspension test according to EN 14476 under clean conditions.

According to EN 14476, 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 %).

The surface disinfectant NERTA OMNIKYLL was examined as 1.0 %, 0.5 % and 0.25 % solutions at 20 °C. 5 minutes were chosen as exposure time. In summary, a virucidal activity against poliovirus type 1 was measured as follows:

0.5 % 5 minutes clean conditions (0.3 g / l BSA)

Dr. Jochen Steinmann

Pieter HERMAN - ANTWERPEN - NOTARIS

Sworn to and subscribed before me this 9/9/2019
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14/08/2018

Test report L18/0256Po.3

Evaluation of the effectiveness of

NERTA OMNIKYLL

Test virus:	poliovirus type 1 strain LSc-2ab
Method:	EN 14476:2013+A1:2015 (clean conditions) quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine

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1. Identification of test laboratory

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

2. Identification of sample

Manufacturer	Advanced Precision Laboratories BVBA
Name of product	NERTA OMNIKYLL
Confirmation no.	204995
Product diluent recommended by the manufacturer	-
Batch number	ENT-160525
Application	surface disinfection
Production date	-
Expiry date	-
Active compound (s) (100 g)	Didecyldimethylammonium chloride 20-30 % glutaral, glutaraldehyde, 1,5-pentanedial 10-20 % Propan-2-ol 1-10 % Fatty alcohol ethoxylated 1-10 %
Appearance, odour	clear, slightly brownish liquid product specific
pH-value	undiluted: 4.96 (20 °C) 1.0 %: 7.22 (20 °C) 0.5 %: 7.29 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	24/04/2018

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 (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).

3.2 Virus and cells

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

BGM cells (*buffalo green monkey* = permanent monkey kidney cell line; supplied by Prof. Dr. Lindl, Institut für angewandte Zellkultur, DE - 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 16) 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).

4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	1.0 %, 0.5 %, 0.25 %, 0.1 % and 0.01 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	5 and 30 minutes
Interfering substance	0.3 g/l bovine serum albumin (clean conditions, EN 14476)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water of standardized hardness (WSH)
Stability of product in the mix with virus and interfering substance (1.0 % solution)	minor clouding, medium precipitation
Virus strain	poliovirus type 1 strain LSc-2ab (Chiron-Behring)
Date of testing	25/04/2018 – 14/08/2018
End of testing	14/08/2018

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 tested as 1.0 %, 0.5 %, 0.25 %, 0.1 % and 0.01 % solutions (1 part test virus suspension + 1 part interfering substance + 8 parts disinfectant). Due to the addition of interfering substance and test virus suspension the solutions had to be prepared by the factor 1.25. These solutions were prepared with WSH immediately before the inactivation tests.

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 trypsinized *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, 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 as 1.0 %, 0.5 %, 0.25 %, 0.1 % and 0.01 % (demonstration of non-active range) solutions in WSH at 20 °C according to EN 14476. 5 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 at the beginning of the test and after the longest exposure time (EN 5.5.7). One part by volume of test virus suspension was mixed with one part interfering substance and eight parts by volume of WSH or Aqua bidest. (RTU products).

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 two parts by volume of water were mixed with eight 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 5.5.5.1).

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}.

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 ≥ 4.38 ± 0.26).

b) The test product (1.0 % solution) showed cytotoxicity in the 1:100 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 6.6.7) was 1.50 ± 0.58 (between 0.5 - 2.5) after 30 min and 2.63 ± 0.53 (between 2.0 - 4.5) after 60 min for poliovirus type 1

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: 7.88 ± 0.45 (PBS) versus 7.75 ± 0.33 (1:1,000 dilutions of disinfectant as 1.0 % solution) $\log_{10}$ $TCID_{50}$/ml.

e) The control of efficacy for suppression of disinfectant's activity (1.0 % solution) showed no decrease (≤ 0.5 $\log_{10}$; EN 5.5.5.1) in virus titre (8.38 ± 0.41 versus 7.88 ± 0.37 $\log_{10}$ $TCID_{50}$/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 is valid.

7. Results

Results of examination are shown in tables 1 to 11. Tables 1 to 10 demonstrate the raw data, whereas table 11 (a+b) gives a summary of results.

The test product as 1.0 % solution was able to inactivate poliovirus type 1 after 5 minutes under clean conditions in this quantitative suspension test (tables 1 and 2). The reduction factors were ≥ 4.25 ± 0.44 and ≥ 4.38 ± 0.26. The mean value was ≥ 4.31 ± 0.26. This corresponded to an inactivation of ≥ 99.99 %.

The test product as 0.5 % solution was also able to inactivate poliovirus type 1 after 5 minutes under clean conditions in this quantitative suspension test (tables 3 and 4). The reduction factors were ≥ 4.38 ± 0.26 and ≥ 4.38 ± 0.26. The mean value was ≥ 4.38 ± 0.18. This corresponded to an inactivation of ≥ 99.99 %.

Tested as 0.25 % and 0.01 % solutions, the test product was not active within 5 minutes of exposure time (tables 5 and 7).

Tested as 0.1 % solution, the test product was not active within 30 minutes of exposure time (table 6).

8. Conclusion

The surface disinfectant NERTA OMNIKYLL tested as 0.5 % solution demonstrated effectiveness against poliovirus type 1 after an exposure time of 5 minutes under clean conditions.
Therefore, the surface disinfectant NERTA OMNIKYLL can be declared as active against poliovirus type 1 as follows:

0.5 % **5 minutes** **clean conditions**

Bremen, 14/08/2018

- Dr. Britta Becker -
Head of Laboratory

- Dr. Dajana Paulmann -
Scientific Project Manager

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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.

11. Literature

1. EN 14476:2013+A1:2015: 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. Brit J Psychol; 2 1908, 227-242

3. Kärber, G.: Beitrag zur kollektiven Behandlung pharmakologischer Reihenversuche. Arch Exp Path Pharmak; 162, 1931, 480-487

Appendix:

Legend to the Tables

Table 1:	Raw data for NERTA OMNIKYLL (1.0 %) tested against poliovirus type 1 (1st assay)
Table 2:	Raw data for NERTA OMNIKYLL (1.0 %) tested against poliovirus type 1 (2nd assay)
Table 3:	Raw data for NERTA OMNIKYLL (0.5 %) tested against poliovirus type 1 (1st assay)
Table 4:	Raw data for NERTA OMNIKYLL (0.5 %) tested against poliovirus type 1 (2nd assay)
Table 5:	Raw data for NERTA OMNIKYLL (0.25 %) tested against poliovirus type 1
Table 6:	Raw data for NERTA OMNIKYLL (0.1 %) tested against poliovirus type 1
Table 7:	Raw data for NERTA OMNIKYLL (0.01 %) tested against poliovirus type 1
Table 8:	Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1
Table 9:	Raw data for control of efficacy for suppression of disinfectant's activity (1.0 %)
Table 10:	Raw data (poliovirus type 1) for cell sensitivity (1.0 %)
Table 11 (a+b):	Summary of results with NERTA OMNIKYLL and poliovirus type 1

Legend to the Figures

Figure 1:	Virus-inactivating properties of NERTA OMNIKYLL (0.5 %)
Figure 2:	Virus-inactivating properties of formaldehyde (0.7 %)

Table 1: Raw data for NERTA OMNIKYLL (1.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5515) (1st assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	1.0 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	tttt tttt	tttt tttt	0000 3000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	1.0 %	clean conditions	n.a.	tttt tttt	tttt tttt	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 4444	4444 4444	4400 0040	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)

Table 2: Raw data for NERTA OMNIKYLL (1.0 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635) (2nd assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	1.0 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	1.0 %	clean conditions	n.a.	tttt tttt	tttt tttt	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 4444	4044 0400	0400 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 3: Raw data for NERTA OMNIKYLL (0.5 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5515) (1st assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.5 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.5 %	clean conditions	n.a.	tttt tttt	tttt tttt	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 4444	4444 4444	4400 0040	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)

Table 4: Raw data for NERTA OMNIKYLL (0.5 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635) (2nd assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.5 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.5 %	clean conditions	n.a.	tttt tttt	tttt tttt	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 4444	4044 0400	0400 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 5: Raw data for NERTA OMNIKYLL (0.25 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.25 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	n.d.	n.a.	4044 0424	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.25 %	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 4444	4044 0400	0400 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 6: Raw data for NERTA OMNIKYLL (0.1 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.1 %	clean conditions	1	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.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.a.	4444 4244	0000 0003	0000 0000	0000 0000	0000 0000	n.d.	n.d.
test product cytotoxicity	0.1 %	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 4444	4044 0400	0400 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 7: Raw data for NERTA OMNIKYLL (0.01 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.01 %	clean conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 0400	0000 0000	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.01 %	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 4444	4044 0400	0400 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 8: Raw data for formaldehyde solution (0.7 %) tested against poliovirus type 1 at 20 °C (quantal test; 8 wells) (#5635)

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	4004 4044	0000 0040	n.d.	n.d.
			15	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	0040 0040	0040 0000	n.d.	n.d.
			30	tttt tttt	tttt tttt	4444 4444	4444 4444	3044 4042	0000 0002	0000 0000	n.d.	n.d.
			60	tttt tttt	tttt tttt	4444 4444	4444 0404	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	0040 4000	0400 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)

Table 9: Raw data for control of efficacy for suppression of disinfectant's activity (1.0 %) (#5635)

Product	Interfering substance	dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
test product	clean conditions	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	4444 4040	4000 0000	n.d.
corresponding virus control	clean conditions	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 4400	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)

Table 10: Raw data (poliovirus type 1) for cell sensitivity (1.0 %) (#5635)

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	0444 4444	0040 4044	0000 0000	n.d.
test product	1:1,000	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0004	0000 0000	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)

Table 11a: Summary of results with NERTA OMNIKYLL 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	5	15	30	
test product (1)	1.0 %	clean conditions	3.50	n.d.	n.d.	≤ 3.63±0.25	n.d.	n.d.	5 (RF ≥ 4.25±0.44)
test product (2)	1.0 %	clean conditions	3.50	n.d.	n.d.	≤ 3.50±0.00	n.d.	n.d.	5 (RF ≥ 4.38±0.26)
test product (1)	0.5 %	clean conditions	3.50	n.d.	n.d.	≤ 3.50±0.00	n.d.	n.d.	5 (RF ≥ 4.38±0.26)
test product (2)	0.5 %	clean conditions	3.50	n.d.	n.d.	≤ 3.50±0.00	n.d.	n.d.	5 (RF ≥ 4.38±0.26)
test product (2)	0.25 %	clean conditions	2.50	n.d.	n.d.	≤ 4.25±0.33	n.d.	n.d.	> 5 (RF ≥ 3.63±0.49)
test product (2)	0.1 %	clean conditions	2.50	n.d.	n.d.	n.d.	n.d.	4.63±0.25	> 30 (RF = 3.25±0.44)
test product (2)	0.01 %	clean conditions	1.50	n.d.	n.d.	7.75±0.33	n.d.	n.d.	> 5 (RF = 0.13±0.49)

*The number in brackets gives the number of the corresponding virus control, see table 11b

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

Table 11b: Summary of results with NERTA OMNIKYLL 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.	7.25±0.44	6.88±0.41	6.38±0.41	5.25±0.33	> 60 (RF = 2.63±0.53)
virus control	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	7.88±0.41	n.a.
virus control (1)	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	7.88±0.37	n.a.
virus control (2) (+ suppression)	n.a.	clean conditions	n.a.	8.13±0.45	n.d.	n.d.	n.d.	7.88±0.37	n.a.
suppression control	1.0 %	clean conditions	3.50	n.d.	n.d.	n.d.	8.38±0.41	n.d.	n.a.
sens.control PBS	n.a.	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	7.88±0.45	n.a.
sens. control test product	1.0 %→ 1:1,000	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	7.75±0.33	n.a.

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

Figure 1: Virus-inactivating properties of NERTA OMNIKYLL (0.5 %)

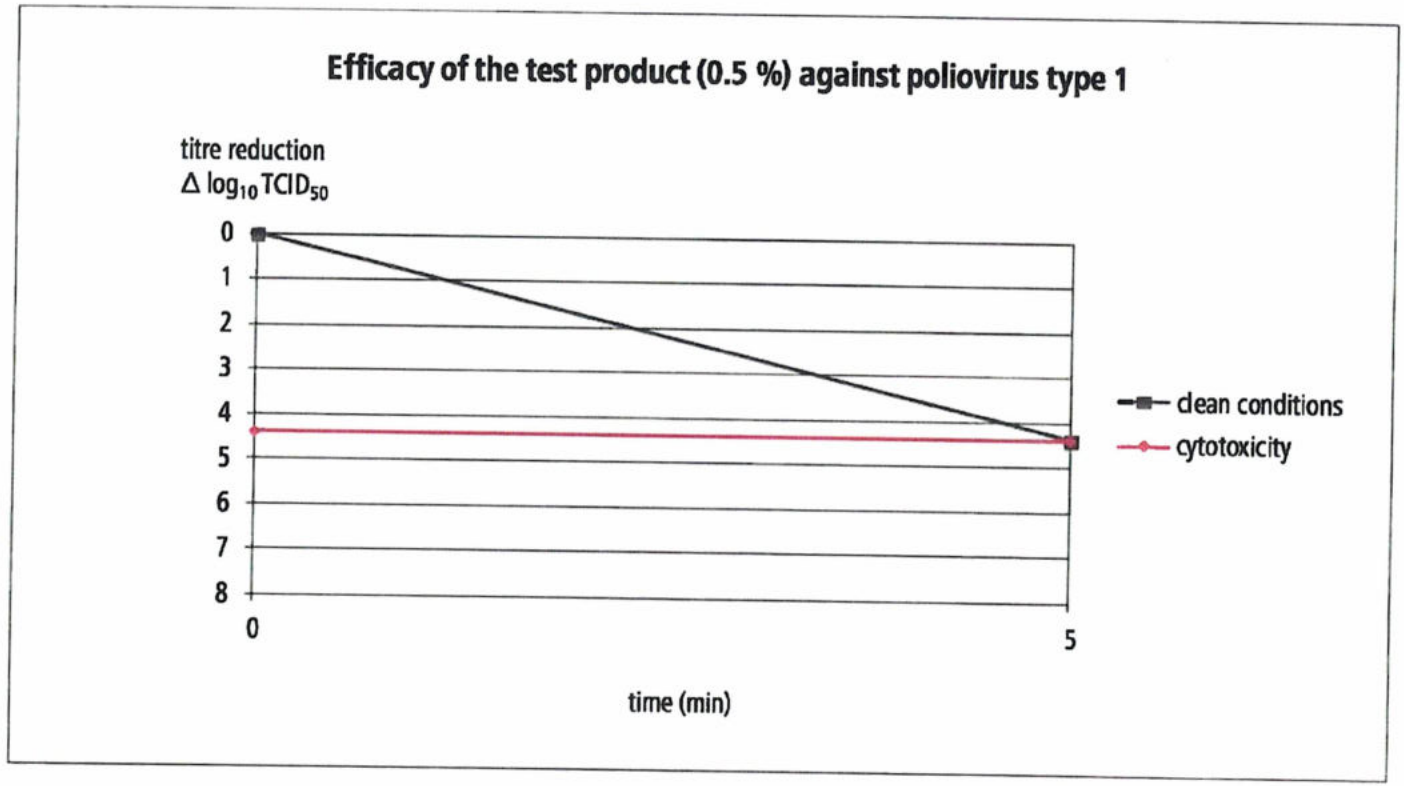

Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)