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

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Test report L16/0797A.2

Evaluation of the effectiveness of

Oxivir Plus (concentrate) and Oxivir Plus Spray RTU (RTU solution)

Test virus: adenovirus type 5

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

Sponsor:
Diversey Europe Operations BV
PO Box 40441
NL – 3504 AE Utrecht

TEST REPORT

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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

2.1 Sample 1: Concentrate (Oxivir Plus)

Manufacturer	Diversey Europe Operations BV
Name of product	Oxivir Plus
Product diluent recommended by the manufacturer	-
Batch number	FM007368
Lab intern number	L16/0797
Application	surface disinfection
Production date	-
Expiry date	01/07/2018
Active compound (s) (100 g)	2.5 % Salicylic acid (CAS: 69-72-7) 6.4 % HydrogenPeroxide (CAS:7722-84-1)
Appearance, odour	clear, slightly viscous colorless liquid product specific
pH-values	undiluted: 0.98 (20 °C) 3.52 %: 2.08 (20 °C) 3.0 %: 2.16 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	31/10/2016

2.2 Sample 2: Ready-to-use solution (Oxivir Plus Spray RTU)

Manufacturer	Diversey Europe Operations BV
Name of product	Oxivir Plus Spray RTU (RTU contains 4.4 % of the concentrate)
Product diluent recommended by the manufacturer	-
Batch number	FM007720
Lab intern number	L17/0060
Application	surface disinfection
Production date	-
Expiry date	04/11/2018
Active compound (s) (100 g)	0.11 % Salicylic acid (CAS: 69-72-7) 0.28 % Hydrogen Peroxide (CAS:7722-84-1)
Appearance, odour	clear, colorless liquid product specific
pH-values	undiluted: 2.38 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	01/02/2017

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).

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 117) originated from Vircell, S.L., Spain, 18320 Santa Fe (now BIOTRIN International GmbH, DE - 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).

4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product (concentrate)	3.52 %, 3.0 %, 2.0 % and 0.5 % (demonstration of non-active range) solutions
Concentration of test product (RTU solution)	undiluted (80.0 %)
Appearance of product dilutions	no precipitation
Contact times (concentrate)	2 minutes
Contact time(s) (RTU solution)	2 minutes
Interfering substance	0.3 g/l bovine serum albumin (clean conditions, EN 14476)
Procedure to stop action of disinfectant	immediate dilution
Diluent (concentrate)	water of standardised hardness (WSH)
Stability of product in the mix with virus and interfering substance (3.52 % solution)	minor clouding, no precipitation
Virus strain	adenovirus type 5 strain adenoid 75 (ATCC VR-5)
Date of testing	31/10/2016 – 02/03/2017
End of testing	02/03/2017

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)

Oxivir Plus (concentrate) was tested as 3.52 %, 3.0 %, 2.0 % and 0.5 % solutions under clean conditions (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 water of standardised hardness immediately before the inactivation tests.

Oxivir Plus Spray RTU (ready-to-use solution) was tested undiluted. Due to the addition of interfering substance and test virus suspension an 80.0 % solution resulted, which corresponds to a 3.52 % solution of Oxivir Plus.

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, 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 (Oxivir Plus Spray RTU) and as 3.52 %, 3.0 %, 2.0 % and 0.5 % (demonstration of non-active range) solutions (Oxivir Plus) in WSH at 20 C according to EN 14476. 2 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).

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 $\geq 5.38 \pm 0.26$).

b) The test product (3.52 %, 3.0 % and 2.0 % solutions) 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 $\geq 4.00 \pm 0.58$ (between 3.0 – 5.0) after 30 min and $\geq 4.38 \pm 0.51$ (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: 8.50 ± 0.35 (PBS) versus 8.25 ± 0.33 (1:100 dilutions of disinfectant as 3.52 % solution) $\log_{10}$ $TCID_{50}$/ml.

e) The control of efficacy for suppression of disinfectant's activity (3.52 % solution) showed no decrease ($\leq$ 0.5 $\log_{10}$; EN 5.5.5.1) in virus titre (8.38 ± 0.25 versus 8.00 ± 0.38 $\log_{10}$ $TCID_{50}$/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 is valid.

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.

Examination of the concentrate:

The test product as 3.52 % solution was able to inactivate adenovirus type 5 after 2 minutes under clean conditions in this quantitative suspension test (tables 1 and 2). The reduction factors were ≥ 5.38 ± 0.26 and ≥ 5.88 ± 0.26 (mean value ≥ 5.63 ± 0.18). This corresponded to an inactivation of ≥ 99.999 %.

The test product as 3.0 % solution was also able to inactivate adenovirus type 5 after 2 minutes under clean conditions in this quantitative suspension test (table 3). The reduction factor was ≥ 5.38 ± 0.26. This corresponded to an inactivation of ≥ 99.999 %.

The test product as 2.0 % solution was also able to inactivate adenovirus type 5 after 2 minutes under clean conditions in this quantitative suspension test (table 4). The reduction factor was ≥ 5.38 ± 0.26. This corresponded to an inactivation of ≥ 99.999 %.

Tested as 0.5 % solution, the test product was not active within 2 minutes of exposure time (table 5).

Examination of the Oxivir Plus Spray RTU:

The ready-to-use test product tested undiluted (80.0 %) was able to inactivate adenovirus type 5 after 2 minutes under dirty conditions in this quantitative suspension test (table 6). The reduction factor was ≥ 5.88 ± 0.26 at this time point. This corresponded to an inactivation of ≥ 99.999 %.

8. Conclusion

Oxivir Plus (Concentrate):

The surface disinfectant Oxivir Plus tested as 2.0 % solution demonstrated effectiveness against adenovirus type 5 after an exposure time of 2 minutes under clean conditions.

Therefore, the surface disinfectant Oxivir Plus can be declared as active against adenovirus type 5 as follows:

2.0 % **2 minutes** **clean conditions**

Oxivir Plus Spray RTU (RTU solution):

The surface disinfectant Oxivir Plus Spray RTU demonstrated effectiveness against adenovirus type 5 after an exposure time of 2 minutes under clean conditions.

Therefore, the surface disinfectant Oxivir Plus Spray RTU can be declared as active against adenovirus type 5 as follows:

undiluted **2 minutes** **clean conditions**

Bremen, 02/03/2017

- 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 (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.

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

Legend to the Figures

Table 1: Raw data for Oxivir Plus (3.52 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4685) (1st assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	3.52 %	clean conditions	2	tttt tttt	0000 0000	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.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	3.52 %	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	4443 3334	0003 2200	0300 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3343 3433	0300 0032	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 Oxivir Plus (3.52 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4853) (2nd assay)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	3.52 %	clean conditions	2	tttt tttt	0000 0000	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.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	3.52 %	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 4444	4444 3444	0320 3331	0003 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 Oxivir Plus (3.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4685)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	3.0 %	clean conditions	2	tttt tttt	0000 0000	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.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	3.0 %	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	4443 3334	0003 2200	0300 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3343 3433	0300 0032	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 Oxivir Plus (2.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4685)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	2.0 %	clean conditions	2	tttt tttt	0000 0000	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.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	2.0 %	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	4443 3334	0003 2200	0300 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3343 3433	0300 0032	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 Oxivir Plus (0.5 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4685)

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	2	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3343 4444	3000 1303	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.
			60	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.	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	4443 3334	0003 2200	0300 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3343 3433	0300 0032	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 Oxivir Plus Spray RTU (80.0 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4853)

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	2	tttt tttt	0000 0000	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.
			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	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 3444	0320 3331	0003 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 formaldehyde solution (0.7 %) tested against adenovirus type 5 at 20 °C (quantal test; 8 wells) (#4685)

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 4443	3022 0003	0000 0000	n.d.	n.d.
			15	tttt tttt	tttt tttt	4444 4444	4334 3133	1003 0000	0020 2000	0000 0000	n.d.	n.d.
			30	tttt tttt	tttt tttt	0023 0101	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			60	tttt tttt	tttt tttt	0000 0010	0000 0000	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	4434 2334	0001 2300	0000 0003	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 control of efficacy for suppression of disinfectant's activity (3.52 %) (#4738)

Product	Interfering substance	dilutions (log_{10})								
		1	2	3	4	5	6	7	8	9
test product	clean conditions	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3023 1333	0000 0000	n.d.
corresponding virus control	clean conditions	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	3334 3444	3220 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)

Table 9: Raw data (adenovirus type 5) for cell sensitivity (3.52 %) (#4738)

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	4334 4444	3333 3034	3000 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	4444 4444	4403 0444	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)

Table 10a: Summary of results with Oxivir Plus and Oxivir Plus Spray RTU and adenovirus type 5

Product	Con-centration	Interfering substance	Level of cytotoxicity	log_{10} $TCID_{50}$/ml after ....min					> 4 log_{10} reduction after ... min
				1	2	15	30	60	
test product (1)	3.52 %	clean conditions	2.50	n.d.	≤ 2.50±0.00	n.d.	n.d.	n.d.	2 (RF ≥ 5.38±0.26)
test product (2)	3.52 %	clean conditions	2.50	n.d.	≤ 2.50±0.00	n.d.	n.d.	n.d.	2 (RF ≥ 5.88±0.26)
test product (1)	3.0 %	clean conditions	2.50	n.d.	≤ 2.50±0.00	n.d.	n.d.	n.d.	2 (RF ≥ 5.38±0.26)
test product (1)	2.0 %	clean conditions	2.50	n.d.	≤ 2.50±0.00	n.d.	n.d.	n.d.	2 (RF ≥ 5.38±0.26)
test product (1)	0.5 %	clean conditions	1.50	n.d.	8.00±0.38	n.d.	n.d.	n.d.	> 2
test product RTU (2)	80.0 %	clean conditions	2.50	n.d.	≤ 2.50±0.00	n.d.	n.d.	n.d.	2 (RF ≥ 5.88±0.26)

The number in brackets gives the number of the corresponding virus control, see Table 10 b

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

Table 10b: Summary of results with Oxivir Plus and adenovirus type 5

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.	7.00±0.38	6.00±0.46	≤ 4.00±0.38	≤ 3.63±0.25	30 (RF ≥ 4.00±0.58)
virus control	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	8.00±0.44	n.a.
virus control (1)	n.a.	clean conditions	n.a.	8.00±0.44	n.d.	n.d.	n.d.	7.88±0.37	n.a.
virus control (1)	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	8.38±0.41	n.a.
virus control (suppression)	n.a.	clean conditions	n.a.	n.d.	n.d.	n.d.	n.d.	8.00±0.38	n.a.
suppression control	3.52 %	clean conditions	2.50	n.d.	n.d.	n.d.	8.38±0.25	n.d.	n.a.
sens.control PBS	n.a.	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.50±0.35	n.a.
sens. control test product	3.52 % → 1:100	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.25±0.33	n.a.

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

Figure 1: Virus-inactivating properties of Oxivir Plus (2.0 %)

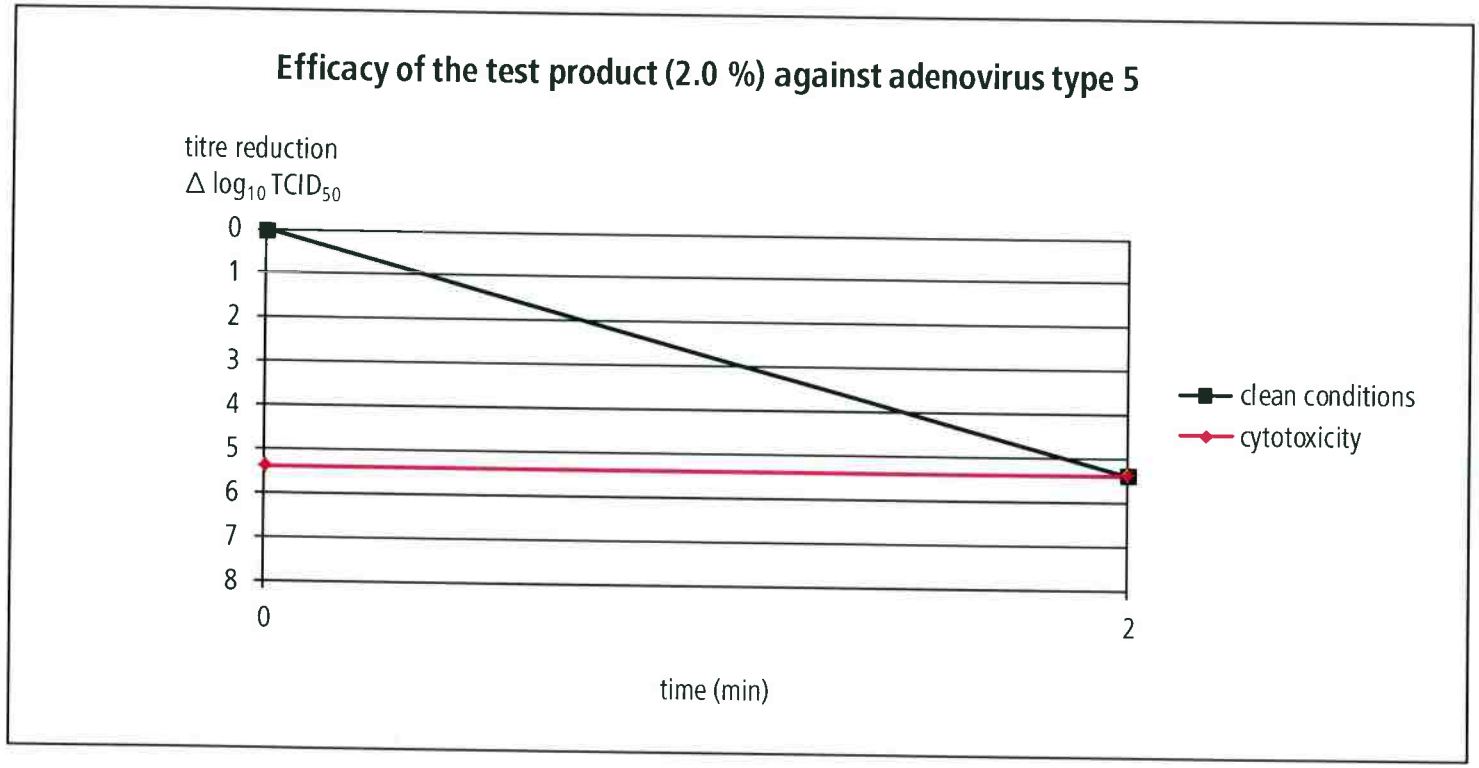

Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)