



Public Health Institute Ostrava

Center of clinical laboratories

Workplace 1 - Ostrava

Laboratory for testing virucidal activity

Partyzánské nám.2633/7, Moravská Ostrava, 702 00 Ostrava

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TEST REPORT n. 3/2019/SVU

Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of disinfectants
Test method and requirements (phase 2/ step 2) according to EN 16777:2018

Customer:

SCHULKE CZ s.r.o.
Lidická 445
735 95 Bohumín
CZ

Order number: not specified
Reference number: ZU/05986/2019

Identification of disinfectant – sample:

Product name:

DESAM EFFEKT+ (DESAM EFFECT)

Lot number:

001A181116

Expiration:

2020-11-16

Producer:

SCHULKE CZ

Storage conditions:

5°C to 25 °C

Diluent product recommended by the producer for use:

potable water

Product appearance:

clear liquid

The active substance(s) and its (their) concentration:

100 g of concentrate contains:

7,2 g N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine

3 g Didecyltrimethylammonium-chloride

19 g Benzyl-C12-16-alkyldimethyl-chloride

10 g 2-fenoxyethanol

Purpose of product:

surface disinfection in medical area

Date of delivery of the product:

6.3.2019

Date of test:

14.3. – 11.4.2019

Results - for details see annex:

According to EN 16777:2018 the test product **DESAM EFEKT+(DESAM EFFECT)**, lot.n. 001A181116, designed for surface disinfection in medical area, diluted by hard water to 5% reduced virus titre $4,500 \pm 0,416$ lg after an exposure time 30 min and 60 min at temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (3,0 g/l Bovine serum albumin + erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Murine norovirus, strain S99*, i.e. **demonstrated virucidal activity to Norovirus by more than 4 lg.***

According to EN 16777:2018 the test product **DESAM EFEKT+(DESAM EFFECT)**, lot.n. 001A181116, designed for surface disinfection in medical area, diluted by hard water to 5% reduced virus titre $4,000 \pm 0,000$ lg after an exposure time 30 min and 60 min at temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (3,0 g/l Bovine serum albumin + erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus, strain Adenoid 75*, i.e. **demonstrated virucidal activity to Adenovirus by more than 4 lg.***

**The statement of compliance is based on a 95% coverage probability for the expanded uncertainty.*

Conclusion and interpretation:

According to EN 16777:2018 the test product **DESAM EFEKT+(DESAM EFFECT)**, lot.n. 001A181116, designed for surface disinfection in medical area, diluted by hard water to 5% demonstrated virucidal activity to Adenovirus and Norovirus under the dirty conditions after exposure time 30 min.

In Ostrava, 17.4.2019


Zdravotní ústav se sídlem v Ostravě
Centrum klinických laboratoří
Oddělení virologie
Partyzánské náměstí 2633/7
Moravská Ostrava 702 00 Ostrava
Telefon: 596 200 111, 310. 312

Mgr. Ludmila Porubová
Guarantor of testing

Annex to the protocol n.: 3/2019/SVU

Identification of product:

Product name:	DESAM EFFEKT+ (DESAM EFFECT)
Lot number:	001A181116
Expiratin:	2020-11-16
Producer:	SCHULKE CZ
Date of delivery of product	6.3.2019
Storage conditions:	5°C to 25 °C
Diluent:	potable water
Product appearance:	clear liquid
The active compound(s) and its (their) concentration:	100 g of concentrate contains: 7,2 g N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine 3 g Didecyldimethylamonium-chloride 19 g Benzyl-C12-16-alkyldimethyl-chloride 10 g 2-fenoxyethanol

Experimental conditions:

	Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of disinfectant according to EN 16777:2018 (SOP n. 1902)
Date of testing:	14.3. – 11.4.2019
Diluent:	hard water
Testing concentration:	5%
Appearance of dilution of the product:	clear colorless solution
Contact times:	30 min, 60 min
Testing temperature:	20°C±1°C
Interfering substance:	dirty conditions – 3,0 g/l Bovine serum albumin + 3,0 ml/l erythrocytes
Stability of mixture during testing:	stable
Incubation temperature:	37°C±1°C
Method of filtration:	none
Test virus:	<i>Adenovirus, strain Adenoid 75</i> (ATCC) 9.passage, EMEM + 2% FBS <i>Murine Norovirus, strain S99</i> (FLI) 10.passage, DMEM + 2% FBS
Proces to stop action of product:	virucidal activity of product is suppressed by transferring the sample into the ice cold diluent
Cell line:	Hela cells (ATCC), 16.- 17. passage, EMEM + 10% FBS RAW 264.7 cells (FLI), 36.- 38. passage, DMEM + 10% FBS
Titration method:	viral titration on monolayer cell culture on the microplates
Reference substance:	Glutaraldehyde (Alfa Aesar, lot.n. 10204382)
Titers calculated by:	Spaerman – Kärber's method

Test detail:

1. Preparation of tissue culture testing
2. Preparation of the test virus suspension
3. Test infectivity of the virus
4. Titration of the virus with the conditions
5. The cytotoxic effect of the product
6. Reference viral inactivation test
7. Viral inactivacion test of product
8. Control of susceptibility

Table n.1 The results and validation of the test for product **DESAM EFEKT+ (DESAM EFFECT)** to *Norovirus, strain S99 - dirty conditions*

Product	Concentration	Interfering substance	Level of cytotoxicity	log 10 TCID ₅₀ / ml after ... min					Reduction factor (Δlog ₁₀ TCID ₅₀ / ml after ... min)	
				5	10	15	30	60	30	60
DESAM EFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	3,500	n.d.	n.d.	n.d.	≤3,500 ± 0,000	≤3,500 ± 0,000	≥ 4,500 ± 0,416	≥ 4,500 ± 0,416
Virus control	n.a.	3,0 g/l BSA + erythrocytes	n.a.	n.d.	n.d.	n.d.	n.d.	8,000 ± 0,208		
				5					5	
GDA	0,1%	0,3 g/l BSA	2,500	6,417 ± 0,070					1,833 ± 0,349	
Virus control	n.a.	0,3 g/l BSA	n.a.	8,250 ± 0,160						

Table n.2 The results and validation of the test for product **DESAM EFEKT+ (DESAM EFFECT)** to *Adenovirus, strain Adenoid 75 - dirty conditions*

Product	Concentration	Interfering substance	Level of cytotoxicity	log 10 TCID ₅₀ / ml after ... min					Reduction factor (Δlog ₁₀ TCID ₅₀ / ml after ... min)	
				5	10	15	30	60	30	60
DESAM EFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	3,500	n.d.	n.d.	n.d.	≤3,500 ± 0,000	≤3,500 ± 0,000	≥ 3,000 ± 0,000	≥ 3,000 ± 0,000
DESAM EFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	2,500	n.d.	n.d.	n.d.	≤2,500 ± 0,000	≤2,500 ± 0,000	≥ 4,000 ± 0,000	≥ 4,000 ± 0,000
Virus control	n.a.	3,0 g/l BSA + erythrocytes	n.a.	n.d.	n.d.	n.d.	n.d.	6,500 ± 0,000		
Virus control - MicroSpin	n.a.	3,0 g/l BSA + erythrocytes	n.a.	n.d.	n.d.	n.d.	n.d.	6,500 ± 0,000		
				5					5	
GDA	0,0125%	0,3 g/l BSA	1,500	3,833 ± 0,178					2,667 ± 0,356	
Virus control	n.a.	0,3 g/l BSA	n.a.	6,500 ± 0,000						

Prepared by: Mgr. Ludmila Porubová



Table n.3: Raw data of test for product **DESAM EFEKT+ (DESAM EFFECT)** to *Norovirus, strain S99 - dirty conditions*

Product	Concentration	Interfering substance	Contact time	Dilution (log 10)							
				-2	-3	-4	-5	-6	-7	-8	
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	CT	000 000	000 000	000 000	000 000	000 000	
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	CT	000 000	000 000	000 000	000 000	000 000	
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	CT	000 000	000 000	000 000	000 000	000 000	
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	CT	000 000	000 000	000 000	000 000	000 000	
Cytotoxicity DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	n.a.	CT	CT	000 000	n.a.	n.a.	n.a.	n.a.	
Cytotoxicity GDA	0,1%	0,3 g/l BSA	n.a.	CT	000 000	000 000	n.a.	n.a.	n.a.	n.a.	
GDA	0,1%	0,3 g/l BSA	5 min	CT	444 444	444 444	444 444	444 440	000 000	000 000	
GDA	0,1%	0,3 g/l BSA	5 min	CT	444 444	444 444	444 444	444 444	000 000	000 000	
Virus control	n.a.	0,3 g/l BSA	5 min	444 444	444 444	444 444	444 444	444 444	444 444	404 440	
Virus control	n.a.	0,3 g/l BSA	5 min	444 444	444 444	444 444	444 444	444 444	444 444	444 040	
Virus control	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	444 444	444 444	444 000	
Virus control	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	444 444	444 444	444 000	
Virus control without surface	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	444 444	444 444	444 000	

1 to 4 virus detectable (1 = 25% CPE, 4 = 100% CPE)

0 no virus/ no cytotoxicity

n.a. not applicable

n.d. not done

CT Cytotoxicologic effect

CPE Cytopathogenic effect

Prepared by: Mgr. Ludmila Porubová



Table n.4: Raw date of test for product **DESAM EFFEKT+ (DESAM EFFECT)** to *Adenovirus, strain Adenoid 75 - dirty conditions*

Product	Concentration	Interfering substance	Contact time	Dilution (log 10)						
				-2	-3	-4	-5	-6	-7	-8
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	CT	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	CT	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	CT	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	CT	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	000 000	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	30 min	CT	000 000	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	000 000	000 000	000 000	000 000	000 000	000 000
DESAM EFFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	60 min	CT	000 000	000 000	000 000	000 000	000 000	000 000
Cytotoxicity DESAM EFFEKT + (DESAM EFFECT)	5,0%	3,0 g/l BSA + erythrocytes	n.a.	CT	CT	000 000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFFEKT + (DESAM EFFECT) - MicroSpin	5,0%	3,0 g/l BSA + erythrocytes	n.a.	CT	000 000	000 000	n.a.	n.a.	n.a.	n.a.
Cytotoxicit GDA	0,0125%	0,3 g/l BSA	n.a.	000 000	000 000	000 000	n.a.	n.a.	n.a.	n.a.
GDA	0,0125%	0,3 g/l BSA	5 min	444 444	232 322	220 000	000 000	000 000	000 000	000 000
GDA	0,0125%	0,3 g/l BSA	5 min	444 444	000 000	000 000	000 000	000 000	000 000	000 000
Virus control	n.a.	0,3 g/l BSA	5 min	444 444	444 444	444 444	444 444	223 312	000 000	000 000
Virus control	n.a.	0,3 g/l BSA	5 min	444 444	444 444	444 444	444 444	323 311	000 000	000 000
Virus control	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	121 132	000 000	000 000
Virus control	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	323 132	000 000	000 000
Virus control - MicroSpin	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	123 223	000 000	000 000
Virus control - MicroSpin	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	232 311	000 000	000 000
Virus control without surface	n.a.	3,0 g/l BSA + erythrocytes	60 min	444 444	444 444	444 444	444 444	223 441	000 000	000 000

1 to 4 virus detectable (1 = 25% CPE, 4 = 100% CPE)

0 no virus/ no cytotoxicity

n.a. not applicable

n.d. not done

CT Cytotoxicologic effect

CPE Cytopathogenic effect

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