



Public Health Institute Ostrava
Center of clinical laboratories
Testing laboratory n. 1554 accredited
according to ISO/IEC 17025
Partyzánské nám.7, 702 00 Ostrava
VAT: CZ71009396
Laboratory for testing virucidal effect



L 1554

TEST REPORT n. 7/2016/SVU

Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/ step 1) - according to EN 14476+A1:2015

Customer:

SCHULKE CZ s.r.o.
Lidická 326
735 95 Bohumín
CZ

Order number:

not specified

Reference number:

ZU/07048/2016

Identification of disinfectant – sample:

Product name:	DESAM EFFEKT+
Lot number:	017A160120
Expiration:	not specified
Producer:	Schulke CZ s.r.o.
Storage conditions:	not specified
Diluent product recommended by the producer for use:	domestic water
Product appearance:	clear liquid
The active substance(s) and its (their) concentration:	CAS 2372-82-9 7,2% CAS 7173-51-5 3,0% CAS 68424-85-1 19,0% CAS 122-99-6 10,0%
Purpose of product:	surface and instrument disinfection
Date of delivery of the product:	14.3.2016
Date of test:	22.3. - 18.4.2016

Results - for details see annex

According to EN 14476+A1:2015 the test product DESAM EFFEKT+, lot n. 017A160120, designed for surface and instrument disinfection, diluted by water to 0,5%, 1,0% and 1,5% solution reduced viral by $4,0 \pm 0,000 \lg$ after an exposure time 30 min, at temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (3,0 g/l Bovine serum albumin and 3,0 ml erythrocytes), using viral titration on monolayer cell culture on a microtitre plate to reference virus *Murine norovirus, strain S99*, i.e. **demonstrate virucidal activity to Murine norovirus more than 4 lg.***

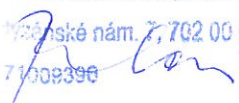
**The statement of compliance is based on a 95% coverage probability for the expanded uncertainty.*

Conclusion:

According to EN 14476+A1:2015 the test product DESAM EFFEKT+, lot n. 017A160120, designed for surface and instrument disinfection, diluted by water to 0,5%, 1,0% and 1,5% solution demonstrate virucidal activity to Norovirus under the dirty conditions after exposure time 30 min.

In Ostrava, 21.4.2016

Státní ústav se sídlem v Ostravě
Městské nám. 7, 702 00 Ostrava
71008390 7



Mgr. Ludmila Porubová
Guarantor of testing

Annex to the protocol n.: 7/2016/SVU

Identification of product:

Product name: DESAM EFFEKT+
Lot number: 017A160120
Expiratin: not specified
Producer: Schulke CZ s.r.o.
Date of delivery of product: 14.3.2016
Storage conditions: not specified
Diluent: domestic water
Product appearance: clear light yellow liquid
The active compound(s)
and its (their) concentration: CAS 2372-82-9 7,2%
CAS 7173-51-5 3,0%
CAS 68424-85-1 19,0%
CAS 122-99-6 10,0%

Experimental conditions:

Quantitative suspension test for the determine of virucidal effect of disinfectant
EN 14476+A1:2015 (SOP n. 1901)
Date of testing: 22.3. - 18.4.2016
Diluent: hard water
Testing concentration: 0,5%;, 1,0%;, 1,5%
Appearance of dilution
of the product: clear solution
Contact times: 30 min
Testing temperature: 20°C±1°C
Interfering substance: dirty conditions – 3,0 g/l bovine serum albumin (BSA) + 3,0 ml erythrocyte
Stability of mixture during testing: formation of precipitate after mixing of solution
Incubation temperature: 37°C±1°C
Method of filtration: MicroSpin
Test virus: *Murine norovirus, strain S99* (FLI) 5.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: RAW 264.7 (FLI), 25. - 31.pasáž, DMEM + 10% FBS
Titration method: viral titration on monolayer cell culture on the microplate
Reference substance: Formaldehyd (Sigma-Aldrich, č.š. SZBC2290V)
Titers callculated 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 EFFEKT+ to Murine 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	
DESAM EFFEKT+	0,5%	3 g/l BSA + erythrocyte	4,5	n.d.	n.d.	n.d.	≥ 4,5 ± 0,000	n.d.	3,0 ± 0,000
DESAM EFFEKT+ - Microspirin	0,5%	3 g/l BSA + erythrocyte	3,5	n.d.	n.d.	n.d.	≥ 3,5 ± 0,000	n.d.	4,0 ± 0,000
DESAM EFFEKT+	1,0%	3 g/l BSA + erythrocyte	4,5	n.d.	n.d.	n.d.	≥ 4,5 ± 0,000	n.d.	3,0 ± 0,000
DESAM EFFEKT+ - Microspirin	1,0%	3 g/l BSA + erythrocyte	3,5	n.d.	n.d.	n.d.	≥ 3,5 ± 0,000	n.d.	4,0 ± 0,000
DESAM EFFEKT+	1,5%	3 g/l BSA + erythrocyte	4,5	n.d.	n.d.	n.d.	≥ 4,5 ± 0,000	n.d.	3,0 ± 0,000
DESAM EFFEKT+ - Microspirin	1,5%	3 g/l BSA + erythrocyte	3,5	n.d.	n.d.	n.d.	≥ 3,5 ± 0,000	n.d.	4,0 ± 0,000
Formaldehyde - Microspirin	0,7% (m/V)	PBS	3,5	n.d.	n.d.	n.d.	4,9 ± 0,185	3,9 ± 0,185	
Virus control	n.a.	3 g/l BSA + erythrocyte	n.a.	n.d.	n.d.	n.d.	7,5 ± 0,000	n.d.	
Virus control - Microspirin	n.a.	3 g/l BSA + erythrocyte	n.a.	n.d.	n.d.	n.d.	7,5 ± 0,000	n.d.	
Susceptibility of cells - PBS	n.a.	3 g/l BSA + erythrocyte	n.a.	n.d.	n.d.	n.d.	n.d.	7,1 ± 0,185	
Susceptibility of cells - DESAM EFFEKT+	0,0005%	3 g/l BSA + erythrocyte	n.a.	n.d.	n.d.	n.d.	n.d.	7,3 ± 0,151	

Prepared by: Mgr. Ludmila Porubová



Table 2: Raw data of test for product DESAM EFEKT+ to *Murine norovirus, strain S99* – dirty conditions

Product	Concentration	Interfering substance	Contact time	Dilution (log 10)							
				-1	-2	-3	-4	-5	-6	-7	-8
DESAM EFEKT+	0,5%	3 g/l BSA + erythrocyte	30 min	CT	CT	CT	00000	00000	00000	00000	00000
DESAM EFEKT+ - Mikrospín	0,5%	3 g/l BSA + erythrocyte	30 min	CT	CT	00000	00000	00000	00000	00000	00000
DESAM EFEKT+	1,0%	3 g/l BSA + erythrocyte	30 min	CT	CT	CT	00000	00000	00000	00000	00000
DESAM EFEKT+ - Mikrospín	1,0%	3 g/l BSA + erythrocyte	30 min	CT	CT	00000	00000	00000	00000	00000	00000
DESAM EFEKT+	1,5%	3 g/l BSA + erythrocyte	30 min	CT	CT	CT	00000	00000	00000	00000	00000
DESAM EFEKT+ - Mikrospín	1,5%	3 g/l BSA + erythrocyte	30 min	CT	CT	00000	00000	00000	00000	00000	00000
Cytotoxicity DESAM EFEKT+	0,5%	3 g/l BSA + erythrocyte	n.a.	CT	CT	CT	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFEKT+	1,0%	3 g/l BSA + erythrocyte	n.a.	CT	CT	CT	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFEKT+	1,5%	3 g/l BSA + erythrocyte	n.a.	CT	CT	CT	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFEKT+ - Mikrospín	0,5%	3 g/l BSA + erythrocyte	n.a.	CT	CT	00000	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFEKT+ - Mikrospín	1,0%	3 g/l BSA + erythrocyte	n.a.	CT	CT	00000	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity DESAM EFEKT+ - Mikrospín	1,5%	3 g/l BSA + erythrocyte	n.a.	CT	CT	00000	00000	n.a.	n.a.	n.a.	n.a.
Cytotoxicity Formaldehyd	0,7% (m/V)	PBS	n.a.	CT	CT	00000	00000	n.a.	n.a.	n.a.	n.a.
Formaldehyde	0,7% (m/V)	PBS	30 min	CT	CT	44444	04040	00000	00000	00000	00000
			60 min	CT	CT	00440	00000	00000	00000	00000	00000
Susceptibility of cells - PBS	n.a.	3 g/l BSA + erythrocyte	60 min	44444	44444	44444	44444	44444	44400	00000	00000
Susceptibility of cells - DESAM EFEKT+	0,01%	3 g/l BSA + erythrocyte	60 min	44444	44444	44444	44444	44444	044444	00000	00000
Virus control	n.a.	3 g/l BSA + erythrocyte	30 min	44444	44444	44444	44444	44444	44444	00000	00000
Virus control - Mikrospín	n.a.	3 g/l BSA + erythrocyte	30 min	44444	44444	44444	44444	44444	44444	00000	00000

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

