

Copy No.: 1
Issue No.: 1

Test report No. D16-2/2016

DETERMINATION OF VIRUCIDAL (EN 14476+A1) ACTIVITY OF THE
PRODUCT **DESAM® EFFEKT +** ON HUMAN ROTAVIRUS

Sample ID: D16/2016
Sample name: **DESAM® EFFEKT +**
Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Producer: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Sampling point: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Page: 1
From pages: 4

Incoming date:
21.1.2016

Delivery date:
3.8.2016

Hodonín, 3.8.2016



Ing. Jana Šliková, Head of Laboratory

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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D16/2016	Sampling date: 20.1.2016
Rep No: 27	Sample delivered: 21.1.2016
Sample name: DESAM® EFFEKT +	Testing date: 23.6. – 1.7.2016
Sampled: by client	Delivered amount: 200 ml
Sampling point: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín	Batch No: 017A160120
Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín	Page: 2

Subject of testing:

Determination of virucidal activity of the product.

Identification of the sample:

Name of the product:	DESAM® EFFEKT +
Batch number:	017A160120
Date of manufacture:	20.1.2016
Expiry date:	20.1.2018
Manufacturer:	SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Incoming date:	21.1.2016
Storage conditions:	stated by the manufacturer
Active compounds and concentrations:	
CAS 68424-85-1 benzyl-C12-16-alkyldimethylammonium chloride	19%
CAS 122-99-6 2-phenoxyethanol	10%
CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine	7.2%
CAS 7173-51-5 didecyldimethylammonium chloride	3%

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

	SOP-M-19-00 (ČSN EN 14476+A1)
Period of analysis:	23.6. – 1.7.2016
Test temperature:	20 °C ± 1 °C
Method of titration:	virus titration on monolayers of cells on microtiter plates
Appearance of the product:	light yellow liquid
Product diluent:	hard water
Test concentration:	0.5%
Contact time:	15 min
Interfering substances:	0.3 g/l BSA (clean conditions) 3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Reference product:	Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K46046503, expiry date: 2016/09/30
Test virus:	<i>Human rotavirus</i> strain WA ATCC-VR-2018 (3 rd passage)
Cell lines:	African green monkey kidney (CV-1) CCL-70 cell line
Incubation:	36 °C ± 1 °C, 5 % CO ₂ , 96 h, and additional period of 96 hours and additional period of 72 hours. After incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the cell culture
3. Preparation of the test virus suspension
4. Test of the viral infectivity
5. Virus titration with the interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for the virucidal activity of the product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders.

The standard:

ČSN EN 14476:2013+A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) May 2016

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The Number of CFU in the tested product **DESAM® EFFEKT +**: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on *Human rotavirus* strain WA ATCC-VR-2018

Tab No. 1.1 Table of results of product **DESAM® EFFEKT +** on *Human rotavirus* strain WA ATCC-VR-2018

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
DESAM® EFFEKT +	0.5%	clean	-	4.83	-	-
DESAM® EFFEKT +	0.5%	dirty	4.50	5.17	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	7.17	5.83
			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.33	9.17
Virus control	-	clean	9.50	9.50	-	-
Virus control	-	dirty	9.50	9.50	-	-

Tab No. 1.2 Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on *Human rotavirus* strain WA ATCC-VR-2018

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
0.5%	9.50	clean	15 min	4.83	4.67
0.5%	9.50	dirty	15 min	5.17	4.33

2. Evaluation of virucidal activity of the product **DESAM® EFFEKT +**

Tab No. 2.1 The efficacy of chemical disinfectant **DESAM® EFFEKT +** on test viruses – virucidal activity

Strain	Virucidal activity of the product					
	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ ČSN EN 14476+A1	Δlog ₁₀ TCID ₅₀
<i>Human rotavirus</i> strain WA ATCC-VR-2018	20	15	0.5	clean	≥ 4	> 4
<i>Human rotavirus</i> strain WA ATCC-VR-2018	20	15	0.5	dirty	≥ 4	> 4

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, Lab Technician

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Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

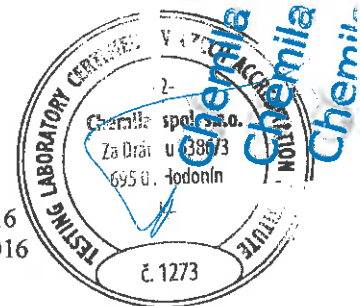
Sample delivered: 21.1.2016

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Delivered amount: 200 ml

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Interpretation:

Results of tests are in Tabs.

The tested product **DESAM® EFFEKT +**, batch No. 017A160120, in the concentration 0.5%, diluted in hard water, in the contact time 15 min under clean and dirty conditions at temperature $20\text{ °C} \pm 1\text{ °C}$ **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Human rotavirus* strain WA ATCC-VR-2018 particles under defined conditions by 4 (lg) orders (ČSN EN 14476+A1).

Conclusion:

The product **DESAM® EFFEKT +** is capable of reducing the number of infectious *Human rotavirus* particles under defined conditions to the declared values and, consequently, may be called virucidal on *Human rotavirus*.

3.8.2016, Hodonín

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Ing. Eva Kremlová

