Public Heath Institute Ostrava
Centre of Clinical Laboratories
Location 1 - Ostrava
Laboratory for testing virucidal activity
Partyzánské nám.2633/7, Moravská Ostrava, 702 00 Ostrava
VAT: CZ71009396

L 1554

TEST REPORT n. 148/2020/SVU_2

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
Lidická 445
735 81 Bohumín

Order number: not provided
Date of delivery: 23.10.2020
Reference number: ZU/30414/2020

Digitally signed by Gritaenco Andrei
Date: 2021.02.15 14:30:14
Reason: MoldSign Signature
Location: Moldova

Identification of disinfectant – sample:

Name of the product [i]:	**desam effect/desam effekt+**
Batch number [i]:	014A200421
Expiry date [i]:	24.1.2022
Manufacturing date [i]:	not provided
Manufacturer [i]:	SCHULKE CZ, s.r.o.
Storage conditions [i]:	-10 °C to +25 °C
Product diluent recommended by the manufacturer [i]:	water
Active substance(s) and concentration(s) [i]:	100 g of product contains: 19g Benzyl-C12-16-alkyldimethylammonium chloride 10g 2-fenoxyethan-1-ol 7,2g N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 3g Didecyldimetylammonium chloride
Purpose of product [i]:	PT2 – surface disinfection in medical area
Appearance of the product:	clear colourless liquid
Date of delivery:	13.10.2020
Date(s) of tests (period of analysis):	29.10.2020 – 27.1.2021

[i] Data provided by customer.

Results - for details see annex:

According to EN 16777:2018 the test product **desam effect/desam effekt+**, lot. n. 014A200421, designed for surface disinfection in medical area, diluted by hard water to 2,0% solution, reduced virus titre 4,000 ± 0,000 lg after an exposure time 5 min and 30 min at temperature 20°C±1°C, under dirty conditions (3,0 g/l Bovine serum albumin + 3,0 ml/l erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Vaccinia virus, strain Modified Vaccinia virus Ankara,* **i.e. demonstrated virucidal activity to *Vacciniavirus* by more than 4 lg.***

According to EN 16777:2018 the test product **desam effect/desam effekt+**, lot. n. 014A200421, designed for surface disinfection in medical area, diluted by hard water to 1,0% solution, reduced virus titre 4,000 ± 0,000 lg after an exposure time 5 min and 30 min at temperature 20°C±1°C, under dirty conditions (3,0 g/l Bovine serum albumin + 3,0 ml/l erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Vaccinia virus, strain Modified Vaccinia virus Ankara,* **i.e. demonstrated virucidal activity to *Vacciniavirus* 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 effect/desam effekt+**, lot. n. 014A200421, designed for surface disinfection in medical area, diluted by hard water to 1,0% and 2,0% solution demonstrated virucidal activity to enveloped viruses under the dirty conditions after exposure time 5 min.

In Ostrava, 10.2.2021

Authorized by: Mgr. Ludmila Porubová

Guarantor of testing

Zdravotní ústav se sídlem v Ostravě
Centrum klinických laboratoří
Oddělení virologie
Laboratoř pro testování virucidního účinku
Partyzánské náměstí 2633/7
Moravská Ostrava 702 00 Ostrava
Telefon: 596 200 400

No part of this report may be reproduced in any form without the written permission of the testing laboratory. The test results relate only to the test sample as received. The laboratory is not responsible for the data provided by the customer. Centre of Clinical Laboratories - Testing Laboratory No. 1554 accredited by ČIA according to ČSN EN ISO / IEC 17025: 2018. The list of accredited methods is available at www.zuova.cz. The sample was examined according to SOP No. 1902.

Annex to the protocol n.: 148/2020/SVU_2

Identification of product:

Name of the product [i]:	**desam effect/desam effekt+**
Batch number [i]:	014A200421
Expiry date [i]:	21.4.2022
Manufacturing date [i]:	not provided
Manufacturer [i]:	SCHULKE CZ, s.r.o.
Date of delivery:	13.10.2020
Storage conditions [i]:	-10 °C to +25 °C
Product diluent recommended by the manufacturer [i]:	water
Appearance of the product:	clear colourless liquid
Active substance(s) and concentration(s) [i]:	100 g of product contains: 19g Benzyl-C12-16-alkyldimethylammonium chloride 10g 2-fenoxyethan-1-ol 7,2g N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 3g Didecyldimetylammonium chloride
Purpose of product i:	PT2 – surface disinfection in medical area
Experimental conditions:	Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of disinfectants according to EN 16777:2018 (SOP n. 1902)
Date(s) of tests (period of analysis):	29.10.2020 – 27.1.2021
Diluent:	hard water
Testing concentration [i]:	2%, 1%, 0,5%
Other testing concentration:	-
Appearance of dilution of the product:	clear liquid
Contact times [i]:	5 min, 30 min
Testing temperature [i]:	20 °C±1 °C
Interfering substance [i]:	dirty conditions – 3,0 g/l Bovine serum albumin + 3,0 ml/l sheep erythrocytes
Stability of mixture during testing:	precipitate formation
Incubation temperature:	37°C±1°C
Method of filtration:	MicroSpin
Test virus:	*Vaccinia virus, strain Modified Vaccinia virus Ankara* (ATCC), 5.passage, EMEM + 2% FBS
Cell line:	BHK-21 cells (ATCC), 116., 31. passage, DMEM + 10% FBS
Process to stop action of product:	virucidal activity of product is suppressed by transferring the sample into the ice cold diluent
Titration method:	viral titration on monolayer cell culture on the microplates
Reference substance:	Formaldehyde (Sigma-Aldrich, lot. n. MKCH0868)
Titers calculated by:	Spaerman – Kärber's method

[i] Data provided by customer

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 inactivation test of product
8. Control of susceptibility

Table n.1 The results and validation of the test for product desam effect/desam effekt+ to *Vaccinia virus, strain Modified Vaccinia virus Ankara - dirty conditions*

Product	Concentration	Interfering substance	Level of cytotoxicity	log 10 TCID50/ ml after ... min				Reduction factor (Δlog_{10} $TCID_{50}$/ ml after ... min)	
				1	5	30	60	5	30
desam effect/desam effekt+	2,0%	3,0 g/l BSA + erythrocytes	3,5	n.d.	≤3,500 ± 0,000	≤3,500 ± 0,000	n.d.	≥3,000 ± 0,000	≥3,000 ± 0,000
desam effect/desam effekt+ - MicroSpin	2,0%	3,0 g/l BSA + erythrocytes	2,5	n.d.	≤2,500 ± 0,000	≤2,500 ± 0,000	n.d.	≥4,000 ± 0,000	≥4,000 ± 0,000
desam effect/desam effekt+	1,0%	3,0 g/l BSA + erythrocytes	2,5	n.d.	≤2,500 ± 0,000	≤2,500 ± 0,000	n.d.	≥4,000 ± 0,000	≥4,000 ± 0,000
desam effect/desam effekt+	0,5%	3,0 g/l BSA + erythrocytes	2,5	n.d.	3,000 ± 0,178	2,833 ± 0,165	n.d.	3,500 ± 0,356	3,667 ± 0,330
Virus control	n.a.	3,0 g/l BSA + erythrocytes	n.a.	n.d.	6,500 ± 0,000	n.d.	n.d.		
Virus control - MicroSpin	n.a.	3,0 g/l BSA + erythrocytes	n.a.	n.d.	6,500 ± 0,000	n.d.	n.d.		
				5				5	
Glutaraldehyde	0,005%	0,3 g/l BSA	3,5	3,750 ± 0,220				2,583 ± 0,476	
Virus control	n.a.	0,3 g/l BSA	n.a.	6,333 ± 0,089					

Prepared by: Mgr. Ludmila Porubová

Table n.2 Raw date of test for product desam effect/desam effekt+ to *Vaccinia virus, strain Modified Vaccinia virus Ankara - dirty conditions*

Product	Concentration	Interfering substance	Contact time	Dilution (log 10)						
				-2	-3	-4	-5	-6	-7	-8
desam effect/desam effekt+	2%	3,0 g/l BSA + erythrocytes	5 min	CT	CT	000000	000000	000000	000000	000000
				CT	CT	000000	000000	000000	000000	000000
desam effect/desam effekt+ - MicroSpin	2%	3,0 g/l BSA + erythrocytes	5 min	CT	000000	000000	000000	000000	000000	000000
				CT	000000	000000	000000	000000	000000	000000
desam effect/desam effekt+	2%	3,0 g/l BSA + erythrocytes	30 min	CT	CT	000000	000000	000000	000000	000000
				CT	CT	000000	000000	000000	000000	000000
desam effect/desam effekt+ - MicroSpin	2%	3,0 g/l BSA + erythrocytes	30 min	CT	000000	000000	000000	000000	000000	000000
				CT	000000	000000	000000	000000	000000	000000
desam effect/desam effekt+ - MicroSpin	1%	3,0 g/l BSA + erythrocytes	5 min	CT	000000	000000	000000	000000	000000	000000
				CT	000000	000000	000000	000000	000000	000000
desam effect/desam effekt+ - MicroSpin	1%	3,0 g/l BSA + erythrocytes	30 min	CT	000000	000000	000000	000000	000000	000000
				CT	000000	000000	000000	000000	000000	000000
desam effect/desam effekt+ - MicroSpin	0,5%	3,0 g/l BSA + erythrocytes	5 min	CT	033304	000000	000000	000000	000000	000000
				CT	043000	000000	000000	000000	004000	000000
desam effect/desam effekt+ - MicroSpin	0,5%	3,0 g/l BSA + erythrocytes	30 min	CT	340040	000000	000000	000000	000000	000000
				CT	040000	000000	000000	000000	004000	000000
Cytotoxicity desam effect/desam effekt+	2%	3,0 g/l BSA + erythrocytes	n.a.	CT	CT	000000	n.d.	n.d.	n.d.	n.d.
Cytotoxicity desam effect/desam effekt+ - MicroSpin	2%	3,0 g/l BSA + erythrocytes	n.a.	CT	000000	000000	n.d.	n.d.	n.d.	n.d.
Cytotoxicity desam effect/desam effekt+	1%	3,0 g/l BSA + erythrocytes	n.a.	CT	000000	000000	n.d.	n.d.	n.d.	n.d.
Cytotoxicity desam effect/desam effekt+	0,5%	3,0 g/l BSA + erythrocytes	n.a.	CT	000000	000000	n.d.	n.d.	n.d.	n.d.
Virus control	n.a.	3,0 g/l BSA + erythrocytes	5 min	444444	444444	444444	444444	332213	000000	000000
				444444	444444	444444	444444	241132	000000	000000
Virus control - MicroSpin	n.a.	3,0 g/l BSA + erythrocytes	5 min	444444	444444	444444	444444	332213	000000	000000
				444444	444444	444444	444444	241132	000000	000000
Cytotoxicity Glutaraldehyde	0,005%	0,3 g/l BSA	n.a.	000000	000000	000000	n.a.	n.a.	n.a.	n.a.
Glutaraldehyde	0,005%	0,3 g/l BSA	5 min	444444	343233	023003	000000	000000	000000	000000
				444444	023022	023000	000000	000000	000000	000000
Virus control	n.a.	0,3 g/l BSA	5 min	444444	444444	444444	444444	323324	000000	000000
				444444	444444	444444	444444	234400	000000	000000

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

END OF THE PROTOCOL