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Centre of Clinical Laboratories  
Location 1 - Ostrava  
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## TEST REPORT n. 148/2020/SVU

Quantitative suspension test for the evaluation of virucidal activity of disinfectants  
Test method and requirements (phase 2/ step 1) according to CSN EN 14476+A2: 2020

**Customer:**  
SCHULKE CZ  
Lidická 445  
735 81 Bohumín

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

### Identification of disinfectant – sample:

|  |  |
|--|--|
| Name of the product <sup>1</sup> :                             | <b>desam effect/desam effekt+</b>  |
| Batch number <sup>1</sup> :                                    | 014A200421   |
| Expiry date <sup>1</sup> :                                     | 24.1.2022  |
| Manufacturing date <sup>1</sup> :                              | not provided   |
| Manufacturer <sup>1</sup> :                                    | SCHULKE CZ, s.r.o.   |
| Storage conditions <sup>1</sup> :                              | -10 °C to +25 °C   |
| Product diluent recommended by the manufacturer <sup>1</sup> : | water  |
| Active substance(s) and concentration(s) <sup>1</sup> :        | 100 g of product contains:<br>19g Benzyl-C12-16-alkyldimethylammonium chloride<br>10g 2-fenoxyethan-1-ol<br>7,2g N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine<br>3g Didecyldimethylammonium chloride |
| Purpose of product <sup>1</sup> :                              | 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 – 20.1.2021   |

<sup>1</sup> Data provided by customer.

### Results - for details see annex:

According to CSN EN 14476+A2:2020 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 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 CSN EN 14476+A2:2020 the test product **desam effect/desam effekt+**, lot. n. 014A200421, designed for surface disinfection in medical area, diluted by hard water to 0,5% solution, reduced virus titre 4,000 ± 0,000 lg after an exposure time 5 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 CSN EN 14476+A2:2020 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 0,5% 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  
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## Annex to the protocol n.: 148/2020/SVU

### Identification of product:

|  |  |
|--|--|
| Name of the product <sup>i</sup> :                             | <b>desam effect/desam effekt+</b>  |
| Batch number <sup>i</sup> :                                    | 014A200421   |
| Expiry date <sup>i</sup> :                                     | 21.4.2022  |
| Manufacturing date <sup>i</sup> :                              | not provided   |
| Manufacturer <sup>i</sup> :                                    | SCHULKE CZ, s.r.o.   |
| Date of delivery:  | 13.10.2020   |
| Storage conditions <sup>i</sup> :                              | -10 °C to +25 °C   |
| Product diluent recommended by the manufacturer <sup>i</sup> : | water  |
| Appearance of the product:                                     | clear colourless liquid  |
| Active substance(s) and concentration(s) <sup>i</sup> :        | 100 g of product contains:<br>19g Benzyl-C12-16-alkyldimethylammonium chloride<br>10g 2-fenoxyethan-1-ol<br>7,2g N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine<br>3g Didecyldimethylammonium chloride |
| Purpose of product <sup>i</sup> :                              | PT2 – surface disinfection in medical area   |

### Experimental conditions:

|  |  |
|--|--|
|  | Quantitative suspension test for the evaluation of virucidal activity of disinfectants according to CSN EN 14476+A2:2020 (SOP n. 1901) |
| Date(s) of tests (period of analysis): | 29.10.2020 – 20.1.2021   |
| Diluent:                               | hard water   |
| Testing concentration <sup>i</sup> :   | 1%, 0,5%, 0,25%  |
| Other testing concentration:           | -  |
| Appearance of dilution of the product: | clear liquid   |
| Contact times <sup>i</sup> :           | 5 min  |
| Testing temperature <sup>i</sup> :     | 20 °C±1 °C   |
| Interfering substance <sup>i</sup> :   | 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:                            | <i>Vaccinia virus, strain Modified Vaccinia virus Ankara</i> (ATCC), 5.passage, EMEM + 2% FBS  |
| Cell line:                             | BHK-21 cells (ATCC), 116., 28. 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   |

<sup>i</sup> 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 effect+ to Vaccinia virus, strain Modified Vaccinia virus Ankara - dirty conditions

| Product                                | Concentration | Interfering substance      | Level of cytotoxicity | log <sub>10</sub> TCID <sub>50</sub> / ml after ... min |                |      |      | Reduction factor<br>(Δlog <sub>10</sub> TCID <sub>50</sub> / ml after ... min) |
|--|---------------|----------------------------|-----------------------|---|----------------|------|------|--|
|  |               |                            |                       | 1   | 5              | 30   | 60   |  |
| desam effect/desam effect+             | 1,0%          | 3,0 g/l BSA + erythrocytes | 3,5                   | n.d.  | ≤3,500 ± 0,000 | n.d. | n.d. | 5<br>≥3,167 ± 0,454  |
| desam effect/desam effect+ - MicroSpin | 1,0%          | 3,0 g/l BSA + erythrocytes | 2,5                   | n.d.  | ≤2,500 ± 0,000 | n.d. | n.d. | ≥4,000 ± 0,000   |
| desam effect/desam effect+             | 0,5%          | 3,0 g/l BSA + erythrocytes | 3,5                   | n.d.  | ≤3,500 ± 0,000 | n.d. | n.d. | ≥3,167 ± 0,454   |
| desam effect/desam effect+ - MicroSpin | 0,5%          | 3,0 g/l BSA + erythrocytes | 2,5                   | n.d.  | ≤2,500 ± 0,000 | n.d. | n.d. | ≥4,000 ± 0,000   |
| desam effect/desam effect+             | 0,25%         | 3,0 g/l BSA + erythrocytes | 3,5                   | n.d.  | 5,500 ± 0,199  | n.d. | n.d. | 1,667 ± 0,604  |
| desam effect/desam effect+ - MicroSpin | 0,25%         | 3,0 g/l BSA + erythrocytes | 2,5                   | n.d.  | 5,167 ± 0,178  | n.d. | n.d. | 1,333 ± 0,356  |
| Virus control                          | n.a.          | 3,0 g/l BSA + erythrocytes | n.a.                  | n.d.  | 6,667 ± 0,227  | 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. |  |
| Formaldehyde - MicroSpin               | 0,7% (m/V)    | PBS                        | 3,5                   | ≤3,500 ± 0,000  | ≤3,500 ± 0,000 | n.d. | n.d. | ≥3,000 ± 0,000   |
| Virus control - MicroSpin              | n.a.          | PBS                        | n.a.                  | 6,500 ± 0,000   | n.d.           | n.d. | n.d. |  |

Prepared by: Mgr. Ludmila Porubová

**Table n.2 Raw data 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) |        |        |        |        |        |        |
|---|---------------|----------------------------|--------------|-------------------|--------|--------|--------|--------|--------|--------|
|   |               |                            |              | -1                | -2     | -3     | -4     | -5     | -6     | -7     |
| desam effect/desam effekt+                            | 1,0%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 000000 | 000000 | 000000 | 000000 | 000000 |
| desam effect/desam effekt+ - MicroSpin                | 1,0%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | 000000 | 000000 | 000000 | 000000 | 000000 | 000000 |
| desam effect/desam effekt+                            | 0,5%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 000000 | 000000 | 000000 | 000000 | 000000 |
| desam effect/desam effekt+ - MicroSpin                | 0,5%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | 000000 | 000000 | 000000 | 000000 | 000000 | 000000 |
| desam effect/desam effekt+                            | 0,25%         | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 444444 | 444440 | 400000 | 000000 | 000000 |
| desam effect/desam effekt+ - MicroSpin                | 0,25%         | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | 444444 | 444444 | 002433 | 000000 | 000000 | 000000 |
| desam effect/desam effekt+ - cytotoxicity             | 1,0%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| desam effect/desam effekt+ - cytotoxicity - MicroSpin | 1,0%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | 000000 | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| desam effect/desam effekt+ - cytotoxicity             | 0,5%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| desam effect/desam effekt+ - cytotoxicity - MicroSpin | 0,5%          | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | 000000 | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| desam effect/desam effekt+ - cytotoxicity             | 0,25%         | 3,0 g/l BSA + erythrocytes | 5 min        | CT                | CT     | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| desam effect/desam effekt+ - cytotoxicity - MicroSpin | 0,25%         | 3,0 g/l BSA + erythrocytes | 5 min        | 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 | 333330 | 330000 | 000000 |
| Virus control - MicroSpin                             | n.a.          | 3,0 g/l BSA + erythrocytes | 5 min        | 444444            | 444444 | 444444 | 444444 | 344322 | 000000 | 000000 |
| Cytotoxicity Formaldehyde - MicroSpin                 | 0,7% (m/V)    | PBS                        | n.a.         | CT                | CT     | 000000 | n.d.   | n.d.   | n.d.   | n.d.   |
| Formaldehyde - MicroSpin                              | 0,7% (m/V)    | PBS                        | 5 min        | CT                | CT     | 000000 | 000000 | 000000 | 000000 | 000000 |
|   |               |                            | 15 min       | CT                | CT     | 000000 | 000000 | 000000 | 000000 | 000000 |
| Virus control - MicroSpin                             | n.a.          | PBS                        | 5 min        | 444444            | 444444 | 444444 | 444444 | 324223 | 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