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**Determination bactericidal and levurocidal activity
of product desam[®] effect (sample no. 2962)
according to the EN 16615**

Summary Report

Laboratory expertise no. 201443/2020

Date of the expert report: February 5, 2021

Bactericidal activity

Levurocidal activity

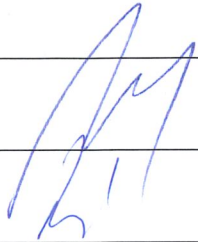
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Characteristics of presented sample

Contracting authority: Schulke CZ, s.r.o.,
Lidická 445, 735 81 Bohumín

Manufacturer: Schulke CZ, s.r.o.,
Lidická 445, 735 81 Bohumín

Product description: (according to manufacturer's specification)
Product desam[®] effect (sample no. 2962) is liquid, clear, colourless.

Product composition (active substance): N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS 2372-82-9) – 7,2 g, Didecyldimethylammonium-chloride (CAS 7173-51-5) – 3 g, Benzyl-C12-C16-alkyldimethyl chlorides (CAS 68424-85-1) – 19 g, 2-phenoxyethanol (CAS 122-99-6) – 10 g

Use of product: Disinfection and cleaning of medical device surfaces.

Documentation included:

Not indicated.

Subject of expertise was the interpretation of results of the disinfection efficiency of the submitted samples in laboratory experiments.

Interpretation of laboratory tests results

Product desam[®] effect (Laboratory sample no. 2962) demonstrated the bactericidal activity (according to the EN 16615) in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 15 minutes at temperature $20\pm 2,5$ °C under clean (bovine albumin 0,3 g/l) and dirty (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area.

Product desam[®] effect (Laboratory sample no. 2962) demonstrated the levurocidal activity (according to the EN 16615) in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 10 and 15 minutes at temperature $20\pm 2,5$ °C under clean (bovine albumin 0,3 g/l) and dirty (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area.

The product desam[®] effect (laboratory sample no. 2962), demonstrates the same results in the bactericidal and levurocidal activity under clean and dirty conditions on the day of soaking the schülke wipes and 28 days after soaking the schülke wipes.

The samples were not evaluated in terms of cleaning performance, corrosivity, toxicity, irritability and safety. This report applies only to the samples submitted and the conclusions drawn from this expertise can be applied to other products of the same kind only if their composition, contents and properties completely match the samples under testing.

The presented test results relate only to the samples referred to in this protocol and are not intended to replace other official manufacturer's documentation.

The protocol can be reproduced only in complete form with the written consent of the testing laboratory.

Determination bactericidal and levurocidal activity
of product desam[®] effect (sample no. 2962)
according to the EN 16615

The microbicidal effectiveness of disinfectants is determined by the following methods:

Accredited methods

1. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics according to the EN 13727+A2 (SOP-NRL/DS-01, method I).
2. Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics according to the EN 13624 (SOP-NRL/DS-01, method J).
3. Quantitative test method for the evaluation of bactericidal and levurocidal (yeasticidal) activity on non-porous surfaces with mechanical action employing wipes of chemical disinfectants according to the EN 16615 (SOP-NRL/DS-02, method H)

The test method used for evaluation of the bactericide and levurocide effectiveness of disinfectants are processed based harmonized standards EN 14885 (EN 13727+A2, EN 13624 and EN 16615). These are quantitative methods. The methods are accredited according to the EN ISO/IEC 17025:2018.

National Reference Laboratory for disinfection and sterilization is "testing laboratory no. 1206.4 accredited by Czech Accreditation Institute according to the standard EN ISO / IEC 17025:2018".

Results - accredited methods

More information you will find in the report of the outcome of laboratory test No. 948/2021 - Annex.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 13727+A2 standard (obligatory conditions) under clean conditions is:

According to the EN 13727+A2, the product desam[®] effect (Laboratory sample No. 2962), demonstrates the bactericidal activity in concentration 0,25 % for 10 and 15 minutes and in concentration 0,5 % for 5 minutes at 20 °C under clean conditions (bovine albumin 0,3 g/l).

The bactericidal activity was tested on test organisms (*Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa*) with the same result.

A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 13727+A2 bactericidal activity for products used in the Medical area.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 13727+A2 standard (obligatory conditions) under dirty conditions is:

According to the EN 13727+A2, the product desam[®] effect (Laboratory sample No. 2962), demonstrates the bactericidal activity in concentration 0,25 % for 10 and 15 minutes and in concentration 0,5 % for 5 minutes at 20 °C under dirty conditions (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l).

The bactericidal activity was tested on test organisms (*Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa*) with the same result.

A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 13727+A2 bactericidal activity for products used in the Medical area.

The levurocidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 13624 standard (obligatory conditions) under clean conditions is:

According to the EN 13624, the product desam[®] effect (Laboratory sample No. 2962), demonstrates the bactericidal activity in concentration 0,25 % for 10 and

15 minutes and in concentration 0,5 % for 5 minutes at 20 °C under clean conditions (bovine albumin 0,3 g/l).

A reduction of microorganisms of 4 log was noticed. This reduction guarantees according EN 13624 levurocidal activity for products used in the Medical area.

The levurocidal (yeasticidal) activity was tested on test organism *Candida albicans*.

The levurocidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 13624 standard (obligatory conditions) under dirty conditions is:

According to the EN 13624, the product desam[®] effect (Laboratory sample No. 2962), demonstrates the bactericidal activity in concentration 0,25 % for 10 and 15 minutes and in concentration 0,5 % for 5 minutes at 20 °C under dirty conditions (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l).

A reduction of microorganisms of 4 log was noticed. This reduction guarantees according EN 13624 levurocidal activity for products used in the Medical area.

The levurocidal (yeasticidal) activity was tested on test organism *Candida albicans*.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under clean conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the bactericidal activity in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 15 minutes at temperature 20±2,5 °C under clean conditions (bovine albumin 0,3 g/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100.

A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 16615 bactericidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under clean conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the bactericidal activity on gram-positive bacteria (*Staphylococcus aureus*, *Enterococcus hirae*) in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 10 and 15 minutes at temperature 20±2,5 °C under clean conditions (bovine albumin 0,3 g/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100.

A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 16615 bactericidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The levurocidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under clean conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the levurocidal activity in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 10 and 15 minutes at temperature 20±2,5 °C under clean conditions (bovine albumin 0,3 g/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100.

A reduction of microorganisms of 4 log was noticed. This reduction guarantees according to the EN 16615 levurocidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under dirty conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the bactericidal activity in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 15 minutes at temperature 20±2,5 °C under dirty

conditions (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100. A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 16615 bactericidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The bactericidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under dirty conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the bactericidal activity on gram-positive bacteria (*Staphylococcus aureus*, *Enterococcus hirae*) in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 10 and 15 minutes at temperature 20±2,5 °C under dirty conditions (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100. A reduction of microorganisms of 5 log was noticed. This reduction guarantees according to the EN 16615 bactericidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The levurocidal activity for the product desam[®] effect (Laboratory sample No. 2962), determined for general purposes according to the EN 16615 standard (obligatory conditions) under dirty conditions is:

According to EN 16615, the product desam[®] effect (laboratory sample no. 2962) demonstrates the levurocidal activity in concentration 0,5 % for 5 minutes and in concentration 0,25 % for 10 and 15 minutes at temperature 20±2,5 °C under dirty conditions (bovine albumin 3,0 g/l plus erythrocytes 3,0 ml/l) on the day of soaking the schülke wipes 100 and 28 days after soaking the schülke wipes 100. A reduction of microorganisms of 4 log was noticed. This reduction guarantees according to the EN 16615 levurocidal activity on non-porous surfaces with mechanical action employing wipes for products used in the Medical area.

The product desam[®] effect (laboratory sample no. 2962), demonstrates the same results in the bactericidal and levurocidal activity under clean and dirty

conditions on the day of soaking the schülke wipes and 28 days after soaking the schülke wipes.

References:

1. EN 13727+A2:2015 - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
2. EN 13624:2013 - Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of levurocidal activity in the medical area - Test method and requirements (phase 2, step 1)
3. EN 16615:2015 - Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)