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**Determination bactericidal and fungicidal activity
of product ChiroSan Plus (sample no. 2751) according to the
EN 13697, EN 16615 and EN 13624,
conditions for products used in the Medical area**

Summary Report

Laboratory expertise no. 181272/2018

Bactericidal activity

Fungicidal and Yeasticidal (levurocidal) activity

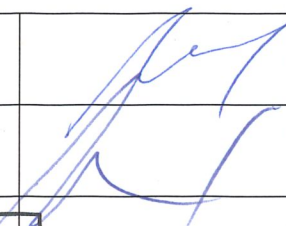
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Characteristics of presented sample

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 ChiroSan Plus (sample no. 2751) is white powder.

Product composition (active substance): In situ generated peracetic acid.

Use of product: product for disinfection of instruments, endoscopes and surfaces of medical devices

Documentation included:

Not indicated

Subject of expertise was the interpretation of results of the bactericidal and fungicidal efficiency of the submitted samples in laboratory experiments.

Interpretation of laboratory tests results

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the bactericidal activity (According to the EN 13697) in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area (According to the EN 14885).

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the levurocidal activity (According to the EN 13624) at the concentrations 0,5 % for 5 minutes and 2 % for 2 and 5 minutes at temperatures 20 ± 1 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l), for products used in the Medical area.

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the levorucidal activity (According to the EN 13697) in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area (According to the EN 14885).

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the fungicidal activity (According to the EN 13624) at the concentration 1 % for 30 minutes at temperatures 20 ± 1 °C under clean (bovine albumin 0,3 ml/l) and dirty (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area.

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the fungicidal activity (According to the EN 13697) concentration 1 % for 30 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under clean conditions (bovine albumin 0,3 ml/l), for products used in the Medical area (According to the EN 14885).

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the fungicidal activity (According to the EN 13624) at the concentration 2 % for 2 and 5 minutes at temperatures 20 ± 1 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l), for products used in the Medical area.

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the fungicidal activity (According to the EN 13697) in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty (bovine albumin 3,0 ml/l plus erythrocytes 3,0 ml/l) conditions, for products used in the Medical area (According to the EN 14885).

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the bactericidal activity (According to the EN 16615) in concentration 2 % for 2 and 5 minutes at temperature $20 \pm 2,5$ °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area.

Product ChiroSan Plus (Laboratory sample No. 2751) demonstrated the levurocidal (yeasticidal) activity (According to the EN 16615) in concentrations 2 % for 2 and 5 minutes at temperature $20 \pm 2,5$ °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area.

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 fungicidal activity
of product ChiroSan Plus (sample no. 2751) according to the
EN 13697, EN 16615 and EN 13624,
conditions for products used in the Medical area**

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

Accredited methods

1. Quantitative suspension test for the evaluation of bactericidal activity in the medical area 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 in the medical area of chemical disinfectants and antiseptics according to the EN 13624 (SOP-NRL/DS-01, method J).
3. Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants according to the EN 13697 (SOP-NRL/DS-02, method F)
4. Quantitative non-porous surface test for the evaluation of fungicidal activity of chemical disinfectants according to the EN 13697 (SOP-NRL/DS-02, method G)
5. Quantitative test method for the evaluation of bactericidal and levurocidal (yeastocidal) 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 fungicide (microscopic yeast and filamentous fungi) effectiveness of disinfectants are processed based on German methods DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie) and harmonized standards EN 14885 (EN 13727+A2, 13624, EN 13697 and 16615). These are quantitative methods. The method is accredited according to the EN ISO/IEC 17025:2005.

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 17025:2005".

Results - accredited methods

More information you will find in the report of the outcome of laboratory test No. 774/2018 - Annex).

The bactericidal activity for the product Chirozan Plus (Laboratory sample No. 2751), 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 Chirozan Plus (Laboratory sample No. 2751), demonstrates the bactericidal activity in concentration 2 % for 2 and 5 minutes at 20 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 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 EN 13727 bactericidal activity for products used in the Medical area.

The fungicidal activity for the product Chirozan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13624 standard (obligatory conditions) under clean conditions is:

According to the EN 13624, the product Chirozan Plus (Laboratory sample No. 2751), demonstrates the fungicidal activity in concentration 1 % for 30 minutes at 20 °C under clean conditions (bovine albumin 0,3 ml/l).

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

The fungicidal activity was tested on test organism *Aspergillus brasiliensis*.

The fungicidal activity for the product Chirozan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13624 standard (obligatory conditions) under dirty conditions is:

According to the EN 13624, the product Chirozan Plus (Laboratory sample No. 2751), demonstrates the fungicidal activity in concentration 2 % for 2, 5 and 10 minutes and in concentration 1 % for 30 minutes at 20 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l).

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

The fungicidal activity was tested on test organism *Aspergillus brasiliensis*.

The levurocidal activity for the product Chirozan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13624 standard (obligatory conditions) under dirty conditions is:

According to the EN 13624, the product Chirozan Plus (Laboratory sample No. 2751), demonstrates the levurocidal activity in concentration 2 % for 2 and 5 minutes and in concentration 0,5 % for 5 minutes at 20 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 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 activity was tested on test organism *Candida albicans*.

The bactericidal activity for the product Chirozan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13697 standard (obligatory conditions) under dirty conditions for products used in the Medical area is:

According to the EN 13697, the product Chirozan Plus (Laboratory sample No. 2751), demonstrates the bactericidal activity in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area (According to the EN 14885).

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

A reduction of microorganisms of 4 log was noticed. This reduction guarantees according to the EN 13697 bactericidal activity for products used in food, industrial, domestic and institutional areas, with clean conditions for products used in the Medical area (According to the EN 14885).

The fungicidal (levurocidal) activity for the product Chirozan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13697

standard (obligatory conditions) under dirty conditions for products used in the Medical area is:

According to the EN 13697, the product ChiroSan Plus (Laboratory sample No. 2751), demonstrates the fungicidal (levurocidal) activity in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area (According to the EN 14885).

A reduction of microorganisms of 3 log was noticed. This reduction guarantees according EN 13697 fungicidal (levurocidal) activity for products used in food, industrial, domestic and institutional areas, with clean conditions for products used in the Medical area (According to the EN 14885).

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

The fungicidal activity for the product ChiroSan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13697 standard (obligatory conditions) under clean conditions for products used in the Medical area is:

According to the EN 13697, the product ChiroSan Plus (Laboratory sample No. 2751), demonstrates the fungicidal activity in concentration 1 % for 30 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under clean conditions (bovine albumin 0,3 ml/l), for products used in the Medical area (According to the EN 14885).

A reduction of microorganisms of 3 log was noticed. This reduction guarantees according EN 13697 fungicidal activity for products used in food, industrial, domestic and institutional areas, with clean conditions for products used in the Medical area (According to the EN 14885).

The fungicidal activity was tested on test organism *Aspergillus brasiliensis*.

The fungicidal activity for the product ChiroSan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 13697 standard (obligatory conditions) under dirty conditions for products used in the Medical area is:

According to the EN 13697, the product ChiroSan Plus (Laboratory sample No. 2751), demonstrates the fungicidal activity in concentration 2 % for 2 and 5 minutes at temperatures ranging between 18 ± 1 °C and 25 ± 1 °C under dirty

conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area (According to the EN 14885).

A reduction of microorganisms of 3 log was noticed. This reduction guarantees according EN 13697 fungicidal activity for products used in food, industrial, domestic and areas, with clean conditions for products used in the Medical area (According to the EN 14885).

The fungicidal activity was tested on test organism *Aspergillus brasiliensis*.

The bactericidal activity for the product ChiroSan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 16615 standard (obligatory conditions) under dirty conditions is:

According to the EN 16615, the product ChiroSan Plus (Laboratory sample No. 2751), demonstrates the bactericidal activity in concentration 2 % for 2 and 5 minutes at temperature $20 \pm 2,5$ °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area.

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 (yeasticidal) activity for the product ChiroSan Plus (Laboratory sample No. 2751), determined for general purposes according to the EN 16615 standard (obligatory conditions) under dirty conditions is:

According to the EN 16615, the product ChiroSan Plus (Laboratory sample No. 2751), demonstrates the levurocidal (yeasticidal) activity in concentration 2 % for 2 and 5 minutes at temperature $20 \pm 2,5$ °C under dirty conditions (bovine albumin 3,0 ml/l plus erythrocytes 3 ml/l), for products used in the Medical area.

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.

References:

1. EN 13727+A2:2016 - 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 13624:2014 - 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 13697:2015 - Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)
4. 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)

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