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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 2
Issue No.: 1

# Test report No. S263/2019

# DETERMINATION OF BACTERICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **AKASPRAY TUCHER**

Sample ID: S263/2019
Sample name: **AKASPRAY TUCHER**
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Producer: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY



Incoming date:
31.7.2019

Digitally signed by Guțan Ghenadie
Date: 2023.01.08 17:22:07 EET
Reason: MoldSign Signature
Location: Moldova

Delivery date:
23.10.2019

Hodonín, 23.10.2019

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Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: S263/2019 | Sampling date: 1.7.2019
Rep No: 131 | Sample delivered: 31.7.2019
Sample name: **AKASPRAY TUCHER** | Testing date: 8.10. – 9.10.2019
Sampled: by client | Delivered amount: 10 pcs
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul Batch No: 1742019003 | Page: 2

Subject of testing:
Determination of bactericidal activity of the product.

Identification of the sample:

| | |
|---|---|
| Name of the product: | **AKASPRAY TUCHER** |
| Batch number: | 1742019003 |
| Date of manufacture: | 01.07.2019 |
| Expiry date: | 01.07.2021 |
| Manufacturer: | Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY |
| Incoming date: | 31.7.2019 |
| Storage conditions: | 5 °C – 35 °C |
| Active compounds and concentrations: | CAS 64-17-5 Ethyl Alcohol 50%<br>CAS 67-63-0 Propan-2-ol 10% |

| | |
|---|---|
| Experimental conditions: | **Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers**<br>SOP-M-19-00 (EN 16615:2015) |
| Period of analysis: | 8.10. – 9.10.2019 |
| Lab temperature: | 20 °C ± 2.5 °C |
| Temperature of media: | 20 °C ± 1 °C |
| Test method: | dilution neutralization method |
| Neutralization medium: | Dey-Engley Neutralizing Broth M 1062 |
| Appearance of the product: | white wipe |
| Water control: | distilled water + polysorbate 80 |
| Test concentration: | 100% (wet wipe prepared by the manufacturer was used per each test) |
| Contact time: | 30 s |
| Interfering substances: | 0.3 g/l BSA (clean conditions) |
| Test organisms: | *Staphylococcus aureus* ATCC 6538 |
| Incubation conditions: | 37 °C ± 1 °C, 24 hours |
| Test surface: | PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls $D_{C0}$ and $D_{Ct}$ are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm). |
| Wipe: | 17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the product solution. The wet wipe is weighed before and after testing. |
| Test weight: | granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg |
| Tampons: | sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical |
| Parafilm: | Parafilm® M, 10.2 cm x 38 m, producer Brand<br>disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping. |

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

Sample ID: S263/2019 Sampling date: 1.7.2019
Rep No: 131 Sample delivered: 31.7.2019
Sample name: **AKASPRAY TUCHER** Testing date: 8.10. – 9.10.2019
Sampled: by client Delivered amount: 10 pcs
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul Batch No: 1742019003 Page: 3

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions on nonporous surface in the field 1 by at least a 5 lg reduction ($10^5$).
$R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} – \lg N_a$ the reduction in viability, the drying time: 15 – 35 min

The standard:
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) April 2015
EN ISO 4833-1 Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique, September 2013

The Number of CFU in the tested product (SOP-M-07-00 (EN ISO 4833-1)): $<10^1$ CFU/g

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

Sample ID: S263/2019 | Sampling date: 1.7.2019
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1. Testing the efficacy of chemical disinfectant **AKASPRAY TUCHER** on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces

Tab No. 1.1 Verification of methodology, temperature 20°C, clean conditions

| Validation of suspension ($N_{V0}$) | | | Neutralizer toxicity control (B) | | | Method validation (C), product conc. 100% (wipe) | | |
|---|---|---|---|---|---|---|---|---|
| $V_{c1}$ | 31 | $\Phi_{Nvo} = 33$ | $V_{c1}$ | 21 | $\Phi_B = 21$ | $V_{c1}$ | 26 | $\Phi_C = 27$ |
| $V_{c2}$ | 35 | | $V_{c2}$ | 21 | | $V_{c2}$ | 28 | |
| $30 \leq \Phi_{Nvo} \leq 160$ | | | $\Phi_B \geq 0.5\ \Phi_{Nvo}$ | | | $\Phi_C \geq 0.5\ \Phi_{Nvo}$ | | |
| x | yes | no | x | yes | no | x | yes | no |

Tab No. 1.2 Test suspension

| Test suspension N | Dilution | $V_{c1}$ | $V_{c1}$ | Test suspension $N_0$ |
|---|---|---|---|---|
| $\Phi = 199 \times 10^7 = \lg 9.30$ | $10^{-7}$ | 196 | 197 | $N_0 = N/20$, $\lg N_0 = 8.00$ |
| $9.17 \leq \lg N \leq 9.70$ | $10^{-8}$ | 20 | 24 | $7.88 \leq \lg N_0 \leq 8.40$ |
| | | | | x yes no |

Tab No. 1.2.1 Drying in time 0

| Drying control ($D_{C0}$) | Dilution | $V_{c1}$ | $V_{c1}$ | $\lg D_{C0} = \lg (\Phi \times 5 \times 10^4) = 7.16$ |
|---|---|---|---|---|
| | $10^{-4}$ | 284 | 290 | $6.88 \leq \lg D_{C0} \leq 8.40$ |
| | $10^{-5}$ | 27 | 28 | |
| | | | | x yes no |

Tab No. 1.2.2 Drying in time t

| Drying control ($D_{Ct}$) | Dilution | $V_{c1}$ | $V_{c1}$ | $\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 7.14$ |
|---|---|---|---|---|
| | $10^{-4}$ | 256 | 296 | $6.88 \leq \lg D_{Ct} \leq 8.40$ |
| | $10^{-5}$ | 26 | 30 | |
| | | | | x yes no |

Tab No. 1.3.1 Test with water $N_w$ – the effect of water (Wipe with distilled water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions

| Field / contact time (s) | Dilution after test procedure | $V_c$ | $N_W = (\Phi \times 5)$ | $N_W$ requirement >10 cfu/25 $cm^2$ |
|---|---|---|---|---|
| 2 / 30 | $10^{-2}$ | 238 | 119000 | yes |
| 3 / 30 | $10^{-1}$ | 152 | 7600 | yes |
| 4 / 30 | $10^{-1}$ | 168 | 8400 | yes |

Tab No. 1.3.2. Test – the effect of **AKASPRAY TUCHER** (Wipe with product solution) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4

| Test concentration (%) /contact time (s) /conditions / field | Dilution after test procedure | $V_c$ | $N_a = (\Phi \times 5)$ | $N_a$ requirement <50 cfu/25 $cm^2$ |
|---|---|---|---|---|
| 100/30/clean/2 | $10^0$ | 5 | 25 | yes |
| 100/30/clean /3 | $10^0$ | 5 | 25 | yes |
| 100/30/clean /4 | $10^0$ | 3 | 15 | yes |

Tab No. 1.3.3 Test – the effect of **AKASPRAY TUCHER** (Wipe with product solution) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 1

| Test concentration (%) /contact time (s) /conditions / field | Dilution after test procedure | $V_{c1}$ | $V_{c2}$ | $\lg N_a (\Phi \times 5)$ | **lg R (lg $D_{Ct}$ = 7.14)** |
|---|---|---|---|---|---|
| 100/30/clean /1 | $10^0$ | 14 | 15 | 1.86 | **5.28** |

Tab No. 1.4 Test – weight of wipes before and after testing

| Weight of wipes | Weight before testing (g) | Weight after testing (g) | Difference (g) |
|---|---|---|---|
| **AKASPRAY TUCHER** (wet wipe) | 1.3 | 0.7 | 0.6 |
| Wipe with distilled water + polysorbate 80 | 19.0 | 18.1 | 0.9 |

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Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul Batch No: 1742019003 Page: 5

2. Evaluation of bactericidal activity of the product **AKASPRAY TUCHER**

Tab No. 2.1 The efficacy of chemical disinfectant **AKASPRAY TUCHER** on test strains – bactericidal activity on non-porous surfaces, clean conditions, field 1

| Bactericidal activity of the product (EN 16615:2015) | | | | | | |
|---|---|---|---|---|---|---|
| Strain | Test temperature [°C] | Contact time [s] | Product test concentrations [%] | Interfering substances – conditions | lg R EN 16615:2015 | **lg R** |
| *Staphylococcus aureus* ATCC 6538 | 20 | 30 | 100 (wet wipe) | clean | ≥ 5 | **> 5** |

Note: $V_c$ = value is the number of cfu per ml, Φ = average $V_{c1}$ a $V_{c2}$ (1. + 2. duplicate $V_c$ values), N = the number of cfu/ml in the test suspension, $N_{V0}$ = the number of cfu/ml in the test suspension for validation, $N_a$ = the number of bacteria and fungi per ml in the test mixture, A, B, C = the number of bacteria and fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} – \lg N_a$ the reduction in viability

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S263/2019 Sampling date: 1.7.2019
Rep No: 131 Sample delivered: 31.7.2019
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Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul Batch No: 1742019003 Page: 6

Interpretation:
Results of tests are in Tabs.
According to EN 16615:2015 the tested product **AKASPRAY TUCHER** (wet wipe), batch No. 1742019003 in the contact time 30 s under clean conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable bacterial cells of *Staphylococcus aureus* ATCC 6538 by at least a 5 lg reduction.

Conclusion:
The product **AKASPRAY TUCHER** is capable of reducing the number of viable bacterial cells of the relevant organism on non-porous surfaces under defined conditions (EN 16615:2015, *Staphylococcus aureus* only - **AKASPRAY TUCHER** (wet wipe), 30 s, clean, 20 ° C ± 2.5 °C) to the declared values and, consequently, can be called bactericidal on *Staphylococcus aureus*.

23.10.2019, Hodonín

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Ing. Eva Kremlová, Leader of Study