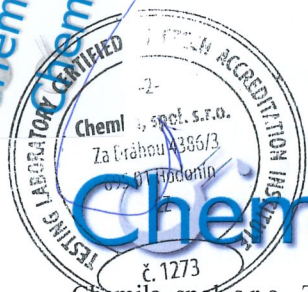


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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025.

Copy No.: 1
Issue No.: 2

Test report No. D16-1/2016

DETERMINATION OF BACTERICIDAL (ČSN EN 13697) ACTIVITY OF THE PRODUCT **DESAM® EFFEKT +** DETERMINATION OF BACTERICIDAL (ČSN EN 16615) ACTIVITY OF THE PRODUCT **DESAM® EFFEKT +**

Sample ID: D16/2016
Sample name: **DESAM® EFFEKT +**
Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Producer: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Sampling point: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Page: 1
From pages: 11

Incoming date:
21.1.2016

Delivery date:
30.10.2017

Hodonín, 30.10.2017



.....
Ing. Jana Štrbová - Head of Laboratory
č. 1273

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Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016
Rep No: 27
Sample name: **DESAM® EFFEKT +**
Sampled: by client
Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín
Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016
Sample delivered: 21.1.2016
Testing date: 3.2. – 25.8.2016
Delivered amount: 200 ml
Batch No: 017A160120
Page: 2

Subject of testing:

Determination of bactericidal activity of the product.

Identification of the sample:

Name of the product: **DESAM® EFFEKT +**
Batch number: 017A160120
Date of manufacture: 20.1.2016
Expiry date: 20.7.2017
Manufacturer: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín
Incoming date: 21.1.2016
Storage conditions: room temperature
Active compounds and concentrations:
CAS 68424-85-1 benzyl-C12-16-alkyldimethylammonium chloride 19%
CAS 122-99-6 2-phenoxyethanol 10%
CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine 7.2%
CAS 7173-51-5 didecyldimethylammonium chloride 3%

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-22-12 (ČSN EN 13697)
3.2. – 4.2.2016 (clean), 22.3. – 23.3.2016 (dirty)
18 °C ± 1 °C to 25 °C ± 1 °C
dilution neutralization method
Dey-Engley Neutralizing Broth M 1062
light yellow liquid
hard water
0.25%
5 min
0.3 g/l BSA (clean conditions)
3 g/l BSA (dirty conditions)
Escherichia coli ATCC 10536
Pseudomonas aeruginosa ATCC 15442
Staphylococcus aureus ATCC 6538
Enterococcus hirae ATCC 10541
37 °C ± 1 °C, 24 hours

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative carrier test
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 on carriers under defined conditions by at least 4 orders (10^4). The drying time: 30-35 min

The standard:

ČSN EN 13697 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) November 2015

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016
 Rep No: 27
 Sample name: **DESAM® EFFEKT +**
 Sampled: by client
 Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín
 Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016
 Sample delivered: 21.1.2016
 Testing date: 3.2. – 25.8.2016
 Delivered amount: 200 ml
 Batch No: 017A160120
 Page: 3

The Number of CFU in the tested product **DESAM® EFFEKT +**: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on carriers – bactericidal activity

Tab No. 1.1 Verification of methodology, clean conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 0.25%) Neutralization test	NC Neutralization control
<i>Escherichia coli</i> ATCC 10536	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 48, 50 N : 7.09	10 ⁻³ : >330, >330 10 ⁻⁴ : 157, 164 10 ⁻⁵ : 14, 17 NT : 7.20	10 ⁻³ : >330, >330 10 ⁻⁴ : 158, 165 10 ⁻⁵ : 15, 17 NC : 7.21
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 44, 45 N : 7.05	10 ⁻³ : >330, >330 10 ⁻⁴ : 137, 145 10 ⁻⁵ : <14, <14 NT : 7.15	10 ⁻³ : >330, >330 10 ⁻⁴ : 140, 155 10 ⁻⁵ : 14, 14 NC : 7.17
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 38, 42 N : 7.00	10 ⁻³ : >330, >330 10 ⁻⁴ : 136, 151 10 ⁻⁵ : 14, 14 NT : 7.16	10 ⁻³ : >330, >330 10 ⁻⁴ : 136, 146 10 ⁻⁵ : <14, 15 NC : 7.15
<i>Enterococcus hirae</i> ATCC 10541	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 47, 50 N : 7.08	10 ⁻³ : >330, >330 10 ⁻⁴ : 174, 186 10 ⁻⁵ : 15, 18 NT : 7.25	10 ⁻³ : >330, >330 10 ⁻⁴ : 169, 174 10 ⁻⁵ : 16, 18 NC : 7.23
Limit	6.57 ≤ lg N ≤ 7.10	NT ≥ 0.5 x Nc	NC ≥ 0.5 x Nc

$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$ where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

NC or NT = $\log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Tab No. 1.2 Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strain, clean conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations (%) / contact time (min)
		0.25/5
<i>Escherichia coli</i> ATCC 10536	10 ⁻³ : >330, >330 10 ⁻⁴ : 158, 167 10 ⁻⁵ : 15, 17 Nc : 7.21 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 5.06
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻³ : >330, >330 10 ⁻⁴ : 141, 156 10 ⁻⁵ : 14, 15 Nc : 7.17 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 5.02
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻³ : >330, >330 10 ⁻⁴ : 139, 143 10 ⁻⁵ : <14, <14 Nc : 7.15 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 5.00
<i>Enterococcus hirae</i> ATCC 10541	10 ⁻³ : >330, >330 10 ⁻⁴ : 170, 183 10 ⁻⁵ : 16, 19 Nc : 7.25 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 5.10
Limit	lg Nc ≥ lg 6.27	Nts : <100 CFU/ml for active concentration

$Nc \text{ or } Nd = \log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Reduction R = Nc – Nd

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016
 Rep No: 27
 Sample name: **DESAM® EFFEKT +**
 Sampled: by client
 Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín
 Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016
 Sample delivered: 21.1.2016
 Testing date: 3.2. – 25.8.2016
 Delivered amount: 200 ml
 Batch No: 017A160120
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2. Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on carriers – bactericidal activity

Tab No. 2.1 Verification of methodology, dirty conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 3%) Neutralization test	NC Neutralization control
<i>Escherichia coli</i> ATCC 10536	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 43, 52 N : 7.07	10 ⁻³ : >330, >330 10 ⁻⁴ : 150, 162 10 ⁻⁵ : 16, 16 NT : 7.19	10 ⁻³ : >330, >330 10 ⁻⁴ : 148, 169 10 ⁻⁵ : 16, 17 NC : 7.20
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 48, 51 N : 7.09	10 ⁻³ : >330, >330 10 ⁻⁴ : 160, 169 10 ⁻⁵ : 15, 16 NT : 7.21	10 ⁻³ : >330, >330 10 ⁻⁴ : 164, 170 10 ⁻⁵ : 14, 16 NC : 7.22
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 50, 49 N : 7.09	10 ⁻³ : >330, >330 10 ⁻⁴ : 118, 127 10 ⁻⁵ : <14, <14 NT : 7.09	10 ⁻³ : >330, >330 10 ⁻⁴ : 109, 117 10 ⁻⁵ : <14, <14 NC : 7.05
<i>Enterococcus hirae</i> ATCC 10541	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 44, 46 N : 7.05	10 ⁻³ : >330, >330 10 ⁻⁴ : 175, 187 10 ⁻⁵ : 17, 18 NT : 7.26	10 ⁻³ : >330, >330 10 ⁻⁴ : 193, 202 10 ⁻⁵ : 18, 19 NC : 7.29
Limit	6.57 ≤ lg N ≤ 7.10	NT ≥ 0.5 x Nc	NC ≥ 0.5 x Nc

$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$ where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

$NC \text{ or } NT = \log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Tab No. 2.2 Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strain, dirty conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations (%) / contact time (min)
		0.25/5
<i>Escherichia coli</i> ATCC 10536	10 ⁻³ : >330, >330 10 ⁻⁴ : 147, 155 10 ⁻⁵ : 14, 15 Nc : 7.18 Nts: >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts: 0 R: ≥ 5.03
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻³ : >330, >330 10 ⁻⁴ : 151, 165 10 ⁻⁵ : 14, 16 Nc : 7.20 Nts: >100	10 ⁻¹ : >330, >330 10 ⁻² : 58, 65 Nd : 4.79 Nts: >100 R: 2.41
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻³ : >330, >330 10 ⁻⁴ : 110, 121 10 ⁻⁵ : <14, <14 Nc : 7.06 Nts: >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts: 0 R: ≥ 4.91
<i>Enterococcus hirae</i> ATCC 10541	10 ⁻³ : >330, >330 10 ⁻⁴ : 183, 192 10 ⁻⁵ : 18, 20 Nc : 7.27 Nts: >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts: 0 R: ≥ 5.02
Limit	lg Nc ≥ lg 6.27	Nts: <100 CFU/ml for active concentration

$Nc \text{ or } Nd = \log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Reduction R= Nc – Nd

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

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

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3. Evaluation of bactericidal activity of the product **DESAM® EFFEKT +** on carriers

Tab No. 3.1 The efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strains – bactericidal activity on carriers

Bactericidal activity of the product on carriers (EN 13697)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	R EN 13697	R
<i>Escherichia coli</i> ATCC 10536	18-25	5	0.25	clean	≥ 4	> 4
<i>Pseudomonas aeruginosa</i> ATCC 15442	18-25	5	0.25	clean	≥ 4	> 4
<i>Staphylococcus aureus</i> ATCC 6538	18-25	5	0.25	clean	≥ 4	> 4
<i>Enterococcus hirae</i> ATCC 10541	18-25	5	0.25	clean	≥ 4	> 4
<i>Escherichia coli</i> ATCC 10536	18-25	5	0.25	dirty	≥ 4	> 4
<i>Pseudomonas aeruginosa</i> ATCC 15442	18-25	5	0.25	dirty	≥ 4	< 4
<i>Staphylococcus aureus</i> ATCC 6538	18-25	5	0.25	dirty	≥ 4	> 4
<i>Enterococcus hirae</i> ATCC 10541	18-25	5	0.25	dirty	≥ 4	> 4

Reduction R= Nc – Nd

Prepared by: Hana Konevalíková, Lab Technician

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

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

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Experimental conditions:

Period of analysis:

Test temperature:

Test method:

Neutralization medium:

Appearance of the product:

Product diluent:

Test concentration:

Contact time:

Interfering substances:

Test organisms:

Incubation conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-22-12 (ČSN EN 13697)

23.8. – 24.8.2016

18 °C ± 1 °C to 25 °C ± 1 °C

dilution neutralization method

Dey-Engley Neutralizing Broth M 1062

light yellow liquid

hard water

0.25%

10 min, 15 min

3 g/l BSA (dirty conditions)

Pseudomonas aeruginosa

ATCC 15442

37 °C ± 1 °C, 24 hours

Test procedure:

1. Preparation of the test suspension
2. Preparation of product test solutions
3. Quantitative carrier test
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 on carriers under defined conditions by at least 4 orders (10^4). The drying time: 30-35 min

The standard:

ČSN EN 13697 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) November 2015

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

Page: 7

4. Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on carriers – bactericidal activity

Tab No. 4.1 Verification of methodology, dirty conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 0.25%) Neutralization test	NC Neutralization control
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 49, 46 N : 7.07	10 ⁻³ : >330, >330 10 ⁻⁴ : >330, >3305 10 ⁻⁵ : 42, 34 NT : 7.58	10 ⁻³ : >330, >330 10 ⁻⁴ : >330, >3305 10 ⁻⁵ : 40, 38 NT : 7.59
Limit	6.57 ≤ lg N ≤ 7.10	NT ≥ 0.5 x Nc	NC ≥ 0.5 x Nc

$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$ where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

NC or NT = $\log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Tab No. 4.2 Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strain, dirty conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations (%) / contact time (min)	
		0.25/10	0.25/15
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻³ : >330, >330 10 ⁻⁴ : >330, >330 10 ⁻⁵ : 41, 45 Nc : 7.63 Nts : >100	10 ⁻¹ : 41, 45 Nd : 3.63 Nts : 0 R : 4.00	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 5.48
Limit	lg Nc ≥ lg 6.27	Nts : <100 CFU/ml for active concentration	

$Nc \text{ or } Nd = \log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies, d is the dilution factor for the dilution taken into account

Reduction R = Nc – Nd

5. Evaluation of bactericidal activity of the product **DESAM® EFFEKT +** on carriers

Tab No. 5.1 The efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strains – bactericidal activity on carriers

Bactericidal and fungicidal activity of the product on carriers (EN 13697)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	R EN 13697	R
<i>Pseudomonas aeruginosa</i> ATCC 15442	18-25	10	0.25	dirty	≥ 4	4
<i>Pseudomonas aeruginosa</i> ATCC 15442	18-25	15	0.25	dirty	≥ 4	> 4

Reduction R = Nc – Nd

Prepared by: Hana Konevalíková, Lab Technician

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

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

Page: 8

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-19-00 (ČSN EN 16615^F)

Period of analysis:

24.8. – 25.8.2016

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:

light yellow liquid

Product diluent:

hard water

Test concentration:

0.25%

Contact time:

5 min

Interfering substances:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)

Test organisms:

Pseudomonas aeruginosa ATCC 15442

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_{C1} 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% polyethyleneterephthalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in PD with 16 ml of the product solution. The wet wipe is weighed before and after testing.

Test weight:

granite, length 12.1 cm, width 8.6 cm, height 8.6 cm, weight 2.3 kg to 2.5 kg

Tampons:

sterile, disposable, tip should be made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms

Paraffin:

disposable, protecting the horizontal surface and vertical surfaces before contamination during wiping

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
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 5 orders (10^5).

$R = D_{C1} / N_a$ or $\lg R = \lg D_{C1} - \lg N_a$ the reduction in viability, the drying time: 40 – 45 min

The standard:

ČSN EN 16615^F 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 – Test method and requirements (phase 2, step 2) October 2015

^F update of the standard

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016

Sampling date: 20.1.2016

Rep No: 27

Sample delivered: 21.1.2016

Sample name: **DESAM® EFFEKT +**

Testing date: 3.2. – 25.8.2016

Sampled: by client

Delivered amount: 200 ml

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Batch No: 017A160120

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

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6. Testing the efficacy of chemical disinfectant **DESAM® EFFEKT +** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces

Tab No. 6.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{v0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 100%			
V_{c1}	36	$\Phi_{N_{v0}} = 38$	no	V_{c1}	37	$\Phi_B = 35$	no	V_{c1}	36	$\Phi_C = 36$	no
V_{c2}	40			V_{c2}	33			V_{c2}	36		
$30 \leq \Phi_{N_{v0}} \leq 160$				$\Phi_B \geq 0.5 \Phi_{N_{v0}}$				$\Phi_C \geq 0.5 \Phi_{N_{v0}}$			
x	yes			x	yes			x	yes		

Tab No. 6.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0 $N_0 = N/20$, $\lg N_0 = 8.27$ $7.88 \leq \lg N_0 \leq 8.40$			
$\Phi = 37 \times 10^8 = \lg 9.57$	10^{-7}	> 330	> 330				
$9.17 \leq \lg N \leq 9.70$	10^{-8}	39	35				
				x	yes		no

Tab No. 6.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\Phi = 264 \times 10^5 = \lg 7.42$ $6.88 \leq \lg D_{C0} \leq 8.40$			
	10^{-5}	260	268				
	10^{-6}	27	26				
				x	yes		no

Tab No. 6.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\Phi = 258 \times 10^5 = \lg 7.41$ $6.88 \leq \lg D_{Ct} \leq 8.40$			
	10^{-5}	262	255				
	10^{-6}	28	22				
				x	yes		no

Tab No. 6.3.1 Test with water N_w – the effect of water on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_w = (\Phi_a \times 5)$	N_w requirement >10 cfu/25 cm ²
2 / 5	10^{-1}	55	2750	yes
3 / 5	10^{-1}	34	1700	yes
4 / 5	10^{-1}	11	550	yes

Tab No. 6.3.2 Test – the effect of **DESAM® EFFEKT +** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_w = (\Phi_a \times 5)$	N_w requirement <50 cfu/25 cm ²
0.5/5/dirty/2	10^0	0	<14	yes
0.5/5/dirty/3	10^0	0	<14	yes
0.5/5/dirty/4	10^0	0	<14	yes

Tab No. 6.3.3 Test – the effect of **DESAM® EFFEKT +** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a$	$\lg R$ ($\lg D_{Ct} = \lg 7.41$)
0.5/5/dirty/1	10^0	<14	<14	<1.85	≥ 5.56

Tab No. 6.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
Wipe with DESAM® EFFEKT +	19.0	17.9	1.1
Wipe with hard water + polysorbate 80	19.3	18.1	1.2

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} + V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{v0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors 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)

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

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7. Evaluation of bactericidal activity of the product **DESAM® EFFEKT +**

Tab No. 7.1 The efficacy of chemical disinfectant **DESAM® EFFEKT +** on test strains – bactericidal activity on non-porous surfaces, dirty conditions, field 1

Bactericidal and yeasticidal activity of the product (ČSN EN 16615 ^F)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	Ig R ČSN EN 16615 ^F	Ig R
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	5	0.5	dirty	≥ 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 of the bacterial test suspension, N_{V0} = the number of cfu/ml of the bacterial test suspension for validation, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation) $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

^F update of the standard

Prepared by: Hana Konevalíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D16/2016

Rep No: 27

Sample name: **DESAM® EFFEKT +**

Sampled: by client

Sampling point: SCHULKE CZ s.r.o., Lidická 326, Bohumín

Client: SCHULKE CZ s.r.o., Lidická 326, 735 81 Bohumín

Sampling date: 20.1.2016

Sample delivered: 21.1.2016

Testing date: 3.2. – 25.8.2016

Delivered amount: 200 ml

Batch No: 017A160120

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Interpretation:

Results of tests are in Tabs.

According to the standard ČSN EN 13697 the tested product **DESAM® EFFEKT +**, batch No. 017A160120, in the concentration 0.25%, diluted in hard water, and in the contact time 5 min under clean conditions at temperature $18\text{ °C} \pm 1\text{ °C}$ to $25\text{ °C} \pm 1\text{ °C}$ by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of alive microbes *Escherichia coli* ATCC 10536, *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least 4 (lg) orders.

According to the standard ČSN EN 13697 the tested product **DESAM® EFFEKT +**, batch No. 017A160120, in the concentration 0.25%, diluted in hard water, and in the contact time 5 min under dirty conditions at temperature $18\text{ °C} \pm 1\text{ °C}$ to $25\text{ °C} \pm 1\text{ °C}$ by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of alive microbes *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least 4 (lg) orders.

According to the standard ČSN EN 13697 the tested product **DESAM® EFFEKT +**, batch No. 017A160120, in the concentration 0.25%, diluted in hard water, and in the contact times 10 and 15 min under dirty conditions at temperature $18\text{ °C} \pm 1\text{ °C}$ to $25\text{ °C} \pm 1\text{ °C}$ by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of alive microbes *Pseudomonas aeruginosa* ATCC 15442 by at least 4 (lg) orders.

According to the standard ČSN EN 16615^F the tested product **DESAM® EFFEKT +**, batch No. 017A160120, in the concentration 0.5%, diluted in hard water, and in the contact time 5 min under dirty conditions at temperature $20\text{ °C} \pm 2.5\text{ °C}$ by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of alive microbes *Pseudomonas aeruginosa* ATCC 15442 by at least 5 (lg) orders.

^F update of the standard

Conclusion:

The product **DESAM® EFFEKT +** is capable of reducing the number of viable bacterial cells of the relevant organisms on carriers under defined conditions to the declared values, and consequently, may be called bactericidal on carriers.

The product **DESAM® EFFEKT +** is capable of reducing the number of viable bacterial cells of the relevant organisms on non-porous surfaces under defined conditions to the declared values, and consequently, may be called bactericidal on non-porous surfaces.

The test report D16-1/2016 was issued on 30.10.2017 again upon client's request for correction.

30.10.2017, Hodonín

Ing. Eva Kremlová, Leader of Study

