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Copy No.: 1 Issue No.: 1

Test report No. D90-2/2017

DETERMINATION OF VIRUCIDAL (EN 14476+A1) ACTIVITY OF THE PRODUCT GLOBACID SF MED 1.25%

Sample ID: D90/2017

Sample name: GLOBACID SF MED 1.25%

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From pages: 12

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404 Producer: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Incoming date: 11.5.2017

Delivery date: 8.12.2017

Hodonín, 8.12.2017

Ing. Jana Šlitrová Head of Laboratory

a Dráhov 4386/3 695 01 1

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Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Delivered amount: 11 Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404 Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

Subject of testing:

Determination of virucidal activity of the product.

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Sampling date: 5.5.2017

Sample delivered: 11.5.2017

Testing date: 27.10. - 8.12.2017

Identification of the sample:

Name of the product:

GLOBACID SF MED 1.25%

Batch number: Date of manufacture: 20042017 20.04.2017

Expiry date:

19.04.2020

Manufacturer:

Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa,

Estonia 76404

Incoming date:

11.5.2017

Storage conditions:

stated by the manufacturer

Active compounds in 100 g:

N-(3-aminopropyl)-N-dodecyl propane-1,3-diamine <1%

DDAC < 1%

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A1:2015)

Period of analysis:

27.10. - 2.11.201720 °C ± 1 °C

Test temperature: Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product:

colourless liquid

Test concentration:

100% (concentrated)*/** 15, 30 and 60 min

Contact time: Interfering substances:

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

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K47740803613, expiry date: 31.3.2018

Test virus:

Vaccinia virus strain Elstree CAMP V-160 (3rd passage)

Cell lines:

Incubation:

36 °C \pm 1 °C, 5 % CO₂, 96 h, and additional period of 48 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product

2. Preparation of cell culture

3. Preparation of the test virus suspension

4. Test of viral infectivity

5. Virus titration with interfering substance

6. Cytotoxicity of the product

7. Reference virus inactivation test

8. Test procedure for virucidal activity of product

Virucidal activity - the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders. The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013+A1:2015).

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sampling date: 5.5.2017 Sample delivered: 11.5.2017 Testing date: 27.10. – 8.12.2017

Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

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The standard:

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Vaccinia virus strain Elstree CAMP V-160

Tab No. 1.1 Table of results of product GLOBACID SF MED 1.25% on Vaccinia virus strain Elstree CAMP V-

100							
Product	Concentration **	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 5 min	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
GLOBACID SF MED 1.25%	100%*	dirty	4.50	-	4.67	4.50	4.50
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	7.17	5.67	-	-
			Virus titration, time = 0				
Virus control	-	PBS	9.50	9.50	9.50	-	-
Virus control	-	dirty	9.50	9.50	9.50	9.50	9.67

Tab No. 1.2 Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Vaccinia virus strain Elstree CAMP V-160

Test concentration**	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
100%*	9.50	dirty	15 min	4.67	4.83
100%*	9.50	dirty	30 min	4.50	5.00
100%*	9.50	dirty	60 min	3.83	5.00

2. Evaluation of virucidal activity of the product GLOBACID SF MED 1.25%

Tab No. 2.1 The efficacy of chemical disinfectant GLOBACID SF MED 1.25% on test viruses - virucidal activity

uotivity						
	Virucida	al activity of the	e product (EN 14476	:2013+A1:2015)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	Δlog ₁₀ TCID ₅₀
Vaccinia virus strain Elstree CAMP V-160	20	15	100*	dirty	≥ 4	> 4
Vaccinia virus strain Elstree CAMP V-160	20	30	100*	dirty	≥ 4	> 4
Vaccinia virus strain Elstree CAMP V-160	20	60	100*	dirty	≥4	>4

Note:

 $TCID_{50}$ - 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, Lab Technician

^{*} Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

^{**} The test was performed by using MicroSpinTM S 400 HR

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Delivered amount: 11 Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404 Sampled: by client

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

Sampling date: 5.5.2017

Sample delivered: 11.5.2017

Testing date: 27.10. - 8.12.2017

antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A1:2015)

20 °C ± 1 °C

Test temperature: Method of titration:

Appearance of the product:

Test concentration:

Period of analysis:

Contact time: Interfering substances:

Reference product:

29.11. - 8.12.2017virus titration on monolayers of cells on microtitre plates

colourless liquid

100% (concentrated)*/**

15, 30 and 60 min

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

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K47740803613, expiry date: 31.3.2018

BVDV strain NADL ATCC-VR-534 (6th passage)

Test virus: MDBK cells

36 °C \pm 1 °C, 5 % CO₂, 96 h, and additional period of 96 hours, and Cell lines:

additional period of 24 hours. After incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product

Preparation of cell culture

3. Preparation of the test virus suspension

4. Test of viral infectivity

5. Virus titration with interfering substance

6. Cytotoxicity of the product

7. Reference virus inactivation test

8. Test procedure for virucidal activity of product

Virucidal activity - the capability of a product to produce a reduction in the number of infectious virus particles

under defined conditions by at least 4 (lg) orders. * Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sampling date: 5.5.2017 Sample delivered: 11.5.2017 Testing date: 27.10. – 8.12.2017

Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

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3. Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on BVDV strain NADL ATCC-VR-534

Tab No. 3.1 Table of results of product GLOBACID SF MED 1.25% on BVDV strain NADL ATCC-VR-534

Product	Concentration	Interfering	Level of	- log ₁₀ TCID ₅₀			
	**	substances	cytoxicity	after 5 min	after 15 min	after 30 min	after 60 min
GLOBACID	100%*	dirty	4.50	-	4.50	4.50	4.50
SF MED							
1.25%							
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	6.50	5.33	-	-
			Virus titration, time = 0				
Virus control	-	PBS	9.00	9.00	9.00	-	-
Virus control	-	dirty	9.00	9.00	9.00	9.00	9.00

Tab No. 3.2 Testing the efficacy of chemical disinfectant **GLOBACID SF MED 1.25%** on *BVDV* strain NADL ATCC-VR-534

11100 11001					
Test concentration**	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	∆log ₁₀ TCID ₅₀
100%*	9.00	dirty	15 min	4.50	4.50
100%*	9.00	dirty	30 min	4.50	4.50
100%*	9.00	dirty	60 min	4.50	4.50

4. Evaluation of virucidal activity of the product GLOBACID SF MED 1.25%

Tab No. 4.1 The efficacy of chemical disinfectant GLOBACID SF MED 1.25% on test viruses - virucidal

activity

	Virucida	al activity of th	e product (EN 14476	5:2013+A1:2015)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	∆log ₁₀ TCID ₅₀
BVDV strain NADL ATCC- VR-534	20	15	100*	dirty	≥ 4	> 4
BVDV strain NADL ATCC- VR-534	20	30	100*	dirty	≥ 4	> 4
BVDV strain NADL ATCC- VR-534	20	60	100*	dirty	≥ 4	> 4

Note:

 $TCID_{50}$ - 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by:

^{*} Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

^{**} The test was performed by using MicroSpinTM S 400 HR

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sampling date: 5.5.2017 Sample delivered: 11.5.2017 Testing date: 27.10. – 8.12.2017

Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A1:2015)

Period of analysis:

23.11. – 1.12.2017 20 °C ± 1 °C

Test temperature: Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product:

colourless liquid

Test concentration:

100% (concentrated)*/**

Contact time:

15, 30 and 60 min

Interfering substances: Reference product:

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

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K47740803613, expiry date: 31.3.2018

Test virus:

Adenovirus type 5, strain Adenoid 75, ATCC VR-5 (3rd passage)

HeLa cells

Cell lines: Incubation:

36 °C \pm 1 °C, 5 % CO₂, 96 h, and additional period of 96 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product

2. Preparation of the cell culture

3. Preparation of the test virus suspension

4. Test of the viral infectivity

5. Virus titration with the interfering substance

6. Cytotoxicity of the product

7. Reference virus inactivation test

8. Test procedure for the virucidal activity of the product

Note

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders.

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

The standard:

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Testing date: 27.10. - 8.12.2017 Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404 Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

Sampling date: 5.5.2017

Sample delivered: 11.5.2017

5. Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Adenovirus type 5, strain Adenoid 75, ATCC VR-5

Tab No. 5.1 Table of results of product GLOBACID SF MED 1.25% on Adenovirus type 5, strain Adenoid 75,

Product	Concentration **	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
GLOBACID SF MED 1.25%	100%*	dirty	4.50	5.17	5.17	5.00
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	-	6.50	5.00
1 or maraen, ac			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.50	9.50
Virus control		dirty	9.50	9.50	9.50	9.33

Tab No. 5.2 Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Adenovirus type 5,

strain Adenoid 75, ATCC VR-5

Test concentration**		Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
100%*	9.50	dirty	15 min	5.17	4.33
100%*	9.50	dirty	30 min	5.17	4.33
100%*	9.50	dirty	60 min	5.00	4.50

6. Evaluation of virucidal activity of the product GLOBACID SF MED 1.25%

Tab No. 6.1 The efficacy of chemical disinfectant GLOBACID SF MED 1.25% on test viruses - virucidal

activity

activity			1 . (5) 1 1 4 4 7 ((2012 A 1,2015)		
	Virucida	al activity of the	e product (EN 14476	:2013+A1:2013)	- marn	II TOID
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	Δlog ₁₀ TCID ₅₀
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	15	100*	dirty	≥ 4	>4
Adenoid 75, ATCC VR-5 Adenoid 75, ATCC VR-5 Adenoid 75, ATCC VR-5	20	30	100*	dirty	≥ 4	>4
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	60	100*	dirty	≥ 4	> 4

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

** The test was performed by using MicroSpinTM S 400 HR

Prepared by:

^{*} Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sampling date: 5.5.2017 Sample delivered: 11.5.2017 Testing date: 27.10. - 8.12.2017

Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

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antiseptic agents by suspension method SOP-M-19-00

Period of analysis:

Test temperature:

Method of titration: Appearance of the product:

Test concentration:

Contact time:

Interfering substances:

Reference product:

Test virus:

Cell lines: Incubation:

(EN 14476:2013 +A1:2015)

28.11. - 8.12.201720 °C ± 1 °C

virus titration on monolayers of cells on microtitre plates

colourless liquid

100% (concentrated)*/**

15, 30 and 60 min

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions) Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K47740803613, expiry date: 31.3.2018

Murine norovirus (MNV) strain S99, RVB-651 (2nd passage)

RAW 264.7 Murine macrophage cell line

36 °C \pm 1 °C, 5 % CO₂, 120 h, and additional period of 120hours.

After incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product

Preparation of cell culture

- Preparation of the test virus suspension
- Test of viral infectivity
- 5. Virus titration with interfering substance
- 6. Cytotoxicity of the product
- 7. Reference virus inactivation test
- Test procedure for virucidal activity of product

Note:

Virucidal activity - the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders.

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sampling date: 5.5.2017 Sample delivered: 11.5.2017 Testing date: 27.10. – 8.12.2017

Delivered amount: 11

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

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7. Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Murine norovirus (MNV) strain S99, RVB-6515

Tab No. 7.1 Table of results of product GLOBACID SF MED 1.25% on Murine norovirus (MNV) strain S99, PVR-6515

Product	Concentration	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
GLOBACID SF MED 1.25%	100%*	dirty	4.50	5.00	4.83	4.83
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	-	7.33	6.00
•			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.50	9.33
Virus control	-	dirty	9.50	9.50	9.50	9.50

Tab No. 7.2 Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Murine norovirus

(MNV) strain S99, RVB-6515

Test concentration**	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
100%*	9.50	dirty	15 min	5.00	4.50
100%*	9.50	dirty	30 min	4.83	4.67
100%*	9.50	dirty	60 min	4.83	4.67

8. Evaluation of virucidal activity of the product GLOBACID SF MED 1.25%

Tab No. 8.1 The efficacy of chemical disinfectant GLOBACID SF MED 1.25% on test viruses – virucidal activity

activity						
	Virucida	al activity of th	e product (EN 14476	5:2013+A1:2015)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	Δlog ₁₀ TCID ₅₀
Murine norovirus (MNV) strain S99, RVB-651	20	15	100*	dirty	≥ 4	> 4
Murine norovirus (MNV) strain S99, RVB-651	20	30	100*	dirty	≥ 4	> 4
Murine norovirus (MNV) strain S99, RVB-651	20	60	100*	dirty	≥ 4	> 4

Note:

 $TCID_{50}$ - 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

** The test was performed by using MicroSpinTM S 400 HR

Prepared by:

^{*} Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sample delivered: 11.5.2017 Testing date: 27.10. - 8.12.2017

Delivered amount: 11

Sampling date: 5.5.2017

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and

antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A1:2015)

Period of analysis:

24.11. - 1.12.2017

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Appearance of the product:

colourless liquid

Test concentration:

100% (concentrated)*/**

Contact time:

15, 30 and 60 min

Interfering substances: Reference product:

3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions) Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K47740803613, expiry date: 31.3.2018

Test virus:

Poliovirus type 1, LSc-2ab (6th passage)

HeLa cells

Cell lines: Incubation:

36 °C \pm 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product

2. Preparation of the cell culture

3. Preparation of the test virus suspension

4. Test of the viral infectivity

5. Virus titration with the interfering substance

6. Cytotoxicity of the product

7. Reference virus inactivation test

8. Test procedure for the virucidal activity of the product

Virucidal activity - the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least 4 (lg) orders.

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

The standard:

EN 14476:2013 +A1:2015 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1) August 2013 + September 2015

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client

Sample delivered: 11.5.2017

CID SF MED 1.25%

Testing date: 27.10. – 8.12.2017

Delivered amount: 11

Sampling date: 5.5.2017

Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

CONFIDENTIAL Page: 11

9. Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on Poliovirus type 1, LSc-2ab

Tab No. 9.1 Table of results of product GLOBACID SF MED 1.25% on Poliovirus type 1, LSc-2ab

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Product	Concentration **	Interfering substances	Level of cytoxicity	- log ₁₀ TCID ₅₀ after 15 min	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
GLOBACID SF MED 1.25%	100%*	dirty	4.50	5.00	4.83	4.83
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	-	7.33	6.00
			Virus titration, time = 0			
Virus control		PBS	9.50	-	9.50	9.33
Virus control		dirty	9.50	9.50	9.50	9.50

Tab No. 9.2 Testing the efficacy of chemical disinfectant GLOBACID SF MED 1.25% on *Poliovirus* type 1, LSc-2ab

Test concentration**	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
100%*	9.50	dirty	15 min	5.00	4.50
100%*	9.50	dirty	30 min	4.83	4.67
100%*	9.50	dirty	60 min	4.83	4.67

10. Evaluation of virucidal activity of the product GLOBACID SF MED 1.25%

Tab No. 10.1 The efficacy of chemical disinfectant GLOBACID SF MED 1.25% on test viruses - virucidal

activity

donvity	Virucida	al activity of th	e product (EN 14476	5:2013+A1:2015)		
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A1:2015	Δlog ₁₀ TCID ₅₀
Poliovirus type 1, LSc-2ab	20	15	100*	dirty	≥ 4	> 4
Poliovirus type 1, LSc-2ab	20	30	100*	dirty	≥ 4	> 4
Poliovirus type 1, LSc-2ab	20	60	100*	dirty	≥ 4	> 4

Note:

 $TCID_{50}$ - 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by:

^{*} Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

^{**} The test was performed by using MicroSpinTM S 400 HR

Sample ID: D90/2017

Rep No: 131

Sample name: GLOBACID SF MED 1.25%

Sampled: by client Sampling point: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Client: Goodpoint Chemicals Ltd, Urda tee 3, Jälgimäe, Saku vald, Harjumaa, Estonia 76404

Batch No: 20042017

Sample delivered: 11.5.2017 Testing date: 27.10. - 8.12.2017Delivered amount: 11

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Sampling date: 5.5.2017



Interpretation:

Results of tests are in Tabs.

According to EN 14476:2013+A1:2015 the tested concentrated*/** product GLOBACID SF MED 1.25%, batch No. 20042017, in the contact times 15 min, 30 min and 60 min under dirty conditions at temperature 20 °C \pm 1 °C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious Vaccinia virus strain Elstree CAMP V-160 particles under defined conditions by at least 4 (lg) orders. The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013+A1:2015).

The tested concentrated*/** product GLOBACID SF MED 1.25%, batch No. 20042017, in the contact times 15 min, 30 min and 60 min under dirty conditions at temperature 20 °C ± 1 °C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious BVDV strain NADL ATCC-VR-534 particles under defined conditions by at least 4 (lg) orders (EN 14476:2013+A1:2015).

According to EN 14476:2013+A1:2015 the tested concentrated*/** product GLOBACID SF MED 1.25%, batch No. 20042017, in the contact times 15 min, 30 min and 60 min under dirty conditions conditions at temperature 20 °C ± 1 °C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious Adenovirus type 5, strain Adenoid 75, ATCC VR-5 particles under defined conditions by at least 4 (lg) orders.

According to EN 14476:2013+A1:2015 the tested concentrated*/** product GLOBACID SF MED 1.25%, batch No. 20042017, in the contact times 15 min, 30 min and 60 min under dirty conditions conditions at temperature 20 °C ± 1 °C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious Murine norovirus (MNV) strain S99, RVB-651 particles under defined conditions by at least 4 (lg) orders.

According to EN 14476:2013+A1:2015 the tested concentrated*/** product GLOBACID SF MED 1.25%, batch No. 20042017, in the contact times 15 min, 30 min and 60 min under dirty conditions conditions at temperature 20 $^{\circ}$ C \pm 1 $^{\circ}$ C proved by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious Poliovirus type 1, LSc-2ab particles under defined conditions by at least 4 (lg) orders.

* Product can only be tested at a concentration of 97% (RTU) or less, as some dilution is always produced by adding the test organisms and interfering substance.

** The test was performed by using MicroSpinTM S 400 HR

Conclusion:

The product GLOBACID SF MED 1.25% is capable of reducing the number of infectious Vaccinia virus and BVDV under defined conditions to the declared values, and consequently, may be called virucidal against enveloped viruses.

The product GLOBACID SF MED 1.25% is capable of reducing the number of infectious Adenovirus, Murine norovirus and Poliovirus under defined conditions to the declared values, and consequently, may be called virucidal.

8.12.2017, Hodonín

Chemila, spol. s.r.o.Za.Dráhou 4386/3

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