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

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Test report No. D89-2/2017

DETERMINATION OF VIRUCIDAL (EN 14476+A1) ACTIVITY OF THE PRODUCT **GLOBACID SF 0.25%**

Sample ID: D89/2017
Sample name: **GLOBACID SF 0.25%**
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

Chemila, spol. s.r.o.
Za Dráhou 4386/3
695 01 Hodonín
CZ

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Ing. Jana Slitrová, Head of Laboratory

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

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

Identification of the sample:

Name of the product:	**GLOBACID SF 0.25%**
Batch number:	20042017
Date of manufacture:	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. – 2.11.2017
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:	5 min, 15 min, 30 min
Interfering substances:	0.3 g/l BSA (clean 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:	VERO cells
Incubation:	36 °C ± 1 °C, 5 % CO_2, 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

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. 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 MicroSpin™ S 400 HR

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

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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 0.25%** on *Vaccinia virus* strain Elstree CAMP V-160

Tab No. 1.1 Table of results of product **GLOBACID SF 0.25%** on *Vaccinia virus* strain Elstree CAMP V-160

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
GLOBACID SF 0.25%	100%*	clean	≤3.50	4.50	3.83	3.83
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	-	clean	9.50	9.50	9.50	9.33

Tab No. 1.2 Testing the efficacy of chemical disinfectant **GLOBACID SF 0.25%** 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	$\Delta\log_{10}$ $TCID_{50}$
100%*	9.50	clean	5 min	4.50	**5.00**
100%*	9.50	clean	15 min	3.83	**5.67**
100%*	9.50	clean	30 min	3.83	**5.67**

2. Evaluation of virucidal activity of the product **GLOBACID SF 0.25%**

Tab No. 2.1 The efficacy of chemical disinfectant **GLOBACID SF 0.25%** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A1:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013+ A1:2015	$\Delta\log_{10}$ $TCID_{50}$
Vaccinia virus strain Elstree CAMP V-160	20	5	100*	clean	≥ 4	**> 4**
Vaccinia virus strain Elstree CAMP V-160	20	15	100*	clean	≥ 4	**> 4**
Vaccinia virus strain Elstree CAMP V-160	20	30	100*	clean	≥ 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
* 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 MicroSpin™ S 400 HR

Prepared by: Bc. Iva Čížová, Lab Technician

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

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:	29.11. – 8.12.2017
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:	5 min, 15 min, 30 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Reference product:	Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K47740803613, expiry date: 31.3.2018
Test virus:	*BVDV* strain NADL ATCC-VR-534 (6th passage)
Cell lines:	MDBK cells
Incubation:	36 °C ± 1 °C, 5 % CO_2, 96 h, and additional period of 96 hours, and 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
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

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 MicroSpin™ 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

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

3. Testing the efficacy of chemical disinfectant **GLOBACID SF 0.25%** on *BVDV* strain NADL ATCC-VR-534

Tab No. 3.1 Table of results of product **GLOBACID SF 0.25%** on *BVDV* strain NADL ATCC-VR-534

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
GLOBACID SF 0.25%	100%*	clean	≤3.50	4.17	3.83	3.50
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	-	clean	9.00	9.00	9.00	9.17

Tab No. 3.2 Testing the efficacy of chemical disinfectant **GLOBACID SF 0.25%** on *BVDV* strain NADL ATCC-VR-534

Test concentration**	Titre of the virus suspension - $\log_{10}$ $TCID_{50}$	Interfering substances	Contact time	- $\log_{10}$ $TCID_{50}$ after test procedure	$\Delta\log_{10}$ $TCID_{50}$
100%*	9.00	clean	5 min	4.17	**4.83**
100%*	9.00	clean	15 min	3.83	**5.17**
100%*	9.00	clean	30 min	3.50	**5.50**

4. Evaluation of virucidal activity of the product **GLOBACID SF 0.25%**

Tab No. 4.1 The efficacy of chemical disinfectant **GLOBACID SF 0.25%** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A1:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013+ A1:2015	$\Delta\log_{10}$ $TCID_{50}$
BVDV strain NADL ATCC-VR-534	20	5	100*	clean	≥ 4	**> 4**
BVDV strain NADL ATCC-VR-534	20	15	100*	clean	≥ 4	**> 4**
BVDV strain NADL ATCC-VR-534	20	30	100*	clean	≥ 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
* 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 MicroSpin™ S 400 HR

Prepared by: Bc. Iva Čížová, Lab Technician

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

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
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:	5 min, 15 min, 30 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Reference product:	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)
Cell lines:	HeLa cells
Incubation:	36 °C ± 1 °C, 5 % CO_2, 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 MicroSpin™ 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

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

5. Testing the efficacy of chemical disinfectant **GLOBACID SF 0.25%** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Tab No. 5.1 Table of results of product **GLOBACID SF 0.25%** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

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 0.25%	100%*	clean	≤3.50	5.50	4.83	4.83	-
Formaldehyde	0.7 % (w/v)	PBS	≤1.50	-	-	6.50	5.00
			Virus titration, time = 0				
Virus control	-	PBS	9.50	-	-	9.50	9.50
Virus control	-	clean	9.50	9.50	9.50	9.33	-

Tab No. 5.2 Testing the efficacy of chemical disinfectant **GLOBACID SF 0.25%** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Test concentration**	Titre of the virus suspension - $\log_{10}$ $TCID_{50}$	Interfering substances	Contact time	- $\log_{10}$ $TCID_{50}$ after test procedure	$\Delta\log_{10}$ $TCID_{50}$
100%*	9.50	clean	5 min	5.50	**4.00**
100%*	9.50	clean	15 min	4.83	**4.67**
100%*	9.50	clean	30 min	4.83	**4.67**

6. Evaluation of virucidal activity of the product **GLOBACID SF 0.25%**

Tab No. 6.1 The efficacy of chemical disinfectant **GLOBACID SF 0.25%** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A1:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]**	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013+ A1:2015	$\Delta\log_{10}$ $TCID_{50}$
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	5	100*	clean	≥ 4	**4**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	15	100*	clean	≥ 4	**> 4**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	30	100*	clean	≥ 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
* 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 MicroSpin™ S 400 HR

Prepared by: Bc. Iva Čížová, Lab Technician

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

Sample ID: D89/2017
Rep No: 130
Sample name: **GLOBACID SF 0.25%**
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

Sampling date: 5.5.2017
Sample delivered: 11.5.2017
Testing date: 27.10. – 8.12.2017
Delivered amount: 1 l

Interpretation:
Results of tests are in Tabs.
According to EN 14476:2013+A1:2015 the tested concentrated*/** product **GLOBACID SF 0.25%,** batch No. 20042017, in the contact times 5 min, 15 min and 30 min under clean 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 *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 0.25%,** batch No. 20042017, in the contact times 5 min, 15 min and 30 min under clean 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 0.25%,** batch No. 20042017, in the contact times 5 min, 15 min and 30 min under clean 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.

* 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 MicroSpin™ S 400 HR

Conclusion:
The product **GLOBACID SF 0.25%** 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 0.25%** is capable of reducing the number of infectious *Adenovirus* under defined conditions to the declared values, and consequently, may be called virucidal on *Adenovirus*.

8.12.2017, Hodonín

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Ing. Barbora Stoklásková, Leader of Study