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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2018.

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Test report No. S569/2020

DETERMINATION OF FUNGICIDAL (EN 13624:2013), MYCOBACTERICIDAL AND TUBERCULOCIDAL (EN 14348:2005) ACTIVITY OF THE PRODUCT **VELOX OXY ETA** DETERMINATION OF VIRUCIDAL (EN 14476:2013 +A2:2019) ACTIVITY OF THE PRODUCT **VELOX OXY ETA**

Sample ID: S569/2020
Sample name: **Velox Oxy ETA**
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Producer: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Incoming date:
27.11.2020

Delivery date:
14.10.2021

Hodonín, 14.10.2021

Ing. Jana Slitrová, Head of Laboratory

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Subject of testing:
Determination of fungicidal, mycobactericidal, tuberculocidal and virucidal activity of the product.

Identification of the sample:

Name of the product:	**Velox Oxy ETA**
Batch number:	231120-92
Date of manufacture:	23.11.2020
Expiry date:	23.05.2022
Manufacturer:	MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Incoming date:	27.11.2020
Storage conditions:	at room temperature in dark area
Active ingredients in 100 g:	Ethanol 72,8 g Propan-2-ol 7,2 g Hydrogen peroxide 3 g

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method
SOP-M-19-00 (EN 14348:2005)

Period of analysis:	15.3. – 5.4.2021
Test temperature:	20 °C ± 1 °C
Test method:	membrane filtration method
Filtration diluent:	rinsing liquid
Appearance of the product:	colourless liquid
Test concentration:	100% (concentrated)*
Contact time:	30 s (0.5 min), 3 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
Incubation conditions:	37 °C ± 1 °C, 21 days

Test procedure:
1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least a 4 lg reduction (10^4).
Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least a 4 lg reduction (10^4).
$R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

The standard:
EN 14348:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test method and requirements (phase 2, step 1) January 2005

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

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

1. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Mycobacterium avium* ATCC 15769

Tab No. 1.1 Verification of methodology, dirty conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	48	$\Phi_{Nvo} = 49.5$	V_{c1}	55	$\Phi_A = 48$	V_{c1}	43	$\Phi_B = 51.5$	V_{c1}	58	$\Phi_C = 48$
V_{c2}	51		V_{c2}	41		V_{c2}	60		V_{c2}	38	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 1.2 Test suspensions

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
$\Phi = 49 \times 10^8 = \lg 9.69$	10^{-7}	> 165	> 165	$\lg N_0 = \lg N/10 = \lg 8.69$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	46	52	$8.17 \leq \lg N_0 \leq 8.70$
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Mycobacterium avium* ATCC 15769

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 8.69$)**
100* / 0.5 / dirty	10^{-4}	26	42	6.53	**2.16**
100* / 3 / dirty	10^{-2}	16	19	4.24	**4.45**

2. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Mycobacterium terrae* ATCC 15755

Tab No. 2.1 Verification of methodology, dirty conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	37	$\Phi_{Nvo} = 37.5$	V_{c1}	36	$\Phi_A = 33.5$	V_{c1}	37	$\Phi_B = 36$	V_{c1}	41	$\Phi_C = 39$
V_{c2}	38		V_{c2}	31		V_{c2}	35		V_{c2}	37	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 2.2 Test suspensions

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
$\Phi = 40.5 \times 10^8 = \lg 9.61$	10^{-7}	> 165	> 165	$\lg N_0 = \lg N/10 = \lg 8.61$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	40	41	$8.17 \leq \lg N_0 \leq 8.70$
				x yes no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Mycobacterium terrae* ATCC 15755

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 8.61$)**
100* / 0.5 / dirty	10^{-2}	95	106	5.00	**3.61**
100* / 3 / dirty	10^{-1}	<14	<14	< 3.15	**≥ 5.46**

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0"), N_a = the number of viable cells per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0}= the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0"), A,B,C = the number of viable cells per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

3. Evaluation of mycobactericidal and tuberculocidal activity of the product **Velox Oxy ETA**

Tab No. 3.1 The efficacy of chemical disinfectant **Velox Oxy ETA** on test strain – mycobactericidal and tuberculocidal activity

Mycobactericidal and tuberculocidal activity of the product (EN 14348:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 14348:2005	**lg R**
Mycobacterium avium ATCC 15769	20	0.5	100	dirty	≥ 4	**< 4**
Mycobacterium terrae ATCC 15755	20	0.5	100	dirty	≥ 4	**< 4**
Mycobacterium avium ATCC 15769	20	3	100	dirty	≥ 4	**> 4**
Mycobacterium terrae ATCC 15755	20	3	100	dirty	≥ 4	**> 4**

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0"), N_a = the number of viable cells per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0}= the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0"), A,B,C = the number of viable cells per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Prepared by: Ing. Eva Kremlová, Lab Technician

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92
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Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 13624:2013)
Period of analysis:	26.3. – 29.3.2021
Test temperature:	20 °C ± 1 °C
Test method:	membrane filtration method
Filtration diluent:	rinsing liquid
Appearance of the product:	colourless liquid
Test concentration:	100% (concentrated)*
Contact time:	15 s (0.25 min), 30 s (0.5 min), 1 min, 3 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis (niger)* ATCC 16404
Incubation conditions:	30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Presence of a high concentration (at least 75%) of *Aspergillus brasiliensis* spiny spores in the test suspension – yes.
Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi belonging to reference strains under defined conditions by at least a 4 lg reduction (10^4).
Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of relevant test organisms under defined conditions by at least a 4 lg reduction (10^4).
$R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

The standard:
EN 13624:2013 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1) September 2013

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

Sample ID: S569/2020
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Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

4. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Candida albicans* ATCC 10231

Tab No. 4.1 Verification of methodology, dirty conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	62	Φ_{Nvo}= 59.5	V_{c1}	58	Φ_A = 53	V_{c1}	58	Φ_B = 59	V_{c1}	47	Φ_C = 49.5
V_{c2}	57		V_{c2}	48		V_{c2}	60		V_{c2}	52	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	63	V_{c2}	55	Φ_{NVB}	59	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x	yes	no

Tab No. 4.2 Test suspension

Test suspension N $\Phi = 21 \times 10^6 = \lg 7.32$ $7.17 \leq \lg N \leq 7.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 6.32$ $6.17 \leq \lg N_0 \leq 6.70$			
	10^{-5}	> 165	> 165				
	10^{-6}	19	23				
				x	yes		no

Tab No. 4.3 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Candida albicans* ATCC 10231

Test concentration (%) / contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 6.32$)**
100* / 0.25 / dirty	10^0	<14	<14	< 2.15	**≥ 4.17**
100* / 0.5 / dirty	10^0	<14	<14	< 2.15	**≥ 4.17**

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N_0/ N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

5. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Aspergillus brasiliensis (niger)* ATCC 16404

Tab No. 5.1 Verification of methodology, dirty conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	50	Φ_{Nvo}= 45.5	V_{c1}	40	Φ_A = 37.5	V_{c1}	41	Φ_B = 44.5	V_{c1}	47	Φ_C = 44
V_{c2}	41		V_{c2}	35		V_{c2}	48		V_{c2}	41	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	57	V_{c2}	45	Φ_{NVB}	51	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x	yes	no

Tab No. 5.2 Test suspension

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
$\Phi = 21.5 \times 10^6 = \lg 7.33$	10^{-5}	> 55	> 55	$\lg N_0 = \lg N/10 = \lg 6.33$
$7.17 \leq \lg N \leq 7.70$	10^{-6}	23	20	$6.17 \leq \lg N_0 \leq 6.70$
				x yes no

Tab No. 5.3 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Aspergillus brasiliensis (niger)* ATCC 16404

Test concentration (%) / contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 6.33$)**
100* / 1 / dirty	10^0	<14	<14	< 2.15	**≥ 4.18**
100* / 3 / dirty	10^0	<14	<14	< 2.15	**≥ 4.18**

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N_0/ N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

6. Evaluation of fungicidal activity of the product **Velox Oxy ETA**

Tab No. 6.1 The efficacy of chemical disinfectant **Velox Oxy ETA** on test strains – fungicidal activity

Fungicidal activity of the product (EN 13624:2013)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 13624:2013	**lg R**
Candida albicans ATCC 10231	20	0.25	100	dirty	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404	20	1	100	dirty	≥ 4	**> 4**
Candida albicans ATCC 10231	20	0.5	100	dirty	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404	20	3	100	dirty	≥ 4	**> 4**

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 test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of surviving fungi per ml in the test mixture, A, B, C = the number of surviving fungi per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N_0/ N_a = the reduction in viability, or lg R = lg N_0 – lg N_a

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

Prepared by: Hana Konevalíková, Lab Technician

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Experiment conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 14476:2013 +A2:2019)
Period of analysis:	5.5. – 12.5.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022
Test virus:	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 (2nd passage)
Cell lines:	HeLa cells (18th passage)
Incubation:	36 °C ± 1 °C, 5 % CO_2, 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 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 a 4 lg reduction.
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

The standard:
EN 14476:2013 +A2:2019 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 + July 2019

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

7. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Tab No. 7.1 Table of results of product **Velox Oxy ETA** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Product	Concentration **	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 15 s	- $\log_{10}$ $TCID_{50}$ after 30 s	- $\log_{10}$ $TCID_{50}$ after 1 min	- $\log_{10}$ $TCID_{50}$ after 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
Velox Oxy ETA	100%*	dirty***	4.50	6.00	5.50	5.33	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-	-	5.83	5.00
			Virus titration, time = 0					
Virus control	-	PBS	9.33	-	-	-	9.50	9.50
Virus control	-	dirty	9.50	-	-	9.50	-	-

Tab No. 7.2 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** 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	dirty***	15 s	6.00	**3.50**
100%*	9.50	dirty***	30 s	5.50	**4.00**
100%*	9.50	dirty***	60 s	5.33	**4.17**

Tab No. 7.3 Testing the efficacy of reference item **Formaldehyde** 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	$\Delta\log_{10}$ $TCID_{50}$
0.7 % (w/v)	9.33	PBS	30 min	5.83	**3.50**
0.7 % (w/v)	9.33	PBS	60 min	5.00	**4.33**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

8. Evaluation of virucidal activity of the product **Velox Oxy ETA**

Tab No. 8.1 The efficacy of chemical disinfectant **Velox Oxy ETA** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations **	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013 +A2:2019	$\Delta\log_{10}$ $TCID_{50}$
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	15	100%*	dirty***	≥ 4	**< 4**
Adenovirus type 5, strain 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**

Tab No. 8.2 The efficacy of reference item **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations **	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013+ A2:2019	$\Delta\log_{10}$ $TCID_{50}$
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	30	0.7 % (w/v)	PBS	3.0 – 5.0	**3.50**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	60	0.7 % (w/v)	PBS	3.5 – 5.5	**4.33**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Ing. Eva Kremlová, Lab Technician
Bc. Iva Čížová, Lab Technician

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Experiment conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 14476:2013 +A2:2019)
Period of analysis:	4.5. – 11.5.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022
Test virus:	*Poliovirus* type 1, LSc-2ab (2nd passage)
Cell lines:	HeLa cells (18th passage)
Incubation:	36 °C ± 1 °C, 5 % CO_2, 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

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 a 4 lg reduction (10^4).
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.
The standard:
EN 14476:2013 +A2:2019 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 + July 2019

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

9. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Poliovirus* type 1, LSc-2ab

Tab No. 9.1 Table of results of product **Velox Oxy ETA** on *Poliovirus* type 1, LSc-2ab

Product	Concentration **	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 15 s	- $\log_{10}$ $TCID_{50}$ after 30 s	- $\log_{10}$ $TCID_{50}$ after 1 min	- $\log_{10}$ $TCID_{50}$ after 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
Velox Oxy ETA	100%*	dirty***	4.50	6.17	6.17	6.00	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-	-	8.50	6.50
			Virus titration, time = 0					
Virus control	-	PBS	9.67	-	-	-	9.67	9.50
Virus control	-	dirty	9.50	-	-	9.50	-	-

Tab No. 9.2 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** 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	$\Delta\log_{10}$ $TCID_{50}$
100%*	9.50	dirty***	15 s	6.17	**3.33**
100%*	9.50	dirty***	30 s	6.17	**3.33**
100%*	9.50	dirty***	60 s	6.00	**3.50**

Tab No. 9.3 Testing the efficacy of reference item **Formaldehyde** 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	$\Delta\log_{10}$ $TCID_{50}$
0.7 % (w/v)	9.67	PBS	30 min	8.50	**1.17**
0.7 % (w/v)	9.67	PBS	60 min	6.50	**3.17**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

10. Evaluation of virucidal activity of the product **Velox Oxy ETA**

Tab No. 10.1 The efficacy of chemical disinfectant **Velox Oxy ETA** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations **	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013 +A2:2019	$\Delta\log_{10}$ $TCID_{50}$
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**

Tab No. 10.2 The efficacy of reference item **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations **	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013+ A2:2019	$\Delta\log_{10}$ $TCID_{50}$
Poliovirus type 1, LSc-2ab	20	30	0.7 % (w/v)	PBS	0.5 – 2.5	**1.17**
Poliovirus type 1, LSc-2ab	20	60	0.7 % (w/v)	PBS	2.0 – 4.5	**3.17**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Ing. Eva Kremlová, Lab Technician
Bc. Iva Čížová, Lab Technician

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Experiment conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 14476:2013 +A2:2019)
Period of analysis:	20.4. – 27.4.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022
Test virus:	*Vaccinia virus* strain Elstree ATCC-VR-1549 (2nd passage)
Cell lines:	VERO cells ATCC-CCL-81 (6th passage)
Incubation:	36 °C ± 1 °C, 5 % CO_2, 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 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 a 4 lg reduction. The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013 +A2:2019).
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

The standard:
EN 14476:2013 +A2:2019 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 + July 2019

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

11. Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Vaccinia virus* strain Elstree ATCC-VR-1549

Tab No. 13.1 Table of results of product **Velox Oxy ETA** on *Vaccinia virus* strain Elstree ATCC-VR-1549

Product	Concentration	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 15 s	- $\log_{10}$ $TCID_{50}$ after 30 s	- $\log_{10}$ $TCID_{50}$ after 1 min	- $\log_{10}$ $TCID_{50}$ after 5 min	- $\log_{10}$ $TCID_{50}$ after 15 min
Velox Oxy ETA	100%*	dirty***	4.50	6.67	6.17	5.83	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	-	-	9.17	8.50
			Virus titration, time = 0					
Virus control	-	PBS	10.50	-	-	-	10.33	10.33
Virus control	-	dirty	10.50	-	-	10.33	-	-

Tab No. 13.2 Testing the efficacy of chemical disinfectant **Velox Oxy ETA** on *Vaccinia virus* strain Elstree ATCC-VR-1549

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%*	10.50	dirty***	15 s	6.67	**3.83**
100%*	10.50	dirty***	30 s	6.17	**4.33**
100%*	10.50	dirty***	60 s	5.83	**4.67**

Tab No. 13.3 Testing the efficacy of chemical disinfectant **Formaldehyde** on *Vaccinia virus* strain Elstree ATCC-VR-1549

Test concentration	Titre of the virus suspension - $\log_{10}$ $TCID_{50}$	Interfering substances	Contact time	- $\log_{10}$ $TCID_{50}$ after test procedure	$\Delta\log_{10}$ $TCID_{50}$
0.7 % (w/v)	10.50	PBS	5 min	9.17	**1.33**
0.7 % (w/v)	10.50	PBS	15 min	8.50	**2.00**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

14. Evaluation of virucidal activity of the product **Velox Oxy ETA**

Tab No. 14.1 The efficacy of chemical disinfectant **Velox Oxy ETA** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [s]	Product test concentrations	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013 +A2:2019	$\Delta\log_{10}$ $TCID_{50}$
Vaccinia virus strain Elstree ATCC-VR-1549	20	15	100%*	dirty***	≥ 4	**< 4**
Vaccinia virus strain Elstree ATCC-VR-1549	20	30	100%*	dirty***	≥ 4	**> 4**
Vaccinia virus strain Elstree ATCC-VR-1549	20	60	100%*	dirty***	≥ 4	**> 4**

Tab No. 14.2 The efficacy of chemical disinfectant **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 14476:2013 +A2:2019	$\Delta\log_{10}$ $TCID_{50}$
Vaccinia virus strain Elstree ATCC-VR-1549	20	5	0.7 % (w/v)	PBS	0.75 – 3.5	**1.33**
Vaccinia virus strain Elstree ATCC-VR-1549	20	15	0.7 % (w/v)	PBS	2.0 – ≥ 4.0	**2.00**

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 product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Bc. Iva Čížová, Lab Technician

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Interpretation:
Results of tests are in Tabs.
The tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact time 3 min under dirty conditions at temperature 20 °C ± 1 °C by the membrane filtration method **decreased** the number of viable mycobacterial cells of *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction (EN 14348:2005).

According to EN 13624:2013 the tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact times 15 s and 30 s under dirty conditions at temperature 20 °C ± 1 °C by the membrane filtration method **decreased** the number of vegetative yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

According to EN 13624:2013 the tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact times 60 s and 180 s under dirty conditions at temperature 20 °C ± 1 °C by the membrane filtration method **decreased** the number of mould spores of *Aspergillus brasiliensis (niger)* ATCC 16404 by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact times 30 s and 60 s under dirty conditions at temperature 20 °C ± 1 °C **proved** by the method of virus titration on monolayers of cells on microtiter plates to reduce the number of infectious *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 particles under defined conditions by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact times 15 s, 30 s and 60 s under dirty conditions at temperature 20 °C ± 1 °C **did not prove** by the method of virus titration on monolayers of cells on microtiter plates to reduce the number of infectious *Poliovirus* type 1, LSc-2ab particles under defined conditions by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested concentrated* product **Velox Oxy ETA**, batch No: 231120-92, in the contact times 30 s and 60 s 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 *Vaccinia virus* strain Elstree ATCC-VR-1549 particles under defined conditions by at least a 4 lg reduction.
The test for virucidal activity against enveloped virus Vaccinia virus will cover all enveloped viruses only (Annex A, standard EN 14476:2013 +A2:2019)

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

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

Sample ID: S569/2020
Rep No: 20
Sample name: **Velox Oxy ETA**
Sampled: by client
Sampling point: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Client: MEDISEPT Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.11.2020
Sample delivered: 27.11.2020
Testing date: 15.3. – 12.5.2021
Delivered amount: 2 x 1 l
Batch No: 231120-92

Conclusion:
The product **Velox Oxy ETA** is capable of reducing the number of viable mycobacterial cells of the relevant test organisms under defined conditions (EN 14348:2005 – concentrated, 3 min, dirty conditions, 20 °C) to the declared values, and consequently, can be called mycobactericidal and tuberculocidal.
The product **Velox Oxy ETA** is capable of reducing the number of vegetative yeast cells of the relevant organism under defined conditions (EN 13624:2013 – concentrated, 15 s and 30 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called yeasticidal.
The product **Velox Oxy ETA** is capable of reducing the number of mould spores of the relevant organism under defined conditions (EN 13624:2013 – concentrated, 60 s and 3 min, dirty conditions, 20 °C) to the declared values, and consequently, can be called fungicidal.
The product **Velox Oxy ETA** is capable of reducing the number of infectious *Adenovirus* particles under defined conditions (EN 14476:2013 +A2:2019 – concentrated, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called virucidal on *Adenovirus*.
The product **Velox Oxy ETA** is not capable of reducing the number of infectious *Poliovirus* particles under defined conditions (EN 14476:2013 +A2:2019 – concentrated, 15 s, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, cannot be called virucidal on *Poliovirus*.
The product **Velox Oxy ETA** is capable of reducing the number of infectious *Vaccinia virus* particles under defined conditions (EN 14476:2013 +A2:2019 – concentrated, 30 s and 60 s, dirty conditions, 20 °C) to the declared values, and consequently, can be called virucidal on enveloped viruses.

14.10.2021, Hodonín

Approved by: Ing. Barbora Stoklásková, Leader of Study

Raw data – product **Velox Oxy ETA** tested against *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Sample S569/2020, the test report S569/2020,

EN14476+A2: *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 – 2nd passage (LGC Standards Sp. z o.o., PL, 26.6. 2013), HeLa cells – 18th passage (DSMZ, 22.5.2019)

Period of analysis:	5.5. – 12.5.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022

Product	Concentration ***	Interfering substance	Contact time min	Dilution (lg)[a]								
				2	3	4	5	6	7	8	9	10
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444 444	444 444	333 333	200 202	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444 444	333 333	222 222	000 000	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	1	n.a.	444 444	333 333	222 202	000 000	000 000	000 000	000 000	000 000
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Velox Oxy ETA cytotoxicity without MicroSpin™ S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	444 444	444 444	n.d.	n.d.	n.d.	n.d.
Formaldehyde	0.7 (w/v)	PBS	30	n.a.	333 333	333 333	200 222	220 220	000 000	000 000	000 000	000 000
			60	n.a.	333 333	222 222	200 022	000 000	000 000	000 000	000 000	000 000
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	n.a.	444 444	000 000	000 000	000 000	000 000	000 000	000 000	000 000
Interference control	non-cytotoxic concentration	n.a.	n.a.	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	222 200	022 000
Neutralization	100%*	dirty***	n.a.	n.d.	n.d.	444 444	444 444	333 333	333 333	222 222	n.d.	n.d.
Virus control	n.a.	PBS	0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	202 222	000 000
			30	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	200 222	000 220
			60	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	020 220	000 222
Virus control	n.a.	dirty	0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	002 222	002 020
			1	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	202 200	002 202
Virus control MicroSpin™ S 400 HR	n.a.	dirty	0	444 444	444 444	444 444	444 444	333 333	333 333	322 222	202 220	020 022

a – dilution, 1 to 4 – degree of CPE in 6 cell culture units, 0 – no CPE, n.a. – not applicable, n.d. – not done

$TCID_{50}$- 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 calculation of the viral infectivity titre according to EN14476+A2

The formula is:

Negative logarithm of the 50 % end point = negative logarithm of the highest virus concentration used – [({Sum of % affected at each dilution/100} - 0,5) x (lg of dilutions)]

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.

** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.

*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Ing. Eva Kremlová, Lab Technician
Bc. Iva Čížová, Lab Technician

Approved by: Ing. Barbora Stoklásková, Leader of Study

Raw data – product **Velox Oxy ETA** tested against *Poliovirus* type 1, LSc-2ab

Sample S569/2020, the test report S569/2020,

EN14476+A2: *Poliovirus* type 1, LSc-2ab – 2nd passage (NIBSC, 28.3.2018),
HeLa cells – 18th passage (DSMZ, 22.5.2019)

Period of analysis:	4.5. – 11.5.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022

Product	Concentration ***	Interfering substance	Contact time min	Dilution (lg)[a]								
				2	3	4	5	6	7	8	9	10
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444 444	444 444	222 222	022 220	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444 444	444 444	222 222	200 222	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	1	n.a.	444 444	444 444	222 222	022 002	000 000	000 000	000 000	000 000
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Velox Oxy ETA cytotoxicity without MicroSpin™ S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Formaldehyde	0.7 (w/v)	PBS	30	n.a.	444 444	444 444	333 333	333 333	222 222	222 222	000 000	000 000
			60	n.a.	444 444	333 333	333 333	222 222	000 000	000 000	000 000	000 000
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	n.a.	444 444	000 000	000 000	000 000	000 000	000 000	000 000	000 000
Interference control	non-cytotoxic concentration	n.a.	n.a.	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	222 020	000 220
Neutralization	100%*	dirty***	n.a.	n.d.	n.d.	444 444	444 444	333 333	333 333	222 222	n.d.	n.d.
Virus control	n.a.	PBS	0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	222 200	000 222
			30	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	022 222	220 000
			60	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	020 220	022 200
Virus control	n.a.	dirty	0	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	220 220	002 020
			1	n.a.	444 444	444 444	444 444	333 333	333 333	222 222	200 220	022 200
Virus control MicroSpin™ S 400 HR	n.a.	dirty	0	444 444	444 444	444 444	444 444	333 333	333 333	222 222	222 222	000 020

a – dilution, 1 to 4 – degree of CPE in 6 cell culture units, 0 – no CPE, n.a. – not applicable, n.d. – not done
$TCID_{50}$- 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 calculation of the viral infectivity titre according to EN14476+A2
The formula is:
Negative logarithm of the 50 % end point = negative logarithm of the highest virus concentration used – [({Sum of % affected at each dilution/100} - 0,5) x (lg of dilutions)]
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Ing. Eva Kremlová, Lab Technician
Bc. Iva Čížová, Lab Technician
Approved by: Ing. Barbora Stoklásková, Leader of Study

Raw data – product **Velox Oxy ETA** tested against *Vaccinia virus* strain Elstree ATCC-VR-1549

Sample S569/2020, the test report S569/2020,

EN 14476+A2: *Vaccinia virus* strain Elstree ATCC-VR-1549 – 2nd passage (LGC Standards Sp. z o.o., PL, 8.10.2019),
VERO cells – Vero, Kidney, African Green Monkey, ATCC-CCL-81 – 6th passage (LGC Standards Sp. z o.o., PL, 25.1. 2019)

Period of analysis:	20.4. – 27.4.2021
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 s (0.25 min), 30 s, (0.5 min), 60 s (1 min)
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: K52955003, expiry date: 30.11.2022

Product	Concentration ***	Interfering substance	Contact time min	Dilution (lg)[a]									
				2	3	4	5	6	7	8	9	10	11
Velox Oxy ETA	100%*	dirty***	0.25	n.a.	444 444	444 444	333 322	222 222	020 000	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	0.5	n.a.	444 444	444 444	222 222	220 022	000 000	000 000	000 000	000 000	000 000
Velox Oxy ETA	100%*	dirty***	1	n.a.	444 444	444 444	222 222	002 200	000 000	000 000	000 000	000 000	000 000
Velox Oxy ETA cytotoxicity	100%*	dirty***	n.a.	n.a.	444 444	444 444	000 000	000 000	n.d.	n.d.	n.d.	n.d.	n.d.
Velox Oxy ETA cytotoxicity without MicroSpin™ S 400 HR	100%*	dirty***	n.a.	444 444	444 444	444 444	444 444	000 000	n.d.	n.d.	n.d.	n.d.	n.d.
Formaldehyde	0.7 (w/v)	PBS	30	n.a.	444 444	444 444	333 333	333 333	222 222	222 222	000 222	200 000	000 000
			60	n.a.	444 444	333 443	333 333	222 222	222 222	222 000	000 222	000 000	000 000
Formaldehyde cytotoxicity	0.7 (w/v)	PBS	n.a.	n.a.	444 444	000 000	000 000	000 000	000 000	000 000	000 000	000 000	000 000
Interference control	non-cytotoxic concentration	n.a.	n.a.	n.a.	444 444	444 444	444 444	444 444	333 333	222 222	222 222	222 220	000 020
Neutralization	100%*	dirty***	n.a.	n.d.	n.d.	444 444	444 444	444 444	333 333	222 222	n.d.	n.d.	n.d.
Virus control	n.a.	PBS	0	n.a.	444 444	444 444	444 444	444 444	333 333	222 232	222 222	222 222	000 000
			30	n.a.	444 444	444 444	444 444	444 444	333 333	222 222	222 222	202 202	020 000
			60	n.a.	444 444	444 444	444 444	444 444	333 333	222 222	222 222	022 222	000 000
Virus control	n.a.	dirty	0	n.a.	444 444	444 444	444 444	444 444	333 333	222 222	222 222	222 220	020 000
			1	n.a.	444 444	444 444	444 444	444 444	333 333	333 222	222 222	202 222	000 000
Virus control MicroSpin™ S 400 HR	n.a.	dirty	0	444 444	444 444	444 444	444 444	333 333	333 333	332 232	222 222	222 222	200 000

a – dilution, 1 to 4 – degree of CPE in 6 cell culture units, 0 – no CPE, n.a. – not applicable, n.d. – not done
$TCID_{50}$- 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 calculation of the viral infectivity titre according to EN14476+A2
The formula is:
Negative logarithm of the 50 % end point = negative logarithm of the highest virus concentration used – [({Sum of % affected at each dilution/100} - 0,5) x (lg of dilutions)]
* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the inoculum and interfering substance.
** Due to the high cytotoxicity of the product the test was performed by using MicroSpin™ S 400 HR according to EN 14476:2013 +A2:2019.
*** The mixture from the product solution and the suspension of microorganism and the interfering substance makes clots despite mixing with glass beads.

Prepared by: Bc. Iva Čížová, Lab Technician
Approved by: Ing. Barbora Stoklásková, Leader of Study