Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2018.

Copy No.: 1
Issue No.: 1

Test report No. S257+S262-1/2019

DETERMINATION OF BACTERICIDAL (EN 13727:2012+A2:2015, EN 14561:2006), FUNGICIDAL (EN 13624:2013, EN 14562:2006), SPORICIDAL (EN 13704:2018) ACTIVITY OF THE PRODUCT **DETRO PAA 1500** DETERMINATION OF VIRUCIDAL ACTIVITY (EN 14476:2013 +A2:2019) OF THE PRODUCT **DETRO PAA 1500**

Sample ID: S257+S262/2019 Page: 1
Sample name: **DETRO PAA 1500** From pages: 25
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Producer: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY

Incoming date: 30.7.2019

Delivery date: 19.12.2019

Hodonín, 19.12.2019

.....
Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 2

Subject of testing:
Determination of bactericidal, fungicidal, sporicidal and virucidal activity of the product.

Identification of the sample:

Sample ID:	S257/2019
Name of the product:	**DETRO PAA 1500**
Batch number:	7762019001
Date of manufacture:	11.07.2019
Expiry date:	11.07.2021
Manufacturer:	Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Incoming date:	30.7.2019
Storage conditions:	stated by the manufacturer

Active ingredients:
Hydrogen Peroxide %3 w/w (CAS 7722-84-1), Complexing agent, pH buffer
Acitvated Solution : %0,15 (1500 ppm) Peracetic Acid (CAS 201-186-8)
Tested Solution: 1500 ppm x %60 = 900 ppm

Sample ID:	S262/2019
Name of the product:	**DETRO PAA 1500 activator**
Batch number:	5432019001
Date of manufacture:	11.07.2019
Expiry date:	11.07.2021
Manufacturer:	Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY
Incoming date:	30.7.2019
Storage conditions:	stated by the manufacturer

Active ingredients:
N-Acetyl Caprolactam <%40 w/w , Isopropanol and solvents.

Product preparation: Peracetic acid generated by mixing base and activator. **DETRO PAA 1500 activator** is poured into **DETRO PAA 1500** base drum. Shake for 5 mins and wait for 30 mins: prepare 60% solution from the **DETRO PAA 1500** generated and 30 mins waited solution. For ex: 1 liter test solution 600 g active **DETRO PAA 1500** solution + 400 g distilled water (the tests are performed with this solution – RTU product – 100%(97%)).

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 3

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 13727:2012+A2:2015)	
Period of analysis:	19.9. – 20.9.2019	
Test temperature:	20 °C ± 1 °C	
Test method:	dilution neutralization method	
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062	
Appearance of the product:	colorless liquid	
Test concentration:	100% (concentrated)*	
Contact time:	5 min	
Interfering substances:	0.3 g/l BSA (clean conditions)	
Test organisms:	*Pseudomonas aeruginosa*	ATCC 15442
	Staphylococcus aureus	ATCC 6538
	Enterococcus hirae	ATCC 10541
Incubation conditions:	37 °C ± 1 °C, 24 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:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least a 5 lg reduction (10^5).
* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:
EN 13727:2012+A2:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1) October 2015

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

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 4

1. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Pseudomonas aeruginosa* ATCC 15442
Tab No. 1.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	55	Φ_{Nvo}= 53.5	V_{c1}	40	Φ_A = 53	V_{c1}	39	Φ_B = 52.5	V_{c1}	44	Φ_C = 52
V_{c2}	52		V_{c2}	66		V_{c2}	66		V_{c2}	60	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	54	V_{c2}	56	Φ_{NVB}	55	$30 < \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x	yes	no

Tab No. 1.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)*
$\Phi = 189 \times 10^7 = \lg 9.28$	10^{-7}	180	189	$\lg N_0 = \lg N/100 = \lg 7.28$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	28	19	$7.17 \leq \lg N_0 \leq 7.70$
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.28$)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.13**

2. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Staphylococcus aureus* ATCC 6538
Tab No. 2.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	81	Φ_{Nvo}= 84	V_{c1}	80	Φ_A = 77.5	V_{c1}	72	Φ_B = 77.5	V_{c1}	72	Φ_C = 76
V_{c2}	87		V_{c2}	75		V_{c2}	83		V_{c2}	80	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	72	V_{c2}	84	Φ_{NVB}	78	$30 < \Phi_{NVB}\ (N_{VB}/1000) \leq 160$		
							x	yes	no

Tab No. 2.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)*
$\Phi = 315 \times 10^7 = \lg 9.50$	10^{-7}	320	309	$\lg N_0 = \lg N/100 = \lg 7.50$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	26	38	$7.17 \leq \lg N_0 \leq 7.70$
				x yes no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Staphylococcus aureus* ATCC 6538

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.50$)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.35**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial 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 bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0/ N_a = the reduction in viability, or $\lg R = \lg N_0 – \lg N_a$
* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 5

3. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Enterococcus hirae* ATCC 10541
Tab No. 3.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	36	Φ_{Nvo}= 46	V_{c1}	37	Φ_A = 37.5	V_{c1}	42	Φ_B = 37	V_{c1}	40	Φ_C = 34.5
V_{c2}	56		V_{c2}	38		V_{c2}	32		V_{c2}	29	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A > 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	43	V_{c2}	36	Φ_{NVB}	39.5	$30 \leq \Phi_{NVB}\ (N_{VB}/1000) \leq 160$			
							x	yes		no

Tab No. 3.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)*			
$\Phi = 155 \times 10^7 = \lg 9.19$	10^{-7}	137	169	$\lg N_0 = \lg N/100 = \lg 7.19$			
$9.17 \leq \lg N \leq 9.70$	10^{-8}	15	19	$7.17 \leq \lg N_0 \leq 7.70$			
				x	yes		no

Tab No. 3.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Enterococcus hirae* ATCC 10541

Test concentration (%)/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.19$)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.04**

4. Evaluation of bactericidal activity of the product **DETRO PAA 1500**
Tab No. 4.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strains – bactericidal activity

Bactericidal activity of the product (EN 13727:2012+A2:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 13727:2012 +A2:2015	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	5	100	clean	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	5	100	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	5	100	clean	≥ 5	**> 5**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial 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 bacteria per ml in the test mixture, A, B, C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $R = N_0/N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$
* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 6

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-22-12 (EN 14561:2006)	
Period of analysis:	19.9. – 20.9.2019	
Test temperature:	20 °C ± 1 °C	
Test method:	dilution neutralization method	
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062	
Appearance of the product:	colorless liquid	
Test concentration:	100% (concentrated)	
Contact time:	5 min	
Interfering substances:	0.3 g/l BSA (clean conditions)	
Test organisms:	*Pseudomonas aeruginosa*	ATCC 15442
	Staphylococcus aureus	ATCC 6538
	Enterococcus hirae	ATCC 10541
Incubation conditions:	37 °C ± 1 °C, 24 hours	

Test procedure:

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

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms on carriers under defined conditions by at least a 5 lg reduction (10^5). The drying time: 35-45 min

The standard:
EN 14561:2006 Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2) May 2006

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 7

5. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Pseudomonas aeruginosa* ATCC 15442 on carriers

Tab No. 5.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%		
V_{c1}	43	Φ_{Nvo} = 46	V_{c1}	50	Φ_A = 44.5	V_{c1}	55	Φ_B = 45	V_{c1}	46	Φ_C = 43
V_{c2}	49		V_{c2}	39		V_{c2}	35		V_{c2}	40	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 5.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 167 \times 10^7 = \lg 9.22$ $9.17 \leq \lg N \leq 9.70$
	10^{-7}	170	161	
	10^{-8}	15	22	
				x yes no

Tab No. 5.2.1 The control test suspension, clean conditions

Test suspension (N_W)	N_W	V_{c1}	V_{c2}	$\Phi \times 10 = 810 \times 10^4 = \lg 7.91$ $\lg N_W = \lg 7.91$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)\ 7.92$
	10^{-5}	85	77	
				x yes no

Tab No. 5.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Pseudomonas aeruginosa* ATCC 15442 on carriers, clean conditions

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_W$ = lg 7.91)**
100 / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.76**

6. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Staphylococcus aureus* ATCC 6538 on carriers

Tab No. 6.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%		
V_{c1}	34	Φ_{Nvo} = 39.5	V_{c1}	44	Φ_A = 37.5	V_{c1}	36	Φ_B = 39	V_{c1}	32	Φ_C = 28.5
V_{c2}	45		V_{c2}	31		V_{c2}	42		V_{c2}	25	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 6.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 42 \times 10^8 = \lg 9.62$ $9.17 \leq \lg N \leq 9.70$
	10^{-7}	> 330	> 330	
	10^{-8}	40	44	
				x yes no

Tab No. 6.2.1 The control test suspension, clean conditions

Test suspension (N_W)	N_W	V_{c1}	V_{c2}	$\Phi \times 10 = 665 \times 10^5 = \lg 7.82$ $\lg N_W = \lg 7.82$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)\ 8.32$
	10^{-5}	61	72	
				x yes no

Tab No. 6.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Staphylococcus aureus* ATCC 6538 on carriers, clean conditions

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_W$ = lg 7.82)**
100 / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.67**

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 8

7. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Enterococcus hirae* ATCC 10541 on carriers

Tab No. 7.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%		
V_{c1}	50	Φ_{Nvo} = 47	V_{c1}	52	Φ_A = 45.5	V_{c1}	49	Φ_B = 46	V_{c1}	41	Φ_C = 38
V_{c2}	44		V_{c2}	39		V_{c2}	43		V_{c2}	35	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 7.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 197 \times 10^7 = \lg 9.29$ $9.17 \leq \lg N \leq 9.70$
	10^{-7}	193	201	
	10^{-8}	22	18	
				x yes no

Tab No. 7.2.1 The control test suspension, clean conditions

Test suspension (N_W)	N_W	V_{c1}	V_{c2}	$\Phi \times 10 = 415 \times 10^5 = \lg 7.62$ $\lg N_W = \lg 7.62$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)\ 7.99$
	10^{-5}	34	49	
				x yes no

Tab No. 7.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Enterococcus hirae* ATCC 10541 on carriers, clean conditions

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_W = \lg 7.62$)**
100 / 5 / clean	10^0	<14	<14	< 2.15	**≥ 5.47**

8. Evaluation of bactericidal activity of the product **DETRO PAA 1500** on carriers

Tab No. 8.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strains – bactericidal activity on carriers

Bactericidal activity of the product on carriers (EN 14561:2006)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	lg R EN 14561:2006	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	5	0.5	clean	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	5	0.5	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	5	0.5	clean	≥ 5	**> 5**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_W = the number of cfu/ml of the control bacterial test suspension, N_a = the number of surviving bacteria per ml in the test mixture at the end of the contact time, N_{v0}= the number of cfu/ml of the bacterial test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of surviving bacteria per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation), $R = N_W / N_a$ nebo $\lg R = \lg N_W - \lg N_a$ = the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 9

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:	24.9. – 26.9.2019
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Appearance of the product:	colorless liquid
Test concentration:	100% (concentrated)*
Contact time:	5 min
Interfering substances:	0.3 g/l BSA (clean 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).
* Product can only be tested at a concentration of 97% (RTU product) or less, as some dilution is always produced by adding the test organisms 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: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 10

9. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Candida albicans* ATCC 10231

Tab No. 9.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%*		
V_{c1}	50	Φ_{Nvo}= 47	V_{c1}	42	Φ_A = 45	V_{c1}	41	Φ_B = 46	V_{c1}	32	Φ_C = 37.5
V_{c2}	44		V_{c2}	48		V_{c2}	51		V_{c2}	43	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	51	V_{c2}	46	Φ_{NVB}	48.5	$30 < \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160		
							x	yes	no

Tab No. 9.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)*
$\Phi = 47 \times 10^7 = \lg 8.67$	10^{-6}	> 330	> 330	$\lg N_0 = \lg N/100 = \lg 6.67$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	49	45	$6.17 \leq \lg N_0 \leq 6.70$
				x yes no

Tab No. 9.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Candida albicans* ATCC 10231

Test concentration (%)/contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 6.67$)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 4.52**

10. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Aspergillus brasiliensis (niger)* ATCC 16404

Tab No. 10.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%*		
V_{c1}	39	Φ_{Nvo}= 37.5	V_{c1}	32	Φ_A = 35.5	V_{c1}	31	Φ_B = 33.5	V_{c1}	25	Φ_C = 36.5
V_{c2}	36		V_{c2}	39		V_{c2}	36		V_{c2}	48	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Validation of suspension (N_{VB})	V_{c1}	35	V_{c2}	45	Φ_{NVB}	40	$30 < \Phi_{NVB}$ (N_{VB}/1000) $\leq$ 160		
							x	yes	no

Tab No. 10.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)*
$\Phi = 153 \times 10^6 = \lg 8.18$	10^{-6}	156	149	$\lg N_0 = \lg N/100 = \lg 6.18$
$8.17 \leq \lg N \leq 8.70$	10^{-7}	16	16	$6.17 \leq \lg N_0 \leq 6.70$
				x yes no

Tab No. 10.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Aspergillus brasiliensis (niger)* ATCC 16404

Test concentration (%)/contact time (min)	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 6.18$)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 4.03**

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 – neutralizer toxicity validation, C – method validation), $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

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

11. Evaluation of fungicidal activity of the product **DETRO PAA 1500**

Tab No. 11.1 The efficacy of chemical disinfectant **DETRO PAA 1500** 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	5	100	clean	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404	20	5	100	clean	≥ 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 – neutralizer toxicity validation, C – method validation), R = N_0/ N_a = the reduction in viability, or lg R = lg N_0 – lg N_a

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

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 12

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-22-12 (EN 14562:2006)	
Period of analysis:	24.9. – 26.9.2019	
Test temperature:	20 °C ± 1 °C	
Test method:	dilution neutralization method	
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062	
Appearance of the product:	colorless liquid	
Test concentration:	100% (concentrated)	
Contact time:	5 min	
Interfering substances:	0.3 g/l BSA (clean 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 the test suspension
2. Preparation of the product test solutions
3. Quantitative carrier test
4. Incubation and calculation
5. Expression and interpretation of the 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 relevant organisms on carriers 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 fungi belonging to reference strain *Candida albicans* on carriers under defined conditions by at least a 4 lg reduction (10^4).
The drying time: 35-40 min

The standard:
EN 14562:2006 Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2) May 2006

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 13

12. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Candida albicans* ATCC 10231 on carriers

Tab No. 12.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%		
V_{c1}	44	Φ_{Nvo} = 47.5	V_{c1}	42	Φ_A = 44.5	V_{c1}	41	Φ_B = 43	V_{c1}	32	Φ_C = 39
V_{c2}	51		V_{c2}	47		V_{c2}	45		V_{c2}	46	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x yes		no	x yes		no	x yes		no	x yes		no

Tab No. 12.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 49 \times 10^7 = \lg 8.69$ $8.17 \leq \lg N \leq 8.70$
	10^{-6}	> 330	> 330	
	10^{-7}	49	49	
				x yes no

Tab No. 12.2.1 The control test suspension, clean conditions

Test suspension (N_W)	N_W	V_{c1}	V_{c2}	$\Phi \times 10 = 2040 \times 10^3 = \lg 6.31$ $\lg N_W = \lg 6.31$ $6.15 \leq \lg N_w \leq (\lg N - 1.3)\ 7.39$
	10^{-3}	208	197	
	10^{-4}	19	25	
				x yes no

Tab No. 12.3.1 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Candida albicans* ATCC 10231 on carriers, clean conditions

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_W = lg 6.31)**
100 / 5 / clean	10^0	<14	<14	< 2.15	**≥ 4.16**

13. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Aspergillus brasiliensis (niger)* ATCC 16404 on carriers

Tab No. 13.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 100%		
V_{c1}	48	Φ_{Nvo} = 43	V_{c1}	46	Φ_A = 42.5	V_{c1}	44	Φ_B = 44.5	V_{c1}	50	Φ_C = 44
V_{c2}	38		V_{c2}	39		V_{c2}	45		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. 13.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 38.5 \times 10^7 = \lg 8.59$ $8.17 \leq \lg N \leq 8.70$
	10^{-6}	> 165	> 165	
	10^{-7}	47	30	
				x yes no

Tab No. 13.2.1 The control test suspension, clean conditions

Test suspension (N_W)	N_W	V_{c1}	V_{c2}	$\Phi \times 10 = 330 \times 10^4 = \lg 6.52$ $\lg N_W = \lg 6.52$ $6.15 \leq \lg N_w \leq (\lg N - 1.3)\ 7.29$
	10^{-3}	> 165	> 165	
	10^{-4}	37	29	
				x yes no

Tab No. 13.3.1 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Aspergillus brasiliensis (niger)* ATCC 16404 on carriers, clean conditions

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_W = lg 6.52)**
100 / 5 / clean	10^0	<14	<14	< 2.15	**≥ 4.37**

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 14

14. Evaluation of fungicidal activity of the product **DETRO PAA 1500** on carriers

Tab No. 14.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strains – fungicidal activity on carriers

Fungicidal activity of the product on carriers (EN 14562:2006)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	lg R EN 14562:2006	**lg R**
Candida albicans ATCC 10231	20	5	100	clean	≥ 4	> **4**
Aspergillus brasiliensis (niger) ATCC 16404	20	5	100	clean	≥ 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 fungal test suspension, N_W = the number of cfu/ml of the control fungal test suspension, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_{v0}= the number of cfu/ml of the fungal test suspension in the mixture A,B,C at the beginning of the contact time (time „0“), A,B,C = the number of survivors per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation), $R = N_W / N_a$ nebo $\lg R = \lg N_W - \lg N_a$ = the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 15

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 13704:2018)
Period of analysis:	4.10. – 7.10.2019
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Appearance of the product:	colourless liquid
Test concentration:	100% (concentrated)*
Contact time:	5 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* ATCC 19404
Incubation conditions:	30 °C ± 1 °C, minimum 3 and maximum 7 days

Test procedure:

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

Note:
Sporicidal activity – the capability of a product to produce a reduction in the number of bacterial spores belonging to reference strain of *Bacillus subtilis* under defined conditions by at least a 3 lg reduction (10^3).
For specific applications aditional strain may be chosen, for example *Bacillus cereus* (ATCC 12826), *Clostridium sporogenes* (ATCC 19404).
* Product can only be tested at a concentration of 97% (RTU product – modified method according to EN 13624 - 9.7 parts of the product + 0.2 part of the 5 fold concentrated interfering substance + 0.1 part of the 10 fold concentrated test suspension) or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:
EN 13704:2018 Chemical disinfectants – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) July 2018

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 16

15. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Bacillus subtilis* ATCC 6633

Tab No. 15.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	64	Φ_{Nv} = 71.5	V_{c1}	78	Φ_A = 65.5	V_{c1}	66	Φ_B = 68	V_{c1}	77	Φ_C = 68
V_{c2}	79		V_{c2}	53		V_{c2}	70		V_{c2}	59	
$30 \leq \Phi_{Nv0} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nv0}$			$\Phi_B \geq 0.5\ \Phi_{Nv0}$			$\Phi_C \geq 0.5\ \Phi_{Nv0}$		
x yes		no	x yes		no	x yes		no	x yes		no

Tab No. 15.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0*
$\Phi = 180 \times 10^5 = \lg 7.26$	10^{-5}	182	178	$\lg N_0 = \lg N/100 = \lg 5.26$
$7.17 \leq \lg N \leq 7.70$	10^{-6}	20	17	$5.17 \leq \lg N_0 \leq 5.70$
				x yes / No

Tab No. 15.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Bacillus subtilis* ATCC 6633

Test concentration (%) / contact time (min)/ conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0$ = 5.26)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 3.11**

16. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Bacillus cereus* ATCC 12826

Tab No. 16.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	60	Φ_{Nv} = 63.5	V_{c1}	66	Φ_A = 63	V_{c1}	61	Φ_B = 52.5	V_{c1}	59	Φ_C = 53.5
V_{c2}	67		V_{c2}	60		V_{c2}	44		V_{c2}	48	
$30 \leq \Phi_{Nv0} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nv0}$			$\Phi_B \geq 0.5\ \Phi_{Nv0}$			$\Phi_C \geq 0.5\ \Phi_{Nv0}$		
x yes		no	x yes		no	x yes		no	x yes		no

Tab No. 16.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0*
$\Phi = 165 \times 10^5 = \lg 7.22$	10^{-5}	167	162	$\lg N_0 = \lg N/100 = \lg 5.22$
$7.17 \leq \lg N \leq 7.70$	10^{-6}	17	18	$5.17 \leq \lg N_0 \leq 5.70$
				x yes / No

Tab No. 16.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Bacillus cereus* ATCC 12826

Test concentration (%) / contact time (min)/ conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0$ = 5.22)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 3.07**

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 spore test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_{v0} = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of surviving spores per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), lg R = lg N_0- lg N_a = the reduction in viability

* Product can only be tested at a concentration of 97% (RTU product – modified method according to EN 13624 - 9.7 parts of the product + 0.2 part of the 5 fold concentrated interfering substance + 0.1 part of the 10 fold concentrated test suspension) or less, as some dilution is always produced by adding the test organisms and interfering substance.

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

Sample ID: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 17

17. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Clostridium sporogenes* ATCC 19404
Tab No. 17.1 Verification of methodology, clean conditions

Validation of suspension (N_{v0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	41	Φ_{Nv} = 44.5	V_{c1}	49	Φ_A = 38.5	V_{c1}	33	Φ_B = 43.5	V_{c1}	46	Φ_C = 43
V_{c2}	48		V_{c2}	28		V_{c2}	54		V_{c2}	40	
$30 \leq \Phi_{Nv0} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nv0}$			$\Phi_B \geq 0.5\ \Phi_{Nv0}$			$\Phi_C \geq 0.5\ \Phi_{Nv0}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 17.2 Test suspension

Test suspension N*	N	V_{c1}	V_{c1}	Test suspension N_0*
$\Phi = 154 \times 10^5 = \lg 7.19$	10^{-5}	160	145	$\lg N_0 = \lg N/100 = \lg 5.19$
$7.17 \leq \lg N \leq 7.70$	10^{-6}	15	18	$5.17 \leq \lg N_0 \leq 5.70$
				x yes No

Tab No. 17.3 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Clostridium sporogenes* ATCC 19404

Test concentration (%) / contact time (min)/ conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0$ = 5.19)**
100* / 5 / clean	10^0	<14	<14	< 2.15	**≥ 3.04**

18. Evaluation of sporicidal activity of the product **DETRO PAA 1500**
Tab No. 18.1 The efficacy of chemical disinfectant **DETRO PAA 1500** on test strains – sporicidal activity

Sporicidal activity of the product (EN 13704:2018)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 13704:2018	**lg R**
Bacillus subtilis ATCC 6633	20	5	100	clean	≥ 3	**> 3**
Bacillus cereus ATCC 12826	20	5	100	clean	≥ 3	**> 3**
Clostridium sporogenes ATCC 19404	20	5	100	clean	≥ 3	**> 3**

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 spore test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_{v0} = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of surviving spores per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), lg R = $\lg N_0 - \lg N_a$ = the reduction in viability
* Product can only be tested at a concentration of 97% (RTU product – modified method according to EN 13624 - 9.7 parts of the product + 0.2 part of the 5 fold concentrated interfering substance + 0.1 part of the 10 fold concentrated test suspension) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Ing. Eva Kremlová, Lab Technician

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 18

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:	3.10. – 10.10.2019
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
Interfering substances:	0.3 g/l BSA (clean conditions)
Reference product:	Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K50163503815, expiry date: 30.4.2020
Test virus:	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 (2nd passage)
Cell lines:	HeLa cells (21th 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).
* Product can only be tested at a concentration of 97% (RTU product) 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 +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: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 19

19. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Tab No. 19.1 Table of results of product **DETRO PAA 1500** 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 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
DETRO PAA 1500	100%*	clean	4.50	5.17	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	6.33	5.83
			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.33	9.33
Virus control	-	clean	9.50	9.50	-	-

Tab No. 19.2 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** 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	5.17	**4.33**

Tab No. 19.3 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)	9.50	PBS	30 min	6.33	**3.17**
0.7 % (w/v)	9.50	PBS	60 min	5.83	**3.67**

20. Evaluation of virucidal activity of the product **DETRO PAA 1500**

Tab No. 20.1 The efficacy of chemical disinfectant **DETRO PAA 1500** 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	5	100*	clean	≥ 4	> **4**

Tab No. 20.2 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	**3.17**
Adenovirus type 5, strain Adenoid 75, ATCC VR-5	20	60	0.7 % (w/v)	PBS	3.5 – 5.5	**3.67**

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 product) 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: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 20

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:	10.10. – 18.10.2019
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
Interfering substances:	0.3 g/l BSA (clean conditions)
Reference product:	Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K50163503815, expiry date: 30.4.2020
Test virus:	*Murine norovirus (MNV)* strain S99, RVB-651 (3rd passage)
Cell lines:	RAW 264.7 *Murine macrophage* cell line (4th passage)
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 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 (10^4).
* Product can only be tested at a concentration of 97% (RTU product) 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 +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: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 21

21. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Murine norovirus (MNV)* strain S99, RVB-651

Tab No. 21.1 Table of results of product **DETRO PAA 1500** on *Murine norovirus (MNV)* strain S99, RVB-6515

Product	Concentration **	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 5 min	- $\log_{10}$ $TCID_{50}$ after 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
DETRO PAA 1500	100%*	clean	4.50	4.50	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	6.67	6.00
			Virus titration, time = 0			
Virus control	-	PBS	9.00	-	9.17	9.33
Virus control	-	clean	9.00	9.00	-	-

Tab No. 21.2 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Murine norovirus (MNV)* strain S99, RVB-651

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	4.50	**4.50**

Tab No. 21.3 Testing the efficacy of reference item **Formaldehyde** on *Murine norovirus (MNV)* strain S99, RVB-651

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)	9.00	PBS	30 min	6.67	**2.33**
0.7 % (w/v)	9.00	PBS	60 min	6.00	**3.00**

22. Evaluation of virucidal activity of the product **DETRO PAA 1500**

Tab No. 22.1 The efficacy of chemical disinfectant **DETRO PAA 1500** 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	$\Delta\log_{10}$ $TCID_{50}$
Murine norovirus (MNV) strain S99, RVB-651	20	5	100*	clean	≥ 4	**> 4**

Tab No. 22.2 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	$\Delta\log_{10}$ $TCID_{50}$
Murine norovirus (MNV) strain S99, RVB-651	20	30	0.7 % (w/v)	PBS	1.0 – 3.0	**2.33**
Murine norovirus (MNV) strain S99, RVB-651	20	60	0.7 % (w/v)	PBS	2.0 – 4.0	**3.00**

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
* Product can only be tested at a concentration of 97% (RTU product) 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: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 22

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:	16.10. – 24.10.2019
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
Interfering substances:	0.3 g/l BSA (clean conditions)
Reference product:	Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K50163503815, expiry date: 30.4.2020
Test virus:	*Poliovirus* type 1, LSc-2ab (3rd passage)
Cell lines:	HeLa cells (23rd 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).
* Product can only be tested at a concentration of 97% (RTU product) 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 +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: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 23

23. Testing the efficacy of chemical disinfectant **DETRO PAA 1500** on *Poliovirus* type 1, LSc-2ab

Tab No. 23.1 Table of results of product **DETRO PAA 1500** on *Poliovirus* type 1, LSc-2ab

Product	Concentration **	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 5 min	- $\log_{10}$ $TCID_{50}$ after 30 min	- $\log_{10}$ $TCID_{50}$ after 60 min
DETRO PAA 1500	100%*	clean	4.50	5.33	-	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	-	7.17	5.83
			Virus titration, time = 0			
Virus control	-	PBS	9.50	-	9.50	9.33
Virus control	-	clean	9.50	9.50	-	-

Tab No. 23.2 Testing the efficacy of chemical disinfectant **DETRO PAA 1500** 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	10 min	5.33	**4.17**

Tab No. 23.3 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)	9.50	PBS	30 min	7.17	**2.33**
0.7 % (w/v)	9.50	PBS	60 min	5.83	**3.67**

24. Evaluation of virucidal activity of the product **DETRO PAA 1500**

Tab No. 24.1 The efficacy of chemical disinfectant **DETRO PAA 1500** 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	5	100*	clean	≥ 4	> **4**

Tab No. 24.2 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	**2.33**
Poliovirus type 1, LSc-2ab	20	60	0.7 % (w/v)	PBS	2.0 – 4.5	**3.67**

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 product) 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: S257+S262/2019 Sampling date: 26.7.2019
Rep No: 128 Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** Testing date: 19.9. – 24.10.2019
Sampled: by client Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY Page: 24

Interpretation:
Results of tests are in Tabs.
According to EN 13727:2012+A2:2015 the tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

The tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60% solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** on carriers the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction (EN 14561:2006).

According to EN 13624:2013 the tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number vegetative yeast cells of *Candida albicans* ATCC 10231 and the number of mould spores of *Aspergillus brasiliensis (niger)* ATCC 16404 by at least a 4 lg reduction.

The tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60% solution of Detro PAA 1500**, diluted in distilled water, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** on carriers the number vegetative yeast cells of *Candida albicans* ATCC 10231 and the number of mould spores of *Aspergillus brasiliensis (niger)* ATCC 16404 by at least a 4 lg reduction (EN 14562:2006).

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

The tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of viable bacterial spoores of *Bacillus subtilis* ATCC 6633, *Bacillus cereus* ATCC 12826 and *Clostridium sporogenes* ATCC 19404 by at least a 3 lg reduction (EN 13704:2018).
* Product can only be tested at a concentration of 97% (RTU product – modified method according to EN 13624 - 9.7 parts of the product + 0.2 part of the 5 fold concentrated interfering substance + 0.1 part of the 10 fold concentrated test suspension) or less, as some dilution is always produced by adding the test organisms and interfering substance.

According to EN 14476:2013 +A2:2019 the tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 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.

According to EN 14476:2013 +A2:2019 the tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%* solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 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 *Murine norovirus (MNV)* strain S99, RVB-651 particles under defined conditions by at least 4 (lg) orders.

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

Sample ID: S257+S262/2019 | Sampling date: 26.7.2019
Rep No: 128 | Sample delivered: 30.7.2019
Sample name: **DETRO PAA 1500 + DETRO PAA 1500 activator** | Testing date: 19.9. – 24.10.2019
Sampled: by client | Delivered amount: 10 x 500 ml, 10 x 50 ml
Sampling point: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Batch No: 7762019001, 5432019001
Client: Detro Healthcare Kimya San. A.S., Atatürk Mah. Adnan Menderes Cad. No.7 Esenyurt / Istanbul, TURKEY | Page: 25

Interpretation:
Results of tests are in Tabs.
According to EN 14476:2013 +A2:2019 the tested product **DETRO PAA 1500 + DETRO PAA 1500 activator,** batch No. 7762019001, 5432019001, in the concentration **60%*** **solution of Detro PAA 1500**, diluted in distilled water, and in the contact time 5 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 *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 product) 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 **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable bacterial cells of the relevant organisms under defined conditions (EN 13727:2012+A2:2015 – real concentration 58.2% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C) to the declared values, and consequently, can be called bactericidal.
The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number vegetative yeast cells and the number of mould spores of the relevant organisms under defined conditions (EN 13624:2013 – real concentration 58.2% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C) to the declared values, and consequently, can be called fungicidal.
The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable bacterial cells of the relevant organisms on carriers under defined conditions (EN 14561:2006 – carriers, real concentration 60% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C) to the declared values, and consequently, can be called bactericidal on carriers.
The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable vegetative yeast cells and the number of mould spores of the relevant organism of the relevant organism on carriers under defined conditions (EN 14562:2006 – carriers, real concentration 60% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C) to the declared values, and consequently, can be called fungicidal on carriers.
The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of viable bacterial spores of the relevant organisms under defined conditions (EN 13704:2018 – real concentration 58.2% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C) to the declared values, and consequently, can be called sporicidal.
The product **DETRO PAA 1500 + DETRO PAA 1500 activator** is capable of reducing the number of infectious *Adenovirus*, *Poliovirus* and *Murine norovirus* particles under defined conditions (EN 14476:2013 +A2:2019 – real concentration 58.2% solution of activated **Detro PAA 1500**, 5 min, clean conditions, 20 °C, MicroSpin™ S 400 HR) to the declared values, and consequently, can be called virucidal.

19.12.2019, Hodonín

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Ing. Barbora Stoklásková, Leader of Study