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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.

Copy No.: 1
Issue No.: 1

Test report No. S33/2020

DETERMINATION OF BACTERICIDAL AND YEASTICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**

Sample ID: S33/2020

Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Producer: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Incoming date:
30.1.2020

Delivery date:
16.4.2020

Digitally signed by Granaci Boris
Date: 2025.09.11 10:48:40 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Hodonín, 16.4.2020

Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: S33/2020 — Sampling date: 29.1.2020
Rep No: 48 — Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 — Testing date: 17.3. – 1.4.2020
Sampled: by client — Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Subject of testing:
Determination of bactericidal and yeasticidal activity of the product.

Identification of the sample:

Name of the product:	**OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch number:	KAFG35-1200212001
Date of manufacture:	22.01.2020
Expiry date:	22.01.2022
Manufacturer:	KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Incoming date:	30.1.2020
Storage conditions:	room temperature
Active ingredients:	CAS 64-17-5 Ethanol 30% CAS 67-63-0 2-Propanol 10% CAS 94667-33-1 Didecyldimethylpoly(oxethyl) Ammonium Propionate 0.25%

Experimental conditions: **Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers**
SOP-M-19-00 (EN 16615:2015)

Period of analysis:	17.3. – 18.3.2020
Lab temperature:	20 °C ± 2.5 °C
Temperature of media:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	distilled water
Appearance of the product:	ready to use wipes (wet white wipes)
Water control:	distilled water + polysorbate 80
Test concentration:	100% (wet white wipes)
Contact time:	1 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 surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{Ct} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the distilled water and polysorbate 80. The wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical

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

Sample ID: S33/2020 | Sampling date: 29.1.2020
Rep No: 48 | Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 | Testing date: 17.3. – 1.4.2020
Sampled: by client | Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY | Page: 3

Parafilm: Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping.

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions on nonporous surface in the field 1 by at least a 5 lg reduction (10^5).
$R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability, the drying time: 20 – 30 min

The standard:
EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015
EN ISO 4833-1 Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique, September 2013

The Number of CFU in the tested product (SOP-M-07-00 (EN ISO 4833-1)): 0 CFU/ml (solution)

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

Sample ID: S33/2020 — Sampling date: 29.1.2020
Rep No: 48 — Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 — Testing date: 17.3. – 1.4.2020
Sampled: by client — Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

1. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces

Tab No. 1.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N_{V0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 100%		
V_{c1}	64	$\Phi_{Nvo} = 58.5$	V_{c1}	62	$\Phi_B = 51.5$	V_{c1}	59	$\Phi_C = 56$
V_{c2}	53		V_{c2}	41		V_{c2}	53	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no

Tab No. 1.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 47.5 \times 10^8 = \lg 9.68$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.38$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	46	49	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 1.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 6.92$
	10^{-4}	161	172	$6.88 \leq \lg D_{C0} \leq 8.40$
	10^{-5}	17	14	
				x yes no

Tab No. 1.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 6.88$
	10^{-4}	140	162	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	15	17	
				x yes no

Tab No. 1.3.1 Test with water N_w – the effect of water (Wipe with distilled water + polysorbate 80) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 1	10^0	86	430	yes
3 / 1	10^0	72	160	yes
4 / 1	10^0	103	515	yes

Tab No. 1.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
100/1/clean/2	10^0	0	<14	yes
100/1/clean/3	10^0	0	<14	yes
100/1/clean/4	10^0	0	<14	yes

Tab No. 1.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	**lg R ($\lg D_{Ct} = 6.88$)**
100/1/clean/1	10^0	<14	<14	<1.85	**≥ 5.03**

Tab No. 1.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments (ready to use wipes)	12.3	11.3	1.0
Wipe with distilled water + polysorbate 80	19.0	18.0	1.0

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

Sample ID: S33/2020
Rep No: 48
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001
Sampled: by client
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Sampling date: 29.1.2020
Sample delivered: 30.1.2020
Testing date: 17.3. – 1.4.2020
Delivered amount: 2 x 1,5 kg + 2 x 100 pcs

2. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces

Tab No. 2.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N_{V0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 100%		
V_{c1}	35	$\Phi_{Nvo} = 46$	V_{c1}	36	$\Phi_B = 36.5$	V_{c1}	34	$\Phi_C = 36$
V_{c2}	57		V_{c2}	37		V_{c2}	38	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no

Tab No. 2.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 43 \times 10^8 = \lg 9.63$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.33$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	34	52	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 2.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 7.65$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{C0} \leq 8.40$
	10^{-5}	84	96	
				x yes no

Tab No. 2.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 7.65$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	89	88	
				x yes no

Tab No. 2.3.1 Test with water N_w – the effect of water (Wipe with distilled water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 1	10^0	92	460	yes
3 / 1	10^0	5	25	yes
4 / 1	10^0	4	20	yes

Tab No. 2.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
100/1/clean/2	10^0	1	<14	yes
100/1/clean/3	10^0	2	<14	yes
100/1/clean/4	10^0	2	<14	yes

Tab No. 2.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a$ ($\Phi \times 5$)	**lg R ($\lg D_{Ct} = 7.65$)**
100/1/clean/1	10^0	<14	<14	<1.85	**≥ 5.80**

Tab No. 2.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments (ready to use wipes)	11.1	10.4	0.7
Wipe with distilled water + polysorbate 80	18.8	17.8	1.0

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

Sample ID: S33/2020
Rep No: 48
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001
Sampled: by client
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Sampling date: 29.1.2020
Sample delivered: 30.1.2020
Testing date: 17.3. – 1.4.2020
Delivered amount: 2 x 1,5 kg + 2 x 100 pcs

3. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Enterococcus hirae* ATCC 10541 on non-porous surfaces

Tab No. 3.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N_{V0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 100%		
V_{c1}	55	$\Phi_{Nvo} = 54.5$	V_{c1}	55	$\Phi_B = 52.5$	V_{c1}	31	$\Phi_C = 36$
V_{c2}	54		V_{c2}	50		V_{c2}	41	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no

Tab No. 3.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 49.5 \times 10^8 = \lg 9.69$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.39$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	48	51	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 3.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 7.65$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{C0} \leq 8.40$
	10^{-5}	98	81	
				x yes no

Tab No. 3.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 7.58$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	86	65	
				x yes no

Tab No. 3.3.1 Test with water N_w – the effect of water (Wipe with distilled water + polysorbate 80) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 1	10^0	21	105	yes
3 / 1	10^0	35	175	yes
4 / 1	10^0	33	165	yes

Tab No. 3.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
100/1/clean/2	10^0	2	<14	yes
100/1/clean/3	10^0	1	<14	yes
100/1/clean/4	10^0	1	20	yes

Tab No. 3.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	**lg R ($\lg D_{Ct} = 7.58$)**
100/1/clean/1	10^0	<14	<14	<1.85	**≥ 5.73**

Tab No. 3.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments (ready to use wipes)	14.2	12.7	1.5
Wipe with distilled water + polysorbate 80	19.3	18.4	0.9

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

Sample ID: S33/2020 Sampling date: 29.1.2020
Rep No: 48 Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 Testing date: 17.3. – 1.4.2020
Sampled: by client Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY Page: 7

4. Evaluation of bactericidal activity of the product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**

Tab No. 4.1 The efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on test strains – bactericidal activity on non-porous surfaces, clean conditions, field 1

Bactericidal activity of the product (EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R EN 16615:2015	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	1	100	clean	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	1	100	clean	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	1	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 in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of bacteria per ml in the test mixture, A, B, C = the number of bacteria per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation R = D_{Ct}/ N_a or lg R = lg D_{Ct} – lg N_a the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S33/2020 | Sampling date: 29.1.2020
Rep No: 48 | Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 | Testing date: 17.3. – 1.4.2020
Sampled: by client | Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-19-00 (EN 16615:2015)
Period of analysis:	30.3. – 1.4.2020
Lab temperature:	20 °C ± 2.5 °C
Temperature of media:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	distilled water
Appearance of the product:	ready to use wipes (wet white wipes)
Water control:	distilled water + polysorbate 80
Test concentration:	100% (wet white wipes)
Contact time:	1 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	*Candida albicans* ATCC 10231
Incubation conditions:	30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours
Test surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{Ct} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the distilled water and polysorbate 80. The wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical
Parafilm:	Parafilm® M, 10.2 cm x 38 m , producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping,

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of *Candida albicans* under defined conditions on nonporous surface in the field 1 by at least a 4 lg reduction (10^4).
$R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} – \lg N_a$ the reduction in viability, the drying time: 20 – 30 min

The standard:
EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

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

Sample ID: S33/2020 — Sampling date: 29.1.2020
Rep No: 48 — Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 — Testing date: 17.3. – 1.4.2020
Sampled: by client — Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

5. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Candida albicans* ATCC 10231 on non-porous surfaces

Tab No. 5.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 100%			
V_{c1}	47	$\Phi_{Nvo} = 41.5$		V_{c1}	35	$\Phi_B = 41$		V_{c1}	44	$\Phi_C = 38$	
V_{c2}	36			V_{c2}	47			V_{c2}	32		
$30 \leq \Phi_{Nvo} \leq 160$				$\Phi_B \geq 0.5\ \Phi_{Nvo}$				$\Phi_C \geq 0.5\ \Phi_{Nvo}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 5.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0			
$\Phi = 40 \times 10^7 = \lg 8.60$	10^{-6}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 7.30$			
$8.17 \leq \lg N \leq 8.70$	10^{-7}	44	36	$6.88 \leq \lg N_0 \leq 7.40$			
				x	yes		no

Tab No. 5.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^4) = 6.43$			
	10^{-3}	> 330	> 330	$5.88 \leq \lg D_{C0} \leq 7.40$			
	10^{-4}	57	51				
				x	yes		no

Tab No. 5.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 6.40$			
	10^{-3}	> 330	> 330	$5.88 \leq \lg D_{Ct} \leq 7.40$			
	10^{-4}	53	47				
				x	yes		no

Tab No. 5.3.1 Test with water N_w – the effect of water (Wipe with distilled water + polysorbate 80) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 1	10^0	34	170	yes
3 / 1	10^0	3	15	yes
4 / 1	10^0	4	20	yes

Tab No. 5.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
100/1/clean/2	10^0	4	20	yes
100/1/clean/3	10^0	0	<14	yes
100/1/clean/4	10^0	0	<14	yes

Tab No. 5.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 1

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	**lg R ($\lg D_{Ct} = 6.40$)**
100/1/clean/1	10^0	<14	<14	<1.85	**≥ 4.55**

Tab No. 5.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments (ready to use wipes)	14.7	13.6	1.1
Wipe with distilled water + polysorbate 80	18.5	17.6	0.9

6. Evaluation of yeasticidal activity of the product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**

Tab No. 6.1 The efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on test strains – yeasticidal activity on non-porous surfaces, clean conditions, field 1

Bactericidal and yeasticidal activity of the product (EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R EN 16615:2015	**lg R**
Candida albicans ATCC 10231	20	1	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 in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of bacteria and fungi per ml in the test mixture, A, B, C = the number of bacteria and fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

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

Sample ID: S33/2020 | Sampling date: 29.1.2020
Rep No: 48 | Sample delivered: 30.1.2020
Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments**
Batch No: KAFG35-1200212001 | Testing date: 17.3. – 1.4.2020
Sampled: by client | Delivered amount: 2 x 1,5 kg + 2 x 100 pcs
Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY
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Interpretation:
Results of tests are in Tabs.
According to EN 16615:2015 the tested product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), batch No. KAFG35-1200212001, in the contact time 1 min under clean conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 and *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

According to EN 16615:2015 the tested product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), batch No. KAFG35-1200212001, in the contact time 1 min under clean conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable vegetative yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

Conclusion:
The product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** is capable of reducing the number of viable bacterial cells of the relevant organisms on non-porous surfaces under defined conditions (EN 16615:2015 – **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), 1 min, clean, 20 °C ± 2.5 °C) to the declared values and, consequently, can be called bactericidal on non-porous surfaces.
The product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** is capable of reducing the number of viable vegetative yeast cells of the relevant organism on non-porous surfaces under defined conditions (EN 16615:2015 – **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), 1 min, clean, 20 °C ± 2.5 °C) to the declared values and, consequently, can be called yeasticidal on non-porous surfaces.

16.4.2020, Hodonín

Approved by: Ing. Barbora Stoklásková, Leader of Study

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