



**REPUBLIC OF TURKEY
YEDİTEPE UNIVERSITY
BİOCİDAL AND R&D LABORATORİES**

**ONESPRAY
MICROBİOLOGİCAL EFFİCACY
RESULT REPORT**



REPUBLIC OF TURKEY
YEDITEPE UNIVERSITY
BIOCIDAL AND R&D LABORATORIES
REPORT OF RESULT OF ANALYSIS AND TEST

Republic of Turkey YEDİTEPE UNIVERSITY

Sample name	ONESPRAY
Sample registry nr	2020-3/200003
Report No-Rev. No / Report code	200933-01 / 06
Reporting date	02.03.2020

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1. SAMPLE INFORMATION

Trade Name Of Products	ONESPRAY
Sample Admission Date/Time	13.1.2020 15:27:00
Product / License Owner	Kafgrup Health Services
Formulation Type	Liquid
Formulation Content	Etil Alkol 30% w / w, 2 Propanol 10% w / w Didecylmethylpoly (oxethyl) Ammonium Propionate 0.25% w / w
Institution Sending The Sample/Date, Number	İstanbul İSM / 31.12.2019, E.63315
Reason For Sample Arrival, Seal Status And Amount	Basis to license/ Sealed 15x400ml
Address Where Sample Is Taken	Kaf Grup Sağlık Hizm. İnş. San. ve Tic. Ltd.Şti. Hadımköy Mah. Deniz Kızı Sok.No :4/5 Amavutköy İstanbul
Sample Production Place Address	Kaf Grup Sağlık Hizm. İnş. San. ve Tic. Ltd.Şti. Hadımköy Mah. Deniz Kızı Sok.No :4/5 Amavutköy İstanbul
Type Of Packaging Material	Pe
Sample Charge Nr / Serial Nr	ONCR271219/002
Sample Production And Expiry Date	27.12.2019/ 27.12.2021



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2. ANALYSIS RESULTS

2.1 Microbiological Activity Trial Method / Method Information

Trial Start and End Date	27.01.2020/ 13.02.2020
Trial Repetition Count	2 (two)
Results	On the Table (Table-2.2)

Microbiological Parameter	Microorganism Name	Method / Technique	Used plate count	Method summary
Bactericidal Activity of Chemical Disinfectants and Antiseptics Used in the Medical Field	Staphylococcus aureus ATCC 6538	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
	Pseudomonas aeruginosa ATCC 15442	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
	Enterococcus hirae ATCC 10541	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
In Medicine (Device Disinfectants Included) Used Chemical Disinfectants Mycobactericidal Activity	Mycobacterium avium ATCC 15769	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
	Mycobacterium terrae ATCC 15755 (Strain W45)	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
Fungicidal and Yeastocidal Activity of Chemical Disinfectants and Antiseptics Used in Medical Devices	Candida albicans ATCC 10231	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.
	Aspergillus niger ATCC 16404	Spreading Plate Method	2(two)	It is the logarithmic calculation of the number of microorganisms remaining as a result of the reduction of the microorganism at a certain concentration at the end of the contact period.



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2.2. Microbiological Efficacy Trial Method / Method Application Details

Microorganism Name	Method	Product Usage Field	Application Dosage	Contact Time	Environment Conditions	Deforming Substance	Neutralizer
Staphylococcus aureus ATCC 6538	TS EN 13727	Medical Field	100%	30 Seconds	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Pseudomonas aeruginosa ATCC 15442	TS EN 13727	Medical Field	100%	30 Seconds	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Enterococcus hirae ATCC 10541	TS EN 13727	Medical Field	100%	30 Seconds	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Mycobacterium avium ATCC 15769	TS EN 14348	Medical Field	100%	5 Minutes 60 Minutes	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Mycobacterium terrae ATCC 15755 (Strain W45)	TS EN 14348	Medical Field	100%	5 Minutes 60 Minutes	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Candida albicans ATCC 10231	TS EN 13624	Medical Field	100%	30 Seconds	20°C	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)
Aspergillus niger ATCC 16404	TS EN 13624	Medical Field	100%	30 Seconds	//	0.3 g/L BSA	Yumurta lesitini (3gr/L) + Tween 80 (30 gr/L) + Saponin (30 gr/L)



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2.3 Trial Results and Results Evaluation Table

Microorganism Name	Method	Product Usage Field	Antimicrobial Effect (% Reducing)	Antimicrobial Effect (Logarithmic Reduction)	Result Evaluation		D
					Source	Limit	
Staphylococcus aureus ATCC 6538	TS EN 13727	Medical Field	% 99,999	>105 >5,39	TS EN 13727	>5 log	U
Pseudomonas aeruginosa ATCC 15442	TS EN 13727	Medical Field	% 99,999	>105 >5,02	TS EN 13727	>5 log	U
Enterococcus hirae ATCC 10541	TS EN 13727	Medical Field	% 99,999	>105 >5,02	TS EN 13727	>5 log	U
Mycobacterium avium ATCC 15769	TS EN 14348	Medical Field	% 99,99 % 99,99	> 104; > 104 > 6,15; > 6,15	TS EN 14348	> 4 log	U U
Mycobacterium terrae ATCC 15755 (Strain W45)	TS EN 14348	Medical Field	% 99,99 % 99,99	> 104; > 104 > 6,15; > 6,15	TS EN 14348	> 4 log	U U
Candida albicans ATCC 10231	TS EN 13624	Medical Field	% 99,99	>104 >4,15	TS EN 13624	> 4 log	U
Aspergillus niger ATCC 16404	TS EN 13624	Medical Field	% 99,99	>104 >4,15	TS EN 13624	> 4 log	U



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2.4 Trial Results Method / Method Validation and Controls Table

Microorganism Name	Vc	N	LgN	No	Lg No	Na	Lg Na	Control Suspension				A	B	C
								Nv	Nvo	Vc1	Vc2			
Staphylococcus aureus ATCC 6538	< 14	3,5*108	8,54	3,5x107	7,54	< 140	<2,15	6x102	6x10'	65	56	6x10' 61-60	6x10' 61-59	5x10' 54-50
Pseudomonas aeruginosa ATCC 15442	< 14	1,5x 108	8,17	1,5x107	7,17	< 140	<2,15	7x102	7x10*	70	69	6x10' 66-55	5x10' 52-50	4x10' 42-40
Enterococcus hirae ATCC 10541	< 14	1,5x108	8,17	1,5x107	7,17	< 140	<2,15	8x102	8x10'	80	79	8x10' 83-78	6x10' 62-60	6,5x10' 67-63
Mycobacterium avium ATCC 15769	< 14 < 14	2x109	9,30	2x108	8,30	< 140 < 140	<2,15 <2,15	5x102	5 x 101	53	48	5x10' 50-50	4x10' 42-40	4x10' 40-38
Mycobacterium terrae ATCC 15755 (Strain W45)	< 14 < 14	2x109	9,30	2x108	8,30	< 140 < 140	<2,15 <2,15	5 x 102	5x10'	51	49	5x10' 52-50	4x10' 40-40	5x10' 51-50
Candida albicans ATCC 10231	< 14	2x107	7,30	2x106	6,30	< 140	<2,15	6x102	6x10'	60	59	6x10' 64-58	6x10' 62-58	5x10' 52-49
Aspergillus niger ATCC 16404	< 14	2x107	7,30	2x106	6,30	< 140	<2,15	5X102	5x10'	50	49	5x10' 51-50	5x10' 52-50	4x10' 42-38



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3. APPROVAL AND SIGNATURES

Sadık KALAYCI
Biologist
Microbiological Activity Lab. Unit
responsible

19.08.2020

Serap DELİMEHMETOĞULLARI
Biologist
Sample Acceptance and Reporting Unit
Supervisor

Confirmable
Prof. Dr. Fikretin SAHİN
Laboratory Supervisor

4. LEGAL INFORMATION

Copying of all or part of the final report can only be done with the written approval of Yeditepe University Biocidal and R&D Laboratories. In addition, Yeditepe University Biocidal and R & D Laboratories cannot be used for other than official purposes (for advertising purposes) and the name of the university cannot be written on the product label without the written permission. If otherwise is determined, Yeditepe University Rectorate reserves all kinds of legal applications and demands.



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5.GENERAL INFORMATION

- As a result of the examination and analysis, the values mentioned above were determined.
- Analysis results are valid for the sample specified above.
- No part of this analysis report can be used alone or separately.
- This report cannot be partially copied or reproduced without the written permission of the laboratory.
- This report cannot be used in judicial / administrative proceedings and for advertising purposes.
- Unsigned and unsealed reports are invalid.
- Abbreviations; D:Evaluation. U: An appropriate. U.D.: Not Available. D.Y.: Evaluation Could Not Be Made. G.K.:Recovery. Ö.B.:Measurement Uncertainty. Ö.L.:Measurement Limit. U.S.S.:Long Term Stability. K.S.S.:Short Term Stability. A.U.S.:Opened Product Stability.
- * The marked analyzes are within the scope of accreditation.
- The declared expanded measurement uncertainty is the value found by multiplying the standard uncertainty with the expansion coefficient taken as $k = 2$ and provides 95% reliability.
- The results that were commented / commented on are not related to the accredited scope.
- As stated in the "Biocidal Products Regulation" published in the Official Gazette dated 31.12.2009 and numbered 27449 4 repeated, and the "Instruction on Biocidal Product Analysis and Authorized Laboratories" approved with the consent of 28.01.2019 and number 19020089-704.99-519. ; Physical tests of biocidal products are made. These tests are repeated and reported in each stability test. If the tests performed do not comply with the product specification, the product is considered unsuitable and chemical and biological activity tests are not performed. Therefore, the number of reports to be produced for the same sample will vary according to the analysis results.
- The decision rule will be used in favor of the customer.
- Revision Information
- The evaluation of the microbiological test results as APPROPRIATE has shown the desired log decrease in the concentration of the product studied. It is an expression that it is effective against the relevant bacteria, and that it is evaluated as NOT SUITABLE.
- Abbreviations and related evaluation criteria used in the report for microbiological tests;
Vc : Post-reduction microorganism / colony viable counts
Lg N : Initial microorganism / colony number (Logarithmically)
Lg No : Number of microorganisms / colonies before contact time (Logarithmically)
N : Initial microorganism / colony number
No : Number of microorganisms / colonies before contact time
Nv : Validation suspension
Nvo : Validation suspension before contact time
Na : Number of microorganisms / colonies remaining after reduction
Lg Na : Number of microorganisms / colonies remaining after reduction (Logarithmically)
R : Logarithmic reduction (LgNo-LgNA)
A : Control of Experimental Conditions
B : Control of Neutralizer Toxicity
C : Control of the Dilution Neutralization Method
N : It should be between 1.5×10^8 and 5×10^8 . (Bacteria) It should be between $(8.17 < \lg N < 8.70)$ logarithmically.
No : It should be between 1.5×10^7 and 5×10^7 . (Bacteria) It should be between $(7.17 < \lg N < 7.70)$ logarithmically.
N : It should be between 1.5×10^7 and 5×10^7 . (In Yeast and Fungi) It should be between $(7.17 < \lg N < 7.70)$ logarithmically.
No : It should be between 1.5×10^6 and 5×10^6 . (In Yeast and Fungi) It should be between $(6.17 < \lg N < 6.70)$ logarithmically.
N : It should be between 1.5×10^9 and 5×10^9 . (Mycobacterium spp. de) It should be between $(9.17 < \lg N < 9.70)$ logarithmically.
No : It should be between 1.5×10^8 and 5×10^8 . (Mycobacterium spp. de) It should be between $(8.17 < \lg N < 8.70)$ logarithmically.
N : It should be between 3×10^8 and 8×10^8 . (According to EN 14204 in Mycobacterium avium) It should be between $(8.48 < \lg N < 8.90)$ logarithmically.
N : It should be between 3×10^7 and 8×10^7 . (According to EN 14204 in Mycobacterium avium) It should be between $(7.48 < \lg N < 7.90)$ logarithmically.

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Nv; It should be between 3×10^2 and 1.6×10^3 .

Nvo; It should be between 3×10^4 and 1.6×10^5 . (The number of colonies should be between 30-160.)

Average of A; It must be 0.5 times greater than or equal to Nvo. So the average of the number A; It can be the lowest half of the average of the Nvo number.

Average of B; It must be 0.5 times greater than or equal to Nvo. So the average of the B number; It can be the lowest half of the average of the Nvo number.

Average of C; It must be 0.5 times greater than or equal to Nvo. So the average of the number C; It can be the lowest half of the average of the Nvo number.

