



YEDİTEPE UNIVERSITY
FACULTY OF ENGINEERING
DEPARTMENT OF GENETICS AND BIOENGINEERING

REPORT

BIOLOGICAL ACTIVITY TEST RESULTS REPORT

REPORT RECORD NUMBER AND DATE	150-MD-2016	24.10.2016
SAMPLE RECORD NUMBER	2016-197	
SAMPLE SENDING INSTITUTION	Istanbul Governorate Public Health Directorate /83362133/361.99-E.6407//29.08.2016	
SAMPLE MANUFACTURER NAME AND ADDRESS	GBL Gül Biyoloji Laboratuvarı Sanayi Tic.Lim. Şti. İmes Sanayi Sitesi C Blok 305 Sokak No:16 Ümraniye/İstanbul	
THE LICENSE OWNER COMPANY NAME AND ADDRESS	GBL Gül Biyoloji Laboratuvarı Sanayi Tic.Lim. Şti. İmes Sanayi Sitesi C Blok 305 Sokak No:16 Ümraniye/İstanbul	
SAMPLE ARRIVAL FORM (SEALED-UNSEALED)	Sealed	
TEST PURPOSE	Biological Activity	
TEST CONDUCTING INSTITUTION	Yeditepe University, Faculty of Engineering, Department of Genetics and Bioengineering	
PRODUCT ARRIVAL DATE	02.09.2016	
TEST START AND END DATE	03.10.2016/24.10.2016	
TESTED PRODUCT NAME	Manochol EP-70 Alcohol Based Hand Sanitizer	
FORM OF TESTED PRODUCT FORMULATION	Liquid	
SAMPLE CHARGE/SERIAL NO	A2534	
PRODUCTION AND EXPIRATION DATE OF SAMPLE	26.08.2016/26.08.2018	
PRODUCT TYPE	1	
ACTIVE SUBSTANCES OF PRODUCT	Ethyl Alcohol 45%; Propan 2-ol 25%	
PRODUCT DILUENT	Sterile distilled water	
INTERFERING SUBSTANCE	0,3 g/L Bovine Albumin Serum	
NEUTRALIZER	Egg Lecithin (3gr/L)+Tween 80(30 gr/L)	
TEST METHOD	EN 13727, EN 13624, EN 14348	DILUTION-NEUTRALIZATION
TEST CONDITIONS	Bacteria: 37 °C, Candida: 37 °C	
NUMBER OF TEST REPEATS	3	
RESULTS	Presented in the appendix.	
COMMENT	According to EN 13727, EN 13624 and EN 14348 test methods, the product named as Manochol EP-70 Alcohol Based Hand Sanitizer 100% concentrations was investigated for its reduction (%) effect against microorganisms listed in the attachment in 30 second, 5 minutes and 60 minutes contact time at 20 °C under clean conditions (0.3 g/L). The results are presented in the attachment.	

Microbiologist Sadık KALAYCI
Laboratory Manager

Prof. Dr. Fikretin SAHİN
Chair of Biocidal Laboratory



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APPENDIX 1: RESULTS

ANTIMICROBIAL TEST RESULTS

NAME OF MICROORGANISM	BIOLOGICAL ACTIVITY	TEST CONCENTRATION	CONTACT TIME	ANTIMICROBIAL EFFECT (%) REDUCTION
<i>Escherichia coli</i> K12 NCTC 10538	+	100%	30 Second	99.999%
<i>Staphylococcus aureus</i> ATCC 6538	+	100%	30 Second	99.999%
<i>Pseudomonas aeruginosa</i> ATCC 15442	+	100%	30 Second	99.999%
<i>Enterococcus hirae</i> ATCC 10541	+	100%	30 Second	99.999%
<i>Mycobacterium terrae</i> ATCC 15755(Strain W45)	+ +	100%	5 Minutes 60 Minutes	99.99% 99.99%
<i>Mycobacterium avium</i> ATCC 15769	+ +	100%	5 Minutes 60 Minutes	99.99% 99.99%
<i>Candida albicans</i> ATCC 10231	+	100%	30 Second	99.99%



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NAME OF MICROORGANISM	V _c	N	N _A	R	TEST CONCENTRATION
<i>Escherichia coli</i> K12 NCTC 10538	< 14	1.5 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Staphylococcus aureus</i> ATCC 6538	< 14	1.5 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Pseudomonas aeruginosa</i> ATCC 15442	< 14	2.8 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Enterococcus hirae</i> ATCC 10541	< 14	1.6 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Mycobacterium terrae</i> ATCC 15755 (Strain W45)	< 14 < 14	2 × 10 ⁹	< 1.5 × 10 ² < 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%
<i>Mycobacterium avium</i> ATCC 15769	< 14 < 14	1.8 × 10 ⁹	< 1.5 × 10 ² < 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%
<i>Candida albicans</i> ATCC 10231	< 14	1.7 × 10 ⁷	< 1.5 × 10 ²	> 10 ⁴	100%

V_c: Number of viable microorganism

N: Initial number of microorganism

N_A: Number of microorganism after reduction

R: Logarithmic reduction



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APPENDIX 2: CONTROL GROUP RESULTS

NAME OF MICROORGANISM	VALIDATION -CONTROL SUSPENSION <i>N_v - N_{v0}</i>	CONTROL OF EXPERIMENTAL CONDITIONS (A)	CONTROL OF NEUTRALIZING AGENT TOXICITY (B)	CONTROL OF DILUTION NEUTRALIZATION METHOD (C)
	<i>V_{c1}+V_{c2}</i>	<i>V_{c1}+V_{c2}</i>	<i>V_{c1}+V_{c2}</i>	<i>V_{c1}+V_{c2}</i>
<i>Escherichia coli</i> K12 NCTC 10538	6×10 ² -6×10 ¹ 62-60	5×10 ¹ 52-48	6.5×10 ¹ 66-65	6×10 ¹ 63-59
<i>Staphylococcus aureus</i> ATCC 6538	7×10 ² -7×10 ¹ 72-69	6×10 ¹ 65-55	7×10 ¹ 73-70	6×10 ¹ 62-60
<i>Pseudomonas aeruginosa</i> ATCC 15442	5×10 ² -5×10 ¹ 55-45	6×10 ¹ 63-60	7×10 ¹ 72-70	6×10 ¹ 64-58
<i>Enterococcus hirae</i> ATCC 10541	6×10 ² -6×10 ¹ 67-54	6×10 ¹ 61-61	7×10 ¹ 72-68	5.5×10 ¹ 55-54
<i>Mycobacterium terrae</i> ATCC 15755(Strain W45)	4×10 ² -4×10 ¹ 42-40	5×10 ¹ 50-50	5×10 ¹ 53-48	4.5×10 ¹ 45-44
<i>Mycobacterium avium</i> ATCC 15769	5×10 ² -5×10 ¹ 57-45	6×10 ¹ 61-59	5.5×10 ¹ 55-54	4.5×10 ¹ 45-44
<i>Candida albicans</i> ATCC 10231	5.5×10 ² -5×10 ¹ 55-54	6×10 ¹ 61-59	6×10 ¹ 60-59	5×10 ¹ 53-50

---N, 1,5×10⁸ and 5×10⁸ must be between. (Bacteria)
---N, 1,5×10⁷ and 5×10⁷ must be between. (Candida and Fungus)
---N, 1,5×10⁹ ile 5×10⁹ must be between. (*Mycobacterium* spp.)
---N, 3×10⁸ ile 8×10⁸ must be between. (According to EN 14204 test methods *Mycobacterium avium*)
---N_v, 3×10² ile 1,6×10³ must be between.
---N_{v0}, 3×10¹ ile 1,6×10² must be between. Number of viable microorganism 30-160 must be between.

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FORM OF TESTED PRODUCT FORMULATION	Liquid	
SAMPLE CHARGE/SERIAL NO	A2534	
PRODUCTION AND EXPIRATION DATE OF SAMPLE	26.08.2016/26.08.2018	
PRODUCT TYPE	1	
ACTIVE SUBSTANCES OF PRODUCT	Ethyl Alcohol 45%; Propan 2-ol 25%	
PRODUCT DILUENT	Sterile distilled water	
INTERFERING SUBSTANCE	0,3 g/L Bovine Albumin Serum	
NEUTRALIZER	Egg Lecithin (3gr/L)+Tween 80(30 gr/L)	
TEST METHOD	EN 1276, EN 1650, EN 14348	DILUTION-NEUTRALIZATION
TEST CONDITIONS	Bacteria: 37 °C, Candida: 37 °C	
NUMBER OF TEST REPEATS	3	
RESULTS	Presented in the appendix.	
COMMENT	According to EN 1276, EN 1650 and EN 14348 test methods, the product named as Manochol EP-70 Alcohol Based Hand Sanitizer 100% concentrations was investigated for its reduction (%) effect against microorganisms listed in the attachment in 1 minutes, 5 minutes, 15 minutes and 60 minutes contact time at 20 °C under clean conditions (0.3 g/L). The results are presented in the attachment.	

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Laboratory Manager

Prof. Dr. Fikretin SAHİN
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<i>Escherichia coli</i> ATCC 10536	+	100%	1 Minutes	99.999%
<i>Staphylococcus aureus</i> ATCC 6538	+	100%	1 Minutes	99.999%
<i>Pseudomonas aeruginosa</i> ATCC 15442	+	100%	1 Minutes	99.999%
<i>Enterococcus hirae</i> ATCC 10541	+	100%	1 Minutes	99.999%
<i>Mycobacterium terrae</i> ATCC 15755(Strain W45)	+ +	100%	5 Minutes 60 Minutes	99.99% 99.99%
<i>Mycobacterium avium</i> ATCC 15769	+ +	100%	5 Minutes 60 Minutes	99.99% 99.99%
<i>Candida albicans</i> ATCC 10231	+ +	100%	1 Minutes 15 Minutes	99.99% 99.99%
<i>Aspergillus niger</i> ATCC 16404	+ +	100%	1 Minutes 15 Minutes	99.99% 99.99%



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<i>Escherichia coli</i> ATCC 10536	< 14	1.5 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Staphylococcus aureus</i> ATCC 6538	< 14	1.5 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Pseudomonas aeruginosa</i> ATCC 15442	< 14	2.8 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Enterococcus hirae</i> ATCC 10541	< 14	1.6 × 10 ⁸	< 1.5 × 10 ²	> 10 ⁵	100%
<i>Mycobacterium terrae</i> ATCC 15755(Strain W45)	< 14 < 14	2 × 10 ⁹	< 1.5 × 10 ² < 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%
<i>Mycobacterium avium</i> ATCC 15769	< 14 < 14	1.8 × 10 ⁹	< 1.5 × 10 ² < 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%
<i>Candida albicans</i> ATCC 10231	< 14 < 14	1.7 × 10 ⁷	< 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%
<i>Aspergillus niger</i> ATCC 16404	< 14 < 14	1.5 × 10 ⁷	< 1.5 × 10 ²	> 10 ⁴ > 10 ⁴	100%

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	<i>V_{c1}</i> + <i>V_{c2}</i>	<i>V_{c1}</i> + <i>V_{c2}</i>	<i>V_{c1}</i> + <i>V_{c2}</i>	<i>V_{c1}</i> + <i>V_{c2}</i>
<i>Escherichia coli</i> ATCC 10536	6×10 ² -6×10 ¹ 62-60	5×10 ¹ 52-48	6.5×10 ¹ 66-65	6×10 ¹ 63-59
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<i>Candida albicans</i> ATCC 10231	5.5×10 ² -5.5×10 ¹ 55-54	6×10 ¹ 61-59	6×10 ¹ 60-59	5×10 ¹ 53-50
<i>Aspergillus niger</i> ATCC 16404	3.5×10 ² -3.5×10 ¹ 36-35	4×10 ¹ 42-40	4×10 ¹ 40-40	3.5×10 ¹ 35-35

---N, 1,5×10⁸ and 5×10⁸ must be between. (Bacteria)
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