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YEDİTEPE UNIVERSITY
THE BIOCIDES AND RESEARCH AND DEVELOPMENT LABORATORIES

PRON-UP
MICROBIOLOGICAL ACTIVITY
RESULT REPORT

Name of specimen	PRON-UP CE
Reg. No. of specimen	2019-38/190038
Report No. / Revision No. / Report code	190385-00/06
Reporting date	30.05.2019

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ANALYSIS AND TEST RESULTS

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1. SPECIMEN INFORMATION

Trade name of the product	PRON-UP CE
Specimen arrival date / time	03.04.2019 09:55:00
License holder of the product	Sanidez İlaç San. Tic. Ltd. Şti.
Formulation type	Solid
Formulation content	Quaternary ammonium compounds 40% w / w
Institution / date, number of sending the specimen	SAKARYA HSM / 01.04.2019, E.288
Arrival reason, seal status and quantity	Based on license, stamped, 30x20gr
Address from which the specimen was taken	Sanidez İlaç San. Tic. Ltd. Şti. Erenler Mah. 1184 Sok. No: 1 Erenler / Sakarya
Production location and address of the specimen	Erenler Mah. 1184 Sok. No: 1 Erenler / Sakarya
Type of packaging material	Plastic
Specimen charge / serial no	-
Production and expiration date of the specimen	02.04.2019 – 02.04.2021

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2. ANALYSIS RESULTS

2.1. Test method for microbiological activities / method information

Start and end dates of the attempt	10.5.2019 / 29.5.2019
Number of retries	2 (two)
Results	On the table (Table-2.2)

Microbiological parameters	Name of Microorganism	Method / technique	Number of used plates	Method summary
Bactericidal effect 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 remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.
	Pseudomonas aeruginosa ATCC 15442	Spreading plate method	2 (two)	It is the logarithmic calculation of the remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.
	Enterococcus hirae ATCC 10541	Spreading plate method	2 (two)	It is the logarithmic calculation of the remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.
Microbial activity of chemical disinfectants used in medicine (including equipment disinfectants)	Mycobacterium avium ATCC 15769	Spreading plate method	2 (two)	It is the logarithmic calculation of the remaining number of microorganisms due to the reduction of the original microorganism 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 remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.
Fungicidal and yeasticidal effects 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 remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.
	Aspergillus niger ATCC 16404	Spreading plate method	2 (two)	It is the logarithmic calculation of the remaining number of microorganisms due to the reduction of the original microorganism at the end of the contact period.

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2.2. Test method for microbiological activities / application details for the method

Name of microorganism	Method	Product application area	Application dose	Contact time	Environmental conditions	Disruptive substance	Neutralizer
Staphylococcus aureus ATCC 6538	TS EN 13727	Medical area	2g / Litre	5 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Pseudomonas aeruginosa ATCC 15442	TS EN 13727	Medical area	2g / Litre	5 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Enterococcus hirae ATCC 10541	TS EN 13727	Medical area	2g / Litre	5 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Mycobacterium avium ATCC 15769	TS EN 13727	Medical area	2g / Litre	60 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Mycobacterium terrae ATCC 15755 (Strain W45)	TS EN 14348	Medical area	2g / Litre	60 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Candida albicans ATCC 10231	TS EN 13624	Medical area	2g / Litre	5 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)
Aspergillus niger ATCC 16404	TS EN 13624	Medical area	2g / Litre	5 minutes	20 C	0,3 g/L BSA	Egg Lecithin (3gr/L) + Tween 80 (30 gr/L) + Saponin (30gr/L)

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2.3. Test results and result evaluation table

Name of microorganism	Method	Product application area	Antimicrobial effect (Reduction %)	Antimicrobial effect (Logarithmic reduction)	Outcome assessment		D
					Source	Limit	
Staphylococcus aureus ATCC 6538	TS EN 13727	Medical area	99,999 %	> 10 ⁵ ; > 5,39	TS EN 13727	≥ 5 log	U
Pseudomonas aeruginosa ATCC 15442	TS EN 13727	Medical area	99,999 %	> 10 ⁵ ; > 5,10	TS EN 13727	≥ 5 log	U
Enterococcus hirae ATCC 10541	TS EN 13727	Medical area	99,999 %	> 10 ⁵ ; > 5,02	TS EN 13727	≥ 5 log	U
Mycobacterium avium ATCC 15769	TS EN 14348	Medical area	99,99 %	> 10 ⁴ ; > 6,15	TS EN 14348	≥ 4 log	U
Mycobacterium terrae ATCC 15755 (Strain W45)	TS EN 14348	Medical area	99,99 %	> 10 ⁴ ; > 6,15	TS EN 14348	≥ 4 log	U
Candida albicans ATCC 10231	TS EN 13624	Medical area	99,99 %	> 10 ⁴ ; > 4,15	TS EN 13624	≥ 4 log	U
Aspergillus niger ATCC 16404	TS EN 13624	Medical area	99,99 %	> 10 ⁴ ; > 4,02	TS EN 13624	≥ 4 log	U

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2.4. Test results method / method check and control table

Name of microorganism	VC	N	Lg N	N ₀	Lg N ₀	N _A	Lg N _A	Control suspension				A	B	C
								N _V	N _{V0}	V _{C1}	V _{C2}			
Staphylococcus aureus ATCC 6538	<14	3,5x10 ⁸	8,54	3,5x10 ⁷	7,54	< 140	< 2,15	6x10 ²	6x10 ¹	62	60	6x10 ¹ 61-60	5x10 ¹ 54-51	4,5x10 ¹ 47-44
Pseudomonas aeruginosa ATCC 15442	<14	1,8x10 ⁸	8,25	1,8x10 ⁷	7,25	< 140	< 2,15	5x10 ²	5x10 ¹	52	50	5x10 ¹ 51-50	5x10 ¹ 50-49	4x10 ¹ 42-40
Enterococcus hirae ATCC 10541	<14	1,5x10 ⁸	8,17	1,5x10 ⁷	7,17	< 140	< 2,15	8x10 ²	8x10 ¹	86	75	7x10 ¹ 71-69	6x10 ¹ 63-60	6x10 ¹ 60-59
Mycobacterium avium ATCC 15769	<14	2x10 ⁹	9,30	2x10 ⁸	8,30	< 140	< 2,15	4x10 ²	4x10 ¹	44	36	4x10 ¹ 40-39	4,5x10 ¹ 45-44	4x10 ¹ 40-39
Mycobacterium terrae ATCC 15755 (Strain W45)	<14	2x10 ⁹	9,30	2x10 ⁸	8,30	< 140	< 2,15	4x10 ²	4x10 ¹	43	40	4x10 ¹ 40-39	4x10 ¹ 40-40	3,5x10 ¹ 35-34
Candida albicans ATCC 10231	<14	2x10 ⁷	7,30	2x10 ⁶	6,30	< 140	< 2,15	7x10 ²	7x10 ¹	70	69	7x10 ¹ 71-70	6x10 ¹ 62-60	6x10 ¹ 60-59
Aspergillus niger ATCC 16404	<14	1,5x10 ⁷	7,17	1,5x10 ⁶	6,17	< 140	< 2,15	6x10 ²	6x10 ¹	61	59	5x10 ¹ 51-50	5,5x10 ¹ 55-54	5x10 ¹ 50-49

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3. Approvals and Signatures

30.05.2019
Sadık KALAYCI
Biologist
Microbiological Activity Laboratory Unit Manager
SIGNATURE

30.05.2019
Food Technisian
Deputy of Sampling and Reporting Unit
SIGNATURE

30.05.2019
Confirmable
Prof.Dr. Fikretin ŞAHİN
Head of Laboratory
SIGNATURE

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4. Legal Information

The full or partial copying of the final report can only be done with **WRITTEN** approval from the biocide and research and development laboratories of the University of Yeditepe. In addition, these may not be used outside of the **OFFICIAL** purpose without the **WRITTEN** permission of the Yeditepe University's biocide and research and development laboratories, and the name of the university must not be included on the product label. Unless otherwise specified, the Rectorate of Yeditepe University reserves all types of legal applications.

5. General information

1. As a result of the investigation and analysis, the above values were determined.
2. The results of the analysis apply to the sample mentioned above.
3. No part of this analysis report can be used alone or separately.
4. No part of this report may be copied or reproduced without the written permission of the laboratory.
5. This report cannot be used in court / administrative proceedings and for advertising purposes.
6. Unsigned and sealed reports are invalid.
7. Abbreviation: D: Rating, U: Suitable, U.D. Not suitable, D.Y.: No assessment made, G.K.: Recovery, Ö.B.: measurement uncertainty, Ö.L: measuring limit, U.S.S: Long-term stability, K.S.S: short-term stability, A.U.S: Open product stability.
8. * Labeled analyzes are in the accreditation area
9. The declared expanded measurement uncertainty is the value that is obtained by multiplying the standard uncertainty by the expansion coefficient as $k = 2$ and offering a reliability of 95%.
10. The results on which opinions / comments are given do not relate to the accredited scope.
11. The "Biocide Product Ordinance", which was published in the official newspaper of December 31, 2019 and with the number 27449 4th doublet and approved with the number 19020089-704.99-519 on January 28, 2019 "Authorized laboratories for biocide product analyzes; Physical tests of biocidal products are carried out. These tests are repeated with every stability test and a new report is generated. If the tests do not meet the product specification, the product is considered inappropriate and no chemical and biological effectiveness tests are carried out. Therefore, the number of reports to be generated for the same specimen depends on the results of the analysis.
12. The decision rule is used in favor of the customer.
13. Revision information
14. The evaluation of the results of the microbiological test recognized as SUITABLE was given because of the desired log decrease and knowing that it was efficient against the bacteria. That the rating for NOT SUITABLE was because it was not efficient.
15. Abbreviations used in the report and associated evaluation criteria for microbiological tests:

- Vc: Enumeration of microorganisms / colonies after reduction
Lg N: Initial number of microorganisms / colonies (logarithmic)
Lg N0: Number of microorganisms / colonies before the contact time (logarithmic)
N: Number of initial microorganisms / colonies
N0: Number of microorganisms / colonies before the contact time
Nv: Validation suspension
Nv0: Validation suspension before the contact time
NA: Number of microorganisms / colonies remaining after the reduction
Lg NA: Number of microorganisms / colonies remaining after the reduction (logarithmic)
R: Logarithmic Reduction (LgN0 - LgNA)
A: Check the test conditions
B: Control of neutralizing toxicity
C: Control of the dilution neutralization method
N: Must be between $1,5 \times 10^8$ and 5×10^8 . Logarithmically (for bacteria) it must be between $8,17 \leq \lg N \leq 8,70$.
N0: Must be between $1,5 \times 10^7$ and 5×10^7 . Logarithmically (for bacteria) it must be between $7,17 \leq \lg N \leq 7,70$.
N: Must be between $1,5 \times 10^7$ and 5×10^7 . Logarithmically (for yeast and fungus) it must be between $7,17 \leq \lg N \leq 7,70$.
N0: Must be between $1,5 \times 10^6$ and 5×10^6 . Logarithmically (for yeast and fungus) it must be between $6,17 \leq \lg N \leq 6,70$.
N: Must be between $1,5 \times 10^9$ and 5×10^9 . Logarithmically (at Mycobacterium spp) it must be between $9,17 \leq \lg N \leq 9,70$.
N0: Must be between $1,5 \times 10^8$ and 5×10^8 . Logarithmically (at Mycobacterium spp) it must be between $8,17 \leq \lg N \leq 8,70$.
N: Must be between 3×10^8 and 8×10^8 . Logarithmically (With Mycobacterium avium according to EN 14204) it must be between $8,48 \leq \lg N \leq 8,90$.
N0: Must be between 3×10^7 and 8×10^7 . Logarithmically (With Mycobacterium avium according to EN 14204) it must be between $7,48 \leq \lg N \leq 7,90$.
Nv: Must be between 3×10^2 and $1,6 \times 10^3$.
Nv0: Must be between 3×10^1 and $1,6 \times 10^2$. (The number of colonies must be between 30-160).

Average of A: Must be 0.5 times higher or the same as NV0. So the average of A; Should be at least the same as the smallest half of the average of Nv0.

Average of B: Must be 0.5 times higher or the same as NV0. So the average of B; Should be at least the same as the smallest half of the average of Nv0.

Average of C: Must be 0.5 times higher or the same as NV0. So the average of C; Should be at least the same as the smallest half of the average of Nv0.

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İşbu belge **TÜRKÇE** metinden aslına uygun olarak **İNGİLİZCE** diline tarafımca tercüme edilmiştir . **14.03.2020**