TERCÜMEDİR
TRANSLATION

T.R.
YEDİTEPE UNIVERSITY
THE BIOCIDE AND RESEARCH AND DEVELOPMENT LABORATORIES

PRON-UP
ANTIVIRAL EFFICACY ANALYSIS
RESULT REPORT

Name of specimen	PRON-UP CE
Reg. No. of specimen	2019-38/190038
Report No. / Revision No. / Report code	190391-00 / 07
Reporting date	10.06.2019

REPORT CONTENT

Yeditepe Üniversitesi 26 Ağustos Yerleşimi, İnönü Mahallesi Kayışdağı Caddesi 34755 Ataşehir / İSTANBUL
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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 (benzyl-C12-18-alkyldimethyl chlorides)
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	Sanidez İlaç San. Tic. Ltd. Şti. 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. Antiviral test Application details of the method / procedure

Virus and strain tested	Test method	Test start and endtime	Virus and strain properties	Application dose	Contact type	Waiting period	Test, clean environmental conditions	Test, dirty environmental conditions	Cell culture and dilution buffer
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine - Poliovirus Typr 1	Spearman Karber method	8.5.2019 29.5.2019	Reference strain of ATCC with code No 192	2gr / L	Liquid mixture (between test disks)	1 minute	BSA containinmedium (20 C)	Media containing BSA and sheep erythrocytes (20 C)	Always 2 cell cultures (ATCC, CCL-23) MEM, PBS, hard water
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Human Adenovirus Type 5	Spearman Karber method	8.5.2019 29.5.2019	Reference strain of ATCC with code No VR-5	2gr / L	Liquid mixture (between test disks)	1 minute	BSA containinmedium (20 C)	Media containing BSA and sheep erythrocytes (20 C)	Always 2 cell cultures (ATCC, CCL-23) MEM, PBS, hard water
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Murine norovirus	Spearman Karber method	8.5.2019 29.5.2019	Reference strain of ATCC with code No PTA - 5935	2gr / L	Liquid mixture (between test disks)	1 minute	BSA containinmedium (20 C)	Media containing BSA and sheep erythrocytes (20 C)	RAW cell cultures (ATCC, TIB-71) MEM, PBS, hard water

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2.2. Test results and result evaluation table

Name of virus	Disinfectant application area	Referance virus titer (1)	Virus titer with disinfectant (2)		Reduction rate by virus titer (3)		Impact assessment method	D
			Clean conditions	Dirty conditions	Clean conditions	Dirty conditions		
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Poliovirus type 1	public and personal space	6.0	2.0	2.0	4.0	4.0	Spearman Karber method	U
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Human adenovirus type 5	public and personal space	5.5	1.5	1.5	4.0	4.0	Spearman Karber method	U
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine - Murine norovirus	public and personal space	5.0	1.0	1.0	4.0	4.0	Spearman Karber method	U

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2.3. Antiviral efficacy study method / procedure information

Experimental parameters	Method / Technique	Method summary
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Poliovirus type 1	Cell culture – Spearman Karber method	The non-toxic concentration of samples in liquid form are determined in the cell culture. After inoculating reference viruses in cells, a non-toxic sample is tested. Compared to virus controls, the virus titer is calculated using the Spearman-Karber method.
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine – Human adenovirus type 5	Cell culture – Spearman Karber method	The non-toxic concentration of samples in liquid form are determined in the cell culture. After inoculating reference viruses in cells, a non-toxic sample is tested. Compared to virus controls, the virus titer is calculated using the Spearman-Karber method.
Virus destroyer analysis of chemical disinfectants and antiseptics used in medicine - Murine norovirus	Cell culture – Spearman Karber method	The non-toxic concentration of samples in liquid form are determined in the cell culture. After inoculating reference viruses in cells, a non-toxic sample is tested. Compared to virus controls, the virus titer is calculated using the Spearman-Karber method.
COMMENT / EXPLANATION	The minimum solution of 0.1% was used in order not to obtain a cytopathic effect, since the 10% and 1% suspensions of the tested PRON-UP CE disinfectant represent a cytopathic effect for the cells in the cell culture. At the end of the calculation of the test result, it was recognized that when using 2gr / liter of the PRON-UP CE disinfectant at room temperature (20 C) and when used for 1 minute in clean and dirty conditions, that with the virus titer at least 4 log were reduced. (see table of results). Disinfectants with product types 1, 2, 3 and 4 must reduce the virus titer of 4 log (3 log for baths) or more due to their viral activity in accordance with the TS EN 14476:2014-02, TS EN 14675 and OECD ENV/JM/MONO(2012)15 standards and biocide regulations. Result: As a result of this experiment, it was recognized that when using 2gr / liter of the PRON-UP CE disinfectant at room temperature (20 C) and an application time of 1 minute, against the poliovirus type 1, human adenovirus type 5 and murine norovirus Is 99.99% effective.	

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3. Approvals and Signatures

Burcin ASUTAY
Biologist
Antiviral effacy Laboratory Unit Manager
SIGNATURE
10.06.2019

Eyüp YILDIZ
Food Technisian
Deputy of Sampling and Reporting Unit
SIGNATURE
10.06.2019

Confirmable
Prof.Dr. Fikrettin ŞAHİN
Head of Laboratory
SIGNATURE
10.06.2019

4. Legal Information

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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. 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.
9. The APPROPRIATE rating, for which the results of the antiviral efficacy test mean that the product is effective against the relevant virus / active strain at working concentration and NOT APPLICABLE means that it was considered ineffective.
10. Limitations used in the antiviral efficacy test report;

    (1) : The logarithmic TCID50 value of the virus in ml.
    (2) : Logarithmic TCID50 value of the virus treated with disinfectant in different times and environments.
    (3) : Logarithmic TCID50 ratio between virus titer and disinfection virus titer.

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