REPUBLIC OF TURKEY
YEDITEPE UNIVERSITY
BIOCIDAL AND R&D LABORATORIES

WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES ANTIVIRAL ACTIVITY ANALYSIS RESULT REPORT

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ANALYSIS AND TRIAL RESULT REPORT

Sample Name	WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES
Sample Registration No	2019-19/AG210019
Report No-Rev. No / Report Code	210051-00 / AG07
Date of Reporting	22.02.2021

REPORT CONTENTS

Yeditepe Üniversitesi 26 Ağustos Yerleşimi, İnönü Mahallesi Kayışdağı Caddesi 34755 Ataşehir / İstanbul
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1. SAMPLE INFORMATIONS

Trade Name Of The Product	WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES
Sample Arrival Date/Hour	10.02.2021
Sample Arrival Form	Delivered by hand
Sample Acceptance Temperature	23 °C
Sample packaging	Plastic
Sample Quantity / Quantity	2 Packs
Analysis Purpose	Special request
Sample Production	-
Sample Matrix/Content	Ethyl Alcohol 30% w/w, 2-Propanol 10% w/w Didecylmethlypoly(oxethyl) Ammonium Propionate 0,25% w/w
Sample Charge / Serial-Lot No	KAFG35-1200212001
Institution / Person Sending the Sample	KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ Atakent Mah. 221 Sk. No:3A Rota Office A blok Kat: 14 D:83 K.ÇEKMECE/İSTANBUL
Address where the sample was taken	-
Sample Production and Expiry Date	12.02.2020-12.02.2022

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2. ANALYSIS RESULTS

2.1. Antiviral Trial Method/Method Application Details

Tested Virus and Strain	Trial Method	Trial Start and End Date	Characteristics of the Virus and the Strain	Application dose	Contact Type	Waiting time	Trial Clean Environment Conditions	Trial Dirty Environment Conditions	Cell Culture and Dilution Buffer
Virusidal Analysis of Chemical Disinfectants and Antiseptics Used in Medicine – Poliovirus Type 1	TS EN 14476	12.02.2021 12.01.2021	ATCC's reference strain with code VR-192	1/1	Liquid mixture (in test plates)	1 minutes	BSA-containing media, (20 °C)	Media containing BSA and sheep erythrocytes, (20 °C)	Hep-2 cell culture (ATCC CCL-23) MEM, PBS, Hard water
Virusidal Analysis of Chemical Disinfectants and Antiseptics Used in Medicine – Human Adenovirus Type 5	TS EN 14476	12.02.2021 12.01.2021	ATCC's reference strain coded VR-5	1/1	Liquid mixture (in test plates)	1 minutes	BSA-containing media, (20 °C)	Media containing BSA and sheep erythrocytes, (20 °C)	Hep-2 cell culture (ATCC CCL-23) MEM, PBS, Hard water
Virusidal Analysis of Chemical Disinfectants and Antiseptics Used in Medicine – Murine norovirus	TS EN 14476	12.02.2021 12.01.2021	ATCC's reference strain code PTA-5935	1/1	Liquid mixture (in test plates)	1 minutes	BSA-containing media, (20 °C)	Media containing BSA and sheep erythrocytes, (20 °C)	RAW cell culture (ATCC TIB-71) MEM, PBS, Hard water

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2.2. Trial Results and Results Evaluation Table

Virus Name	Disinfectant Usage Area	Reference Virus Titer (1)	Virus Titer with Disinfectant (2)		Reduction in Virus Titer (3)		Impact Assessment Method	Conclusion
			Clean Environment	Dirty Environment	Clean Environment	Dirty Environment		
Virusidal Analysis of Chemical Disinfectants and Antiseptics Used in Medicine – Poliovirus Type 1	Public and personal space	5.0	1.5	1.5	4.0	4.0	Instruction on Biocidal Product Analysis and Authorized Laboratories TS EN 14476	qualified
Virusidal Analysis of Chemical Disinfectants and Antiseptics Used in Medicine – Human Adenovirus Type 5	Public and personal space	5.0	1.5	1.5	4.0	4.0	Instruction on Biocidal Product Analysis and Authorized Laboratories TS EN 14476	qualified
Virucidal 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	Instruction on Biocidal Product Analysis and Authorized Laboratories TS EN 14476	qualified

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2.3. Antiviral Efficacy Trial Method/Method Information

Trial Parameter	Method/Technique	Method Summary
Virusidal 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 in cell culture is determined. After inoculation of the reference viruses with the cells, the non-toxic sample is tested. The virus titer is calculated according to the Spearman-karber method by comparing it with the virus controls.
Virusidal 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 in cell culture is determined. After inoculation of the reference viruses with the cells, the non-toxic sample is tested. The virus titer is calculated according to the Spearman-karber method by comparing it with the virus controls.
Virucidal 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 in cell culture is determined. After inoculation of the reference viruses with the cells, the non-toxic sample is tested. The virus titer is calculated according to the Spearman-karber method by comparing it with the virus controls.
COMMENT / EXPLANATION	Since 10% and 1% suspensions of the tested WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES disinfectant showed cytopathic effect on cells in cell culture, the lowest ratio of the disinfectant solution that did not show cytopathic effect, namely 0.1%, was used in this study. In the calculations made as a result of the test, WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES disinfectant is used undiluted (direct 1/1), at room temperature (20 °C), in clean and dirty conditions, as a result of a 1-minute application period, the titer of the virus is titered under all experimental conditions (see result table).) was found to cause at least 4 log reduction. According to TS EN 14476:2014-02, TS EN 14675 and OECD ENV/JM/MONO(2012)15 standards and Biocidal Regulation, Product types 1,2,3 and 4 disinfectants are required to reduce the virus titer of 4 log (3 log for pool waters) or more for their virucidal activity. In conclusion; The results of this experiment were tested WANCARE ONESPRAY ALCOHOL-BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES disinfectant, when used undiluted (direct 1/1), at room temperature (20 °C) for 1 minute application time against Poliovirus Type 1 virus, Human Adenovirus Type 5 virus, Murine Norovirus % 99.99 shows that it is effective.	

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3. APPROVAL AND SIGNATURES

Ayla Burcin ASUTAY
Biologist
Antiviral Activity Lab. Unit Manager

Serap DELİMEHMETOĞULLARI
Biologist
Sample Acceptance and Reporting Unit Manager

Prof. Dr. Fikrettin ŞAHİN
Chair of Biocidal Laboratory

4. LEGAL INFORMATION

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5. GENERAL INFORMATION

1. As a result of the examination and analysis, the above-mentioned values have been determined.
2. Analysis results are valid fort he sample above-mentioned.
3. Any part of this analysis report may be used alone or separately.
4. This report may not be partially copied or reproduced without the written permission of the laboratory.
5. This report cannot be used in judicial/administrative proceedings and for advertising purposes.
6. Unsigned and unsealed reports are invalid.
7. Abbreviations; D: Evaluation. A: It's ok. UD: Not applicable. DY: Evaluation could not be made. GK: Recovery. Ö.B.: Measurement Uncertainty. Ö.L.: Limit of Measurement. USS: Long Term Stability. CSR:Short Term Stability. AUS:Opened Product Stability.
8. As is stated in the "Biocidal Products Regulation" published in the Official Gazette dated 31.12.2009 and repeating numbered 27449 4, and "Instruction on Biocidal Product Analysis and Authorized Laboratories" approved with the consent dated 28.01.2019 and numbered 19020089-704.99-519, physical tests of biocidal products are made. These tests are repeated and reported in each stability test. In case the tests performed do not comply with the product specification, the product is considered not suitable 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.
9. Evaluation of the anti-viral activity test results as SUITABLE means that the product is active against the relevant virus/strain at the concentration studied, and the evaluation as NOT SUITABLE means that it is not effective.
10. Abbreviations used in the report for anti-viral efficacy tests:
(1) : Logarithmic $TCID_{50}$ value of virus in mL.
(2) : Logarithmic $TCID_{50}$ value of the virus treated with disinfectant in different periods and environments.
(3) : Logarithmic $TCID_{50}$ ratio between virus titer and disinfectant virus titer

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