REPUBLIC OF TURKEY
YEDITEPE UNIVERSITY
BIOCIDAL AND R&D LABORATORIES

IRRITATION RESULT REPORT FOR PURE ANTI B HAND DISINFECTANT

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ANALYSIS AND TEST RESULT REPORT

Sample Name	PURE ANTI B HAND DISINFECTANT
Sample Registration Number	2020-366/200366
Report No-Rev. No / Report Code	202840-01/09
Reporting Date	24.08.2020

CONTENT OF THE REPORT

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1. SAMPLE DETAILS

COMMERCIAL NAME OF THE PRODUCT	PURE ANTI B HAND DISINFECTANT
SAMPLE RECEIPT DATE / TIME	20.7.2020 10:12:00
PRODUCT / LICENCE HOLDER	Anatek Kimya San. ve Tic. A.S.
FORM OF FORMULATION	LIQUID
CONTENT OF FORMULATION	Hydrogen Peroxide 5,10% w/w
SENT BY / DATE AND NUMBER OF THE SAMPLE	Anatek Kimya San. ve Tic. A.S.
REASON FOR SENDING, SEAL STATUS AND QUANTITY OF THE SAMPLE	Based on the Licence / 5 x 250 ml
ADDRESS FROM WHICH THE SAMPLE IS RECEIVED	Anatek Kimya San. ve Tic. A.S.
ADDRESS OF THE SAMPLE PRODUCTION PLACE	Anatek Kimya San. ve Tic. A.S.
TYPE OF THE PACKAGING MATERIAL	Plastic
SAMPLE CHARGE / SERIAL NO	-
SAMPLE PRODUCTION AND EXPIRATION DATE	-

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2. ANALYSIS RESULTS

2.1. Irritation Results

TEST COMMENCEMENT AND COMPLETION DATE	20.07.2020-14.08.2020
TESTED ORGANISM AND ITS TYPE	Human keratinocyte cell, ATCC PCS-200-011
APPLICATION MANNER AND DOSAGE	Liquid mixture (in test plaques) was tested directly on cell culture.
CONTACT AND HOLDING PERIOD	Liquid mixture on cell culture, 30 seconds
TESTING AND HOLDING ENVIRONMENT CONDITIONS	Cell culture medium, Temperature: 37°C, Moisture: 80%, CO2: 5%
RESULT	

In vitro result	**In vivo prediction**
Mean tissue viability ≤ 50%	Irritant (I), (R38 veya GHS kategori 2)
Mean tissue viability > 50%	Non-irritant (NI)

In vitro Result	**Viability Result %**
Positive Control	0 %
Negative Control	100 %
PURE ANTI B HAND DISINFECTANT	51 %

EVALUATION (OK / NOT OK)	Ok

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Method / Technique	**Method Summary**
OECD 439	Keratinocyte cells are made ready for application after having been cultured as 3 dimensional skin like structures in matrigel environment. Irritation analyses which take as basis the cell viability analyses are made together with the substance to be analyzed on the test plaque containing Positive and Negative controls.
COMMENT / DESCRIPTION	The results show that the product researched is not irritant.
REVISION DESCRIPTION	The report was revised on 24.08.2020 due to the reason that the sample formulation content of the product was written incorrectly by mistake. The report dated 21.08.2020 and Report No-Rev.No / Report Code 202840-00/07 has become invalid.

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3. APPROVAL AND SIGNATURES

// Signature //

Ayla Burcin KESKIN ASUTAY
Biologist
Antiviral Effectiveness Laboratory Unit Supervisor
24.08.2020

// Signature //
Serap DELIMEHMETOGULLARI
Biologist
Sample Acceptance and Reporting Unit Supervisor

// Signature //

Certified
Prof. Dr. Fikrettin SAHIN
Laboratory Supervisor
24.08.2020

4. LEGAL INFORMATION

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5. GENERAL INFORMATION

1. As a result of the examinations and analyses made, the above-stated values were found.
2. The analysis results are valid for the sample specified above.
3. Any part of this analysis report may not be used alone or separately.
4. This report may not be partially reproduced without the written consent of the laboratory.
5. This report may not be used for judicial/administrative proceedings and for advertising purpose.
6. The reports without signature and seal are invalid.
7. Abbreviations: D: Evaluation. U: Ok. U.D.: Not Ok. D.Y.: Evaluation could not be made. G.K.: Recovery. O.B.: Measurement Uncertainty. O.L.: Measurement Limit. U.S.S.: Long Term Stability. K.S.S.: Short Term Stability. A.U.S.: Opened Product Stability.
8. As it is stated in “the Biocidal Products Regulation” which was published on the Official Gazette dated 31.12.2009 and repeating number 27449 4 and “the Instruction on Biocidal Product Analyses and Authorizing Laboratories” which was confirmed with the approval dated 28.01.2019 and no 19020089-704.99-519, the physical tests of the Biocidal products are performed. These tests are repeated and reported in each stability test. If the tests performed are not in compliance with the product specification, the product is accepted as non-conforming and the biological effectiveness tests are not performed. Accordingly, the number of the reports to be produced for the same sample will vary according to the analysis results.

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