



ÉMI-TÜV

Értéket teremtünk.
Bizalmat építünk.

SZAKÉRTŐI VÉLEMÉNY

Megbízó neve:
címe:

POLITOOL Tanácsadó és Szolgáltató Kft.
1223 Budapest, Nagytétényi út 180-196.

ÉMI- TÜV SÜD Kft.
Központi Laboratórium
KERMI Osztály
Budapest, 2020.07.28.
Azonosítószám:
E-1554569
Oldal: 1/3

Megbízás kelte:

2020.07.23.

Megbízás tárgya:

Bactakleen Ultra Mist Solution Coronavirus Test
a Test report No. CASSA/200742290-CA37548
alapján

Vizsgálat ideje:

2020.07.23.--2020.07. 28.

Dokumentáció:

Coronavirus Test report
No. CASSA/ 200742290-CA37548



ÉMI-TÜV
KERMI Osztály

Vizsgálati körülmények:

Alkalmazott szerkoncentráció: hígítás nélkül
Hőmérséklet: szobahőmérséklet
Behatási idő: 10 perc
Terhelés: 0,3 g/l marha szérum albumin

Vizsgálati módszer: EN 14476:21013 A1:2005

Első vizsgálat:

Megnevezés	Bactakleen Ultra Mist Solution				
Teszt törzs	Vírus kontroll lg TCID ₅₀ /ml	Citotoxikus hatás lg TCID ₅₀ /ml	Ig R lgTCID ₅₀ /ml	Követel- mény lgTCID ₅₀ /ml	Értékelés
Human coronavirus 229E, ATCC VR-740	7,88 ± 0,37	1,50 ± 00	6,38	≥4	megfelel

Megnevezés	Bactakleen Ultra Mist Solution		
Teszt törzs	Vírus kontroll lg TCID ₅₀ /ml	Citotoxikus hatás lg TCID ₅₀ /ml	R / %
Human coronavirus 229E, ATCC VR-740	7,88 ± 0,37	1,50 ± 00	99,99



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KERMi Osztály

Második vizsgálat:

Megnevezés	Bactakleen Ultra Mist Solution				
Teszt törzs	Vírus kontroll lg TCID ₅₀ /ml	Citotoxikus hatás lg TCID ₅₀ /ml	Ig R lgTCID ₅₀ /ml	Követel- mény lgTCID ₅₀ /ml	Értékelés
Human coronavirus 229E, ATCC VR-740	7,25 ± 0,33	1,50 ± 00	5,75	≥4	megfelel

Megnevezés	Bactakleen Ultra Mist Solution		
Teszt törzs	Vírus kontroll lg TCID ₅₀ /ml	Citotoxikus hatás lg TCID ₅₀ /ml	R / %
Human coronavirus 229E, ATCC VR-740	7,25 ± 0,33	1,50 ± 00	99,99

Schein Miklós

Schein Miklósné
Vizsgáló szakértő



ÉMI-TÜV SÜD Kft.
KERMi Osztály

Varjú András

Varjú András
Osztályvezető

Magasházy György

Magasházy György
Vizsgálati szakértő

Test Report

JOB REF NO. : 2020-05-12-005
DATE RECEIVED : 12th May 2020
DATE REPORTED : 15th July 2020

Test Report No. : CRSSA/200742290-CA37548
Company : Excelsia Technologies Sdn Bhd
Unit 103 1st Floor, Lift 2 Block C,
Damansara Intan, 47400 Petaling Jaya,
Selangor Darul Ehsan

The following merchandise was (were) submitted and identified by the client as:

Sample Description	:	Bactakleen Ultra Mist Solution
Sample Appearance	:	Clear, colourless solution
Sample Receiving Date	:	12 th May 2020
Storage Conditions	:	Room temperature
Testing Period	:	12 th May 2020 – 15 th July 2020
Test Requested	:	Determination of the Virucidal Activity
Test Method	:	EN 14476:2013 + A1: 2015 (E) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)

Test Result : Please see the next page(s)

Tested by : The test was externally provided.

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LOW ZHEN HUI
MULTI-BUSINESS LABORATORY MANAGER
FOOD ANALYST NO. MJMM 0178

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Experimental Conditions

Test Organism(s) : Human coronavirus, strain 229E, ATCC VR-740
Concentration/ Contact Time : 100.00%* / 10 minutes
Loading : 0.30 g/L bovine albumin solution
Test Temperature : 20 ± 1°C
Incubation Period : 5 days, 36 ± 1°C

Test Method and Its Validation

Testing Method : Quantal tests
Inactivation Method : Immediate dilution
Molecular sieving using MicroSpin™ S 400 HR

The results of validation test A, B, and C proved the viability of the method in all cases.

Test Results

The results are stated in Tables A and C.

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Table A: Evaluation of the virucidal activity of Bactakleen Ultra Mist Solution on test strains according to EN 14476

Product : Bactakleen Ultra Mist Solution
Loading : 0.30 g/L bovine albumin solution
Test Strain : *Human coronavirus ATCC VR-740*

Virus control, V_c	Cytotoxicity effect, CE
V_{c1} : 7.88 ± 0.37 V_{c2} : 7.25 ± 0.33	CE_1 : 1.50 ± 0.00 CE_2 : 1.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{s1}	Second assay, N_{s2}	Average reduction
100.00* / 10	N_{s1} : 5.50 ± 0.00 $\lg R_1$: 2.38 ± 0.37	N_{s2} : 5.75 ± 0.33 $\lg R_2$: 1.50 ± 0.47	$\lg R$: 1.94 ± 0.42

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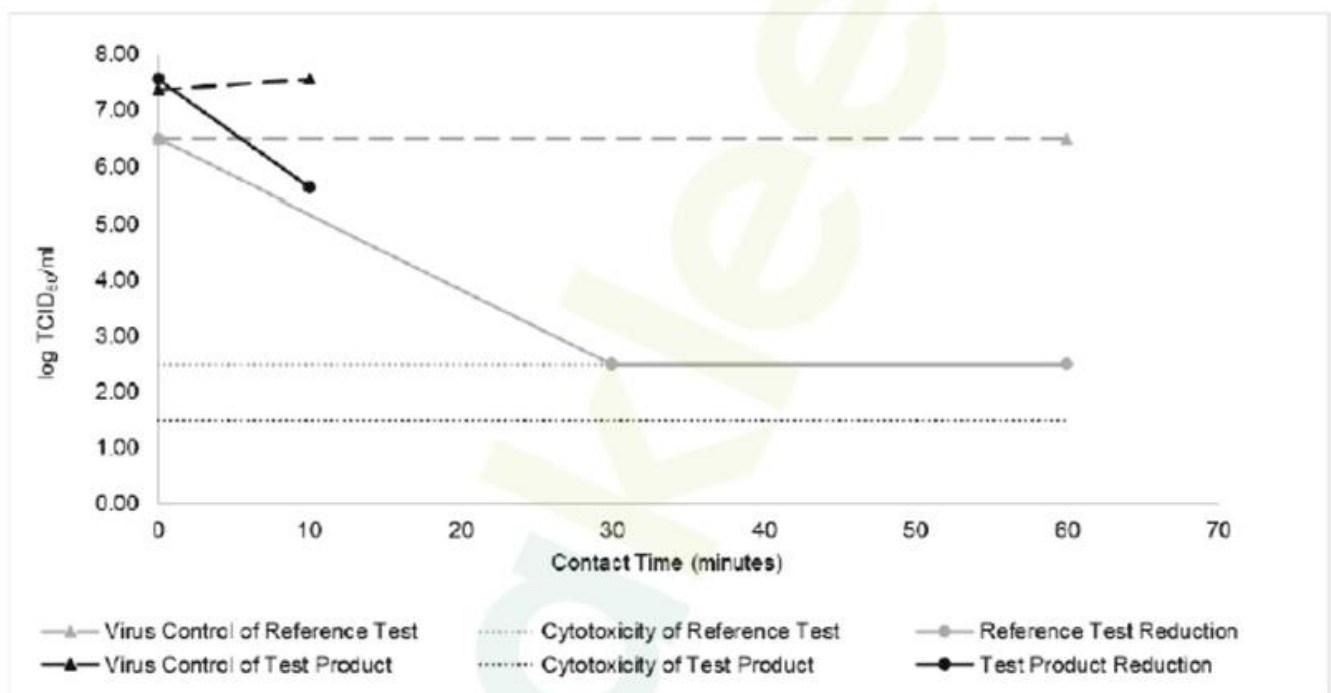
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*The product can only be tested at 80.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

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Table C: Summary of the log reductions of the quantitative suspension test according to EN 14476

Test strain	Test concentration (%) / contact time (min)	Log reduction (TCID ₅₀ /ml)	Associated risk†
Human coronavirus ATCC VR-740	100.00* / 10	1.94 ± 0.42	Minimal risk of false rejection

*The product can only be tested at 80.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

†The decision rule applied is simple acceptance rule with no guard band and up to 50% risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

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Appendix 1

QAU CERTIFICATE*

The results stated in test report CRSSA/200742290-CA37548 dated 15th July 2020 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

*Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

Appendix 2 Raw data

Test Method	EN 14476:2013+A1:2015	Titration Method	Quantal test
Product	Bactakleen Ultra Mist Solution	Batch No.	N/A
Product Diluent	Distilled Water	Lab No.	CA 37548
Test Organism	Human coronavirus, strain 229E, ATCC VR-740	Passage No.	7
Cell Line	MRC-5 cells, ATCC CCL-171	Passage No.	12
Interfering Substance	0.30g/L bovine albumin solution	Inactivation Method	Immediate dilution
Test Temperature (°C)	20	Dilution Method	Standard
	Incubation Temperature (°C)		36

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Validation and Control Procedures

Cell Susceptibility Control	Product Concentration	Dilution	Dilution (log ₁₀)										log ₁₀ TCID ₅₀ /ml	ΔTCID ₅₀ < 1 lg Pass? Yes
			1	2	3	4	5	6	7	8	9	10		
	PBS	Without	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	6.75 ± 0.33	
	100.00 %	1:1000	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	6.50 ± 0.00	

Suppression Efficiency Control	Product Concentration	Contact Time (minutes)	Dilution (log ₁₀)										log ₁₀ TCID ₅₀ /ml	TCID ₅₀ - V _C ≤ 0.5 lg Pass? Yes
			1	2	3	4	5	6	7	8	9	10		
	100.00 %	30	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 0	0 0 0 0	0 0 0 0	n.d.	n.d.	7.25 ± 0.33	
	Virus Control (V _C)	30	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 0	0 0 0 0	0 0 0 0	n.d.	n.d.	7.13 ± 0.37	

Reference Test	Product Concentration	Contact Time (minutes)	Dilution (log ₁₀)										log ₁₀ TCID ₅₀ /ml	lg R = V _C - Na
			1	2	3	4	5	6	7	8	9	10		
	0.70 % Formaldehyde	30	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	2.50 ± 0.00	≥ 4.00 ± 0.00
		60	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	2.50 ± 0.00	≥ 4.00 ± 0.00
	Virus Control (V _C)	0	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	6.50 ± 0.00	
		60	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	6.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	4 4 4 4	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	2.50 ± 0.00	

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Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log ₁₀)										log ₁₀ TCID ₅₀ /ml	
			1	2	3	4	5	6	7	8	9	10		
First Assay (Na ₁)	100.00%	10	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	5.50 ± 0.00	V _{C1} - CE ≥ 4 Pass? Yes
			4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0						
	Virus Control (V _{C1})	0	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	n.d.	n.d.	7.50 ± 0.00	
		10	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 3 0 0	0 0 0 0	n.d.	7.88 ± 0.37	
Cytotoxicity Effect (CE)		-	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
			0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0						

	Product Concentration	Contact Time (minutes)	Dilution (log ₁₀)										log ₁₀ TCID ₅₀ /ml	
			1	2	3	4	5	6	7	8	9	10		
Second Assay (Na ₂)	100.00%	10	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	5.75 ± 0.33	V _{C2} - CE ≥ 4 Pass? Yes
			4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 0 0 0	0 0 0 0						
	Virus Control (V _{C2})	0	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	n.d.	n.d.	7.25 ± 0.33	
		10	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	4 4 4 4	0 0 0 0	0 0 0 0	n.d.	n.d.	7.25 ± 0.33	
Cytotoxicity Effect (CE)		-	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
			0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0						

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na ₁)		Second Assay (Na ₂)		Average Reduction (lg R)
			log ₁₀ TCID ₅₀ /ml	lg R ₁ = V _{C1} - Na ₁	log ₁₀ TCID ₅₀ /ml	lg R ₂ = V _{C2} - Na ₂	
	100.00%	10	5.50 ± 0.00	2.38 ± 0.37	5.75 ± 0.33	1.50 ± 0.47	1.94 ± 0.42

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