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	:	12th May 2020
Storage Conditions	:	Room temperature
Testing Period	:	12th May 2020 – 15th 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.

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

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_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 10	N_{a1}: 5.50 ± 0.00 lg R_1: **2.38 ± 0.37**	N_{a2}: 5.75 ± 0.33 lg R_2: **1.50 ± 0.47**	lg R: **1.94 ± 0.42**

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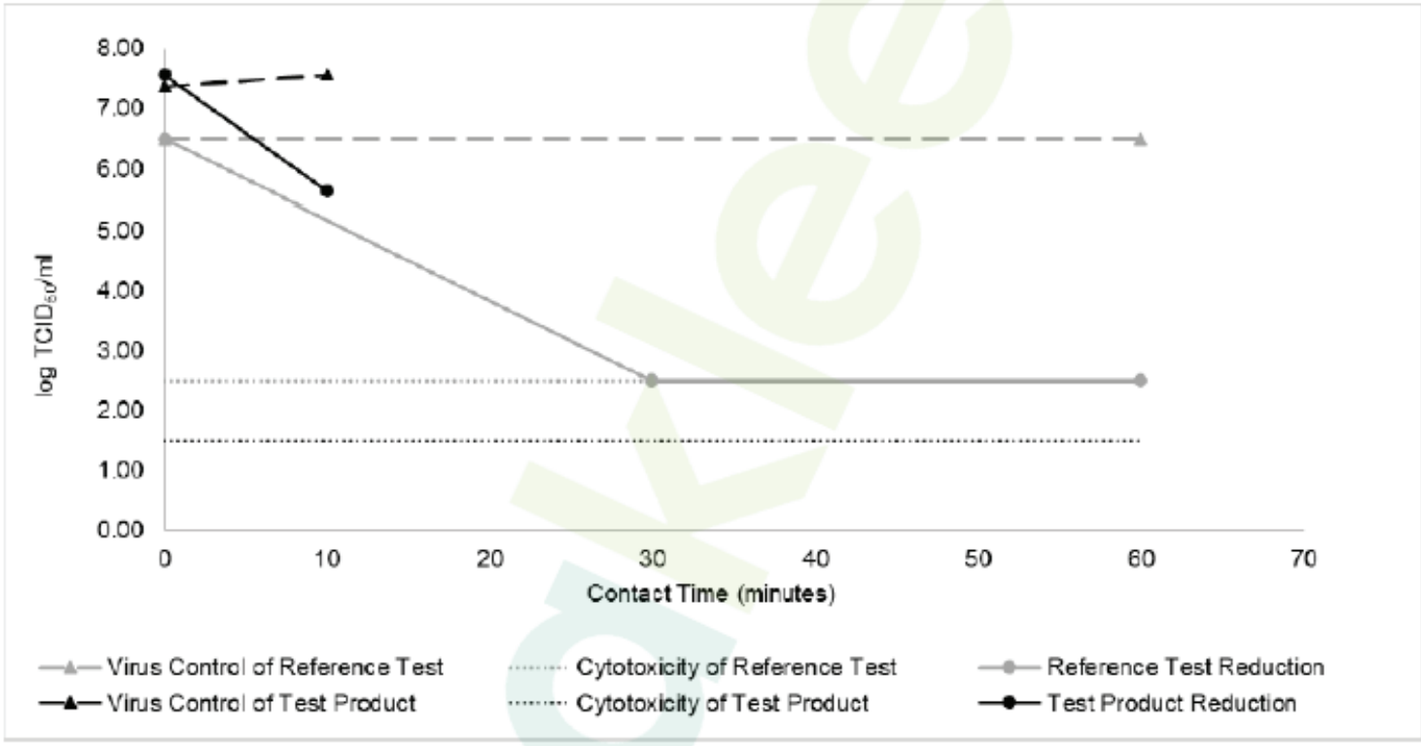

*The product can only be tested at 80.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

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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	Incubation Temperature (°C)	36	Dilution Method	Standard

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Validation and Control Procedures

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

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	t t t t / t t t t	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 4 4 4	4 4 4 0 / 4 3 3 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	7.25 ± 0.33	Pass? Yes
	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 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 3 0 / 4 4 0 0	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	n.d.	n.d.	7.13 ± 0.37	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t / t t t t	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	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.	2.50 ± 0.00	≥4.00 ± 0.00
		60	t t t t / t t t t	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	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.	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 / 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 0 0	0 0 0 0 / 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 / 4 4 4 4	4 4 4 4 / 4 4 4 4	4 4 4 4 / 4 4 3 3	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.	6.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	t t t t / t t t t	0 0 0 0 / 0 0 0 0	0 0 0 0 / 0 0 0 0	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.	2.50 ± 0.00	

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Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00%	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 4 4 4	0 0 0 0 0 0 0 0	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
	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	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	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 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 0 0 3 0 0 0	0 0 0 0 0 0 0 0	n.d.	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	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00%	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 4 4 4	4 0 0 0 4 0 0 0	0 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
	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	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 0 4 4 3 0	0 0 0 0 0 0 0 0	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	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 0 4 4 4 0	0 0 0 0 0 0 0 0	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	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg $R_1 = V_{C1} - Na_1$	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg $R_2 = V_{C2} - Na_2$	Average Reduction (lg R)
	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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