Test Report for Virology
BS EN 14476:2013+A2:2019

Company Name:	**Maclin Sourcing Solutions Ltd**
Contact Name:	Robert Lindfield
Contact Email:	robert@maclingroup.co.uk
Purchase Order No:	DRD20201123
Report Date:	12/03/2021
Melbec Ref Number:	22744
Name of Test Product:	**Prosan Hard Surface Anti-Viral Sanitising Wipes**
Batch Number:	**n/a**

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Sample Details:

Manufacture / Supplier:.....	Maclin Sourcing Solutions Ltd
Product storage conditions:.....	Ambient and out of direct sunlight
Product appearance:.....	Fluid extracted from wipes
Active substance and concentration:.....	Didecyl Dimethylammonium Chloride (DDAC)
Weight/Volume:.....	Volume/Volume
Product dilutions/concentrations:.....	Ready to Use (RTU), 50% and 10%
Diluent used to dilute product:.....	Sterile Deionised Water
Product neutralisation procedure:.....	MicroSpin S 400 HR columns and Large volume plating
Product appearance:.....	Fluid extracted from a wipe
Incubation temperature:	37 ^{o}C ± 1^{o}C CO_2

The test product was in satisfactory condition for testing when received.

Date product received: 27/11/20 Test Date: 25/02/21

Experimental Conditions:

Interfering substance:	Bovine Albumin (dirty 3.0g/l) plus 3.0ml/l erythrocytes
Test temperature:	20 +/- 1 ^{o}C
Contact time:	5 minutes
Test organisms:	*Vaccinia virus VR-1508 (Modified Vaccinia Ankara)*
Cell line identification:	BHK-21 cells
Cell culture media:	Dulbeco's minimum essential medium + 10.0% v/v foetal bovine serum

Requirements of the Standard:

The test product shall demonstrate at least a 4 decimal logarithm (lg) reduction when tested in accordance with this standard under simulated clean or dirty conditions.

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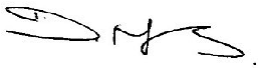
Conclusion:

For the product Vinco-SanWipe, [Batch code: n/a] the log reduction requirements as specified in BS EN 14476:2013+A2:2019 (4 lg within the relevant contact time) were met in dirty conditions with a contact time of 5 minutes.

Testing carried out by:

Name: Dr Nafisa Huq
Position: Head of Virology

Report authorised by:



Name: Dawn Mellors
Position: Technical Director
Date: 12/03/2021

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Method

Test procedure

To determine the virucidal activity of the product, test virus is exposed to product dilutions for the required contact time and subsequently, the product is neutralised. The solution is then serially diluted and titrated on cell monolayers. The surviving virus tissue culture infective dose ($TCID_{50}$) is determined by the appearance of cytopathic effect (CPE) on the cells and is calculated using the Spearman-Kärber calculation.

Several controls are run alongside each test to validate the assay.

Titration of Virus control: The titration of the virus test suspension is determined at the start of the test and at the end of the test to determine its infectivity.

Reference for Virus Inactivation control: Formaldehyde is used instead of the test product, at 2 time points to demonstrate that the virus remains resistant to biocidal action at known concentrations.

Efficiency of Suppression: The test product is neutralised during the test, prior to the addition of test virus. Recovery of the test virus at it's original titre demonstrates effective product neutralisation.

Interference control: Cell are incubated with the test product for 1 hour and subsequently the test virus is added. Recovery of the test virus at it's original titre demonstrates that the presence of the product does prevent infection of the cells by the test virus, and thus does not interfere with quantification of virucidal activity.

Cytotoxicity: Both the product and formaldehyde are incubated with cells, without the addition of test virus, to determine if any morphological changes occur that may mirror CPE normally caused by virus. This ensures any CPE seen is a result of residual virus and not the product.

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Vaccinia virus VR-1508 (Modified Vaccinia Ankara)

Test Results				
Contact time	5 minutes	**Raw data**	**log $TCID_{50}$/ml**	**Log reduction**
Product (RTU)		000000	4.50	4.25
Product (50%)		066400	6.17	2.58
Product (10%)		066660	7.50	1.25
Virus Test Suspension	Start	0666666	**8.75**	
	Finish	0666666		

Inactivation control (0.7% Formaldehyde)			
Contact time	**Raw data**	**log $TCID_{50}$/ml**	**Log reduction**
5 min	066310	6.17	2.58

Formaldehyde cytotoxicity	
Raw data	000000
Level of cytotoxicity	2.50

Product neutralisation		
Raw data	**log $TCID_{50}$/ml**	Log reduction
0066666	8.83	-0.08

Product cytotoxicity	
Raw data	**Level of cytotoxicity**
000000	2.50

Product interference			
	Raw data	**log $TCID_{50}$/ml**	Log reduction
PBS	0666666	8.83	-0.08
Test product	0666666	8.50	
Difference		**0.33**	

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Verification of the methodology

Result Summary	Log of TCID50	Average	Log Reduction	Criteria	met/not met
Titration of Virus Control (Start)	8.83	8.75			
Titration of Virus Control (End)	8.67				
Product (RTU)	4.50		4.25	Log Reduction >= 4 Log	**Met**
Product (50%)	6.17		2.58	Log Reduction >= 4 Log	**N/A**
Product (10%)	7.50		1.25	Log Reduction <= 4 Log	**Met**
Reference test for virus inactivation (15 mins)	5.83		2.92	2.0<=Log reduction=>4.0	**Met**
Efficiency of Suppression	8.83		-0.08	<=0.5 log of Average	**Met**
Inactivation Control (Product)	8.50		0.25	<=0.5 log of Average	**Met**
Inactivation Control (PBS)	8.83		-0.08	<=0.5 log of Average	**N/A**
Product Cytotoxicity	2.50				**N/A**

1) The titre of the test suspension is at least 10^8 TCID50 /ml or is sufficiently high to at least enable a titre reduction of 4 lg to verify the method: detectable titre reduction shall be at least 4 lg.
2) The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test should be between –2,0 and ≥ –4,0 after 15 min for the *Vaccinia virus.*
3) Cytotoxicity of the product test solution should not affect cell morphology and growth or susceptibility for the test organism in the dilutions of the test mixtures which are necessary to demonstrate a 4 lg reduction of the virus.
4) The product should not interfere with susceptibility of the cells to the test organism, the difference in the titre of the test suspension and the recovered titre of the interference control should be <1lg.
5) Control of efficiency for suppression of product activity (the difference to the test suspension shall be ≤ 0,5 lg).
6) At least one concentration per test shall demonstrate a 4 lg or more reduction and at least one concentration shall demonstrate a lg reduction of less than 4.

End of Report

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