Product Information Guide

SilkScreen
Hand Sanitiser

Lasting protection
with a gentle touch

SilkScreen Hand Sanitiser

SilkScreen is a powerful anti-microbial hand sanitiser, available as both a foam and a gel. Once applied it remains active for up to 4 hours, providing ongoing protection from viruses and bacteria. Formulated without alcohol and containing low levels of the active ingredients: chlorhexidine and DDAC.

SilkScreen's gentle action on the skin means it can be used regularly without causing damage to skin or nails. It has been tested against a range of bacteria and enveloped viruses.

While it is recognised that alcohol gels of over 75% are effective against any pathogens present on the hands, they are only active when wet but quickly evaporate and dry out, which can then quickly lead to recontamination. Thanks to its clever formulation, SilkScreen provides up to 4 hours of residual protection once applied, continuing to remain active long after drying.

Features and benefits

The key features and benefits of SilkScreen are as follows:

- Remains active for up to 4 hours.
- Kills 99.999% of bacteria (log 5).
- Kills 99.99% of viruses (log 4).
- Provides an invisible layer of protection which acts like an invisible glove.
- Non-flammable. Cannot combust or explode through heat.
- Gentle on skin.

Recommended usage

SilkScreen can be used wherever high standards of hand hygiene are required and is suitable for use in any environment. Apply sufficient product to cover hands, fingers and nails and rub until dry for a few seconds as the product dries naturally with some friction.

While SilkScreen is best applied to clean hands for maximum, residual protection, it can also be used where hand washing is not possible as an aid to preventing infection and cross contamination by micro-organisms.

Regulatory compliant characteristics

- Colour: **clear**
- Odour: **no odour**
- Oxidising: **non oxidising**
- Solubility: **soluble**
- Viscosity: **foam: non-viscous**
  gel: viscous
- Flash point: **not applicable**
- pH: **6.5 (classed as neutral)**

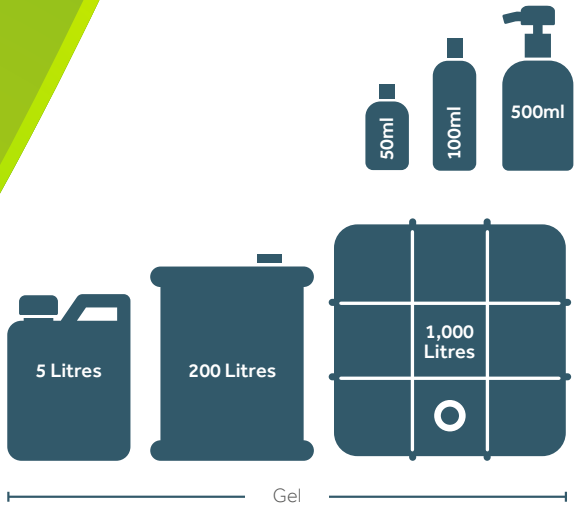
Safety Data Sheet (SDS):

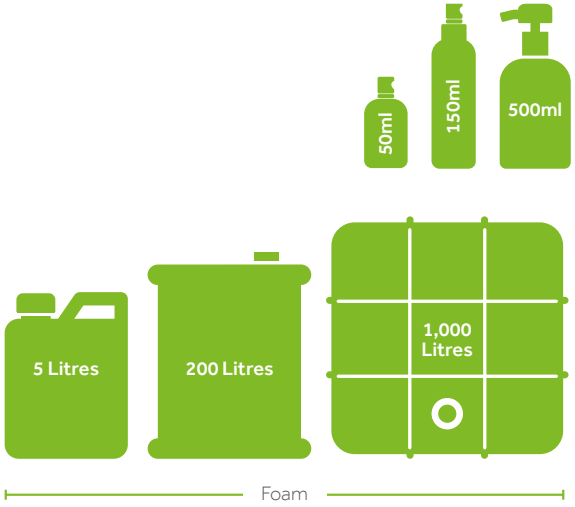
Information on safe handling is contained in the EU safety data sheet which may be obtained on request from the Core Environmental Plc website *here*.

Available product packaging and volume options

Gel: Flip tops 50ml and 100ml, 500ml pump, containers of 5 litre, 200 litres & 1000 litres.

Foam: Pumps 50ml, 150ml and 550ml and containers of 5 litre, 200 Litres & 1000 litres.





Product Test Information:

According to **EN 14476:2013 + A2:2019** SilkScreen possesses Virucidal activity against enveloped viruses with a LOG 4 reduction.

According to **EN 16777:2018** SilkScreen possesses Virucidal activity as per the EN14476:2013 + A2:2019 with residual ongoing activity for at least 4 hours with a LOG 4 reduction.

According to **EN 1276** SilkScreen possesses Bactericidal activity against a vast range of bacteria, achieving a LOG 5 reduction in 5 minutes in dirty (everyday) conditions.

According to **EN 13727:2012+A2:2015 (Medical areas)** SilkScreen possesses a LOG 5 reduction in Bactericidal activity within 30 seconds.

All tests carried out by independent accredited laboratories to the highest standard.

Handling

For handling information of SilkScreen foam or gel please refer to Safety Data Sheet (SDS).

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Environmental

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DECLARATION OF CONFORMITY

SUPPLIER'S DECLARATION OF CONFORMITY

Supplier: Core Environmental PLC, Unit 4 18-20 Millbrook Road East, Southampton, Hampshire, SO15 1HY

Date: 2nd December 2020

Product Type: Hand Sanitiser
Product Name: **SilkScreen**
Product Numbers: SilkScreen Gel (**SSHSG01**) & SilkScreen Foam (**SSHSF01**)
Conforms with the following specifications:

BS EN 1276: 2019 – Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bacterial activity of chemical disinfectants and antiseptics used in food, industrial, domestics and industrial areas.

BS EN 14476:2013 + A2:2019 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area.

BS EN 16777:2018 - Chemical disinfectants and antiseptics. Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants in the medical area.

BS EN 13727:2012+A2:2015 - Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bacterial activity in the medical area.

All tests carried out by independent accredited laboratories to the highest standard.

Stuart Wright
CEO

CORE Environmental

Test Report: EN 16777:2018 Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity in the medical area- Test method and requirements (Phase 2/Step 2)

Test Laboratory	**BluTest Laboratories Ltd** 5 Robroyston Oval, Nova Business Park, Glasgow, G33 1AP

Identification of sample

Name of the product	Silkscreen
Batch number	20108
Client	Core Environmental Plc
Client Address	Unit 4, 18-20 Millbrook Road East, Southampton. SO15 1HY
Project Code	BT-SAM-01
Date of Delivery	18 June 2020
Storage conditions	Ambient
Active substances	Chlohexidine Digluconate, Didecyldimethylammonium Chloride
Manufacturer	Safe Microbial Control Limited

Test Method and its validation

Method	The biocide is applied to the disc and incubated at the indicated contact temperature for the indicated contact times. Product then challenged with 1-part interfering substance + 9-part virus suspension. Assays were validated by a cytotoxicity control, interference control, neutralisation control and an internal standard.
Neutralisation	Dilution-neutralisation/gel filtration Eagle's Minimum Essential Medium + 5% v/v foetal bovine serum at 4°C

Experimental Conditions

Period of analysis	08 October 2020 to 03 November 2020
Product diluents used	Sterile distilled water
Product test concentrations	10.0% v/v; 50.0%; 100.0% v/v
Appearance product dilutions	No changes not- stable
Appearance in test mixture	No changes not- stable
Contact times (minutes)	5 minutes after- 4 hrs; 1 day; 2 days
Test temperature	20°C ± 1°C
Interfering substances	0.3g/l V/V bovine albumin
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification of virus	*Feline coronavirus* VR-929/ CRFK Cells

BLUTEST LABORATORIES LIMITED, 5 Robroyston Oval, Nova Business Park, Glasgow, UK, G33 1AP
Telephone: +44 (0)141 558 2782. Email: info@blutest.com. Web site: www.blutest.com.
Company Registration Number: SC364409 VAT Registration Number: GB 979 1131 96 UKAS Number: 4597

PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with three concentrations of disinfectant and a 5-minute contact time after 4 hours, 1 day and 2 days. Product applied to stainless-steel discs, incubated for the indicated time points and then challenged by the virus. This is then neutralised, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus. *Feline coronavirus* VR-929/ CRFK Cells are assayed in parallel in each test. $TCID_{50}$ is determined by the method of Karber[1].

Cytotoxicity control
The neutralized disinfectant is measured for its effects on the host cells used to propagate the virus, to determine the sensitivity of the assay.

Interference control
The end point titration of the virus is exposed to three different sub-lethal concentrations of neutralized disinfectant to measure the effect of sub-lethal concentrations of disinfectant on virus infectivity in relation to the titre achieved on untreated cells.

Disinfectant suppression control
Virus is added to the highest concentration of disinfectant and then the mixture immediately removed and neutralized. The neutralized virus titre is then determined to assess the efficiency of the neutralization procedure.

Virus recovery control
Virus titre is determined for virus in contact with sterile distilled water at t=0, t= 1 day and at t =2 day. The virus titre after either 0-minute, 1 day or 2 day is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre. The virus titre at 0-minutes is compared to the reference virus inactivation control.

Reference virus inactivation control
Virus is exposed to 0.7% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 30 and 60 minutes, in order to assess that the test virus has retained reproducible biocide resistance. In addition, the formaldehyde cytotoxicity of neutralized formaldehyde is determined, to measure assay sensitivity.

1Kärber, G.: Beitrag zur Kollektiven Behandlung Pharmakologischer Reihenversuche. Arch. Exp. Path. Pharmak. 162 (1931): 480-487.

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Feline coronavirus VR-929 Results

EN16777:2018 Suspension test for the efficacy of Silkscreen, Batch 20108, BT-SAM-01 from Core Environmental Plc. against Feline coronavirus VR-929 under clean conditions

Test Results

Concentration	**10%**		**50%**		**100%**	
Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
t = 4 hours	3.33	**6.76E+04**	1.17	**4.68E+02**	0.00	**3.16E+01**
Raw Data	666200	**6.76E+04**	520000	**4.68E+02**	000000	**3.16E+01**
log		**4.83**		**2.67**		**1.50**
log difference		**0.67**		**2.83**		**4.00**
Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
t = 1 day	2.17	**4.68E+03**	0.00	**3.16E+01**	0.00	**3.16E+01**
Raw Data	652000	**4.68E+03**	000000	**3.16E+01**	000000	**3.16E+01**
log		**3.67**		**1.50**		**1.50**
log difference		**-0.34**		**1.83**		**1.83**
Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
t = 2 days	2.33	**6.76E+03**	0.00	**3.16E+01**	0.67	**1.48E+02**
Raw Data	653000	**6.76E+03**	000000	**3.16E+01**	310000	**1.48E+02**
log		**3.83**		**1.50**		**2.17**
log difference		**-0.50**		**1.83**		**1.16**

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Summary Table

EN16777:2018 Suspension test for the efficacy of Silkscreen, Batch 20108, BT-SAM-01 from Core Environmental Plc. against Feline coronavirus VR-929 under clean conditions									
Summary Table									
Product:	Interfering substance	Concentration	Level of cytotoxicity	lg $TCID_{50}$					>4 lg reduction after 'X' Min
				0 min	60 min	4 hours	1 day	2 days	
Silkscreen	0.3g/l BSA	100%	1.50	1.50	n.a.	1.50	1.50	2.17	4 hours
		50%	1.50	n.a.	n.a.	2.67	1.50	1.50	>2 days
		10%	1.50	n.a.	n.a.	4.83	3.67	3.83	>2 days
Water Control	Clean			5.50	n.a.	n.a.	3.33	3.33	n.a.
							30 min	60 min	
Formaldehyde	PBS	0.7% (w/v)	3.50				2.50	2.50	>60 mins

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Control Data

EN16777:2018 Suspension test for the efficacy of Silkscreen, Batch 20108, BT-SAM-01 from Core Environmental Plc. against Feline coronavirus VR-929 under clean conditions

Controls

Water Control 0 min		Water Control 1 day		Water Control 2 days		Cytotoxicity		Disinfectant Suppression VS		Disinfectant Suppression VS2	
raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
4.00	**3.16E+05**	1.83	**2.14E+03**	1.83	**2.14E+03**	0.00	**3.16E+01**	0.00	**3.16E+01**	4.17	**4.68E+05**
666600	**3.16E+05**	641000	**2.14E+03**	641000	**2.14E+03**	000000	**3.16E+01**	000000	**3.16E+01**	666610	**4.68E+05**
	5.50		**3.33**		**3.33**		**1.50**		**1.50**		**5.67**
									4.00		**-0.17**

Formaldehyde reference inactivation controls

Cytotoxicity		Exposure time	0.7% Formaldehyde			
			30		60	
raw data	$TCID_{50}$/ml		raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
2.00	**3.16E+03**		1.00	**3.16E+02**	1.00	**3.16E+02**
660000	**3.16E+03**		600000	**3.16E+02**	600000	**3.16E+02**
	3.50	log		**2.50**		**2.50**
		log difference		**3.00**		**3.00**

Interference control	Virus dilution					
	-3	**-4**	**-5**	**-6**	**-7**	**-8**
PBS Control	1	1	0.83	0	0	0
	3.16E+02	3.16E+02	2.14E+02	3.16E+01	3.16E+01	3.16E+01
	2.50	**2.50**	**2.33**	**1.50**	**1.50**	**1.50**
Raw Data	**6**	**6**	**5**	**0**	**0**	**0**
Product	1	1	1	0.33	0	0
	3.16E+02	3.16E+02	3.16E+02	6.76E+01	3.16E+01	3.16E+01
	2.50	**2.50**	**2.50**	**1.83**	**1.50**	**1.50**
Raw Data	**6**	**6**	**6**	**2**	**0**	**0**
Log Difference	**0.00**	**0.00**	**-0.17**	**-0.33**	**0.00**	**0.00**
Product Cyt Dilution	-1	-1	-1	-1	-1	-1
PBS Dilution	Neat	Neat	Neat	Neat	Neat	Neat

Stock Virus ($TCID_{50}$) (4 hrs)
5.33
6.76E+06
6666620

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CONCLUSION

Verification of the methodology

A test is only valid if the following criteria are fulfilled:

a) Test virus suspension has at least a concentration which allows the determination of a 4 log_{10} reduction of the virus titre.

b) Detectable titre reduction is at least 4 log_{10}.

c) Difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test is between – 0.5 and – 2.5 after 30 min and between – 2 and – 4.5 after 60 min for virus.

d) Cytotoxicity of the product solution does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4 log_{10} reduction of the virus.

e) The interference control result does not show a difference of > 1.0 log_{10} of virus titre in comparison to the virus recovery control; dilutions of disinfectant to sub-acute levels does not interfere in the generation of viral cytopathic effect.

f) Neutralisation validation. This is called the disinfectant suppression test in this protocol. The disinfectant was neutralized by column chromatography through an Illustra Microspin S-400 HR column to achieve the best possible neutralization available for this test. The difference for virus is slightly elevated indicating rapid irreversible virucidal activity of the disinfectant by dilution at a concentration of 80.0% v/v.

According to EN 16777:2018, **Silkscreen POSSESSES VIRUCIDAL** activity at a concentration of **100.0% v/v** of the working concentration as tested after **4 HOURS** at **20°C** under **CLEAN** conditions (0.3 g/l bovine albumin) against *Feline coronavirus* VR-929/ CRFK Cells.

The water control for the 1-day time point prevented a pass being observed at 50.0% v/v and 100.0%.

The water control for the 2-day time point prevented a pass being observed at 50.0% v/v.

Signed

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
Date: 09 NOVEMBER 2020

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Company Registration Number: SC364409 VAT Registration Number: GB 979 1131 96 UKAS Number: 4597

BS EN 1276:2009

Client Details:	Core Environmental PLC Unit 4 18-20 Millbrook Road East Southampton Hampshire S015 1HY
Client Contact Name:	Stuart Wright
Client Email:	s.wright@corenvironmentalplc
Telephone Number:	
Purchase Order Number:	-
Date Of Report:	21/03/18
MelBec Reference Number:	5167
No. of samples:	1

Sample Details:

Name of Product:	SilkScreen Alcohol free gel and foam hand rub
Batch Number:	-
Manufacturer / Supplier:	SMC (NB. which stands for safe microbial control)
Product Storage conditions:	Ambient
Appearance of the Product (as supplied):	Clear, colourless
Appearance of the Product & Interfering Substance:	Slightly cloudyr, colourless
Active Substance and concentration:	-
Product Dilutions/Concentrations and Diluent:	Ready to Use

Date Product Received: 09/03/18 **Date Tested: 13/03/18**

Obligatory Conditions of EN 1276:

Interfering Substance:	Bovine Albumin
Test Temperature:	20˚C
Contact Time:	5 min or 1 min (Hand disinfection)
Test Organisms:	*Pseudomonas aeruginosa* ATCC 15442, *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541
Incubation Temperature:	36˚C or 37˚C

Experimental Conditions:

Interfering Substance:	Bovine Albumin: 3.0g/l (dirty conditions)
Test Temperature:	20˚C
Contact Time:	30s
Test Organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Staphyloccocus aureus* ATCC 6538 *E.coli* ATCC 10536 *Enterococcus hirae* ATCC 10541 *E.coli* K12 NCTC 10538
Incubation Temperature:	36˚C

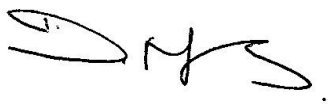
Deviations from the standard (if applicable):

Product Dilutions:	Client only requested testing on the product at one concentration.

Conclusion:

The product SilkScreen Alcohol free gel and foam hand rub met the log reduction requirements as specified in EN 1276 (5 lg within the relevant contact time) in dirty conditions with a contact time of 30s.

Testing carried out by:	Report authorised by:
Gemma Morgan	Dawn Mellors
Technical Manager	Technical Director



Test Results

Membrane Filtration:
Rinsing Liquid N7

Pseudomonas aeruginosa:

Validation and Controls:

Validation Suspension (Nv_0)			Experimental Conditions Control (A)			Neutraliser or Filtration Control (B)			Method Validation (C)		
		Mean			Mean			Mean			Mean
Vc1	106	9.4 x 10^1	Vc1	54	5.45 x 10^1	Vc1	56	5.30 x 10^1	Vc1	59	6.45 x 10^1
Vc2	82		Vc2	55		Vc2	50		Vc2	70	
Is the mean of Nv_0 between 30 and 160:			Is the mean of A ≥ 0.5 x the mean of Nv_0			Is the mean of B ≥ 0.5 x the mean of Nv_0			Is the mean of C ≥ 0.5 x the mean of Nv_0		
Yes:X	No:		Yes:X	No:		Yes:X	No:		Yes:X	No:	

Test Suspension: (N & N_0):

N:

Dilution:		Vc1	Vc2	Mean	
				cfu	lgN
1)	10^{--7}	29	20	3.03 x 10^8	8.48
2)	10^{-6}	315	362		

N_0:

N_0 (N/10) =	3.03 x 10^7	lg N_0 =	7.48
Is lg N_0 between 7.17 and 7.70 (required inoculum)		Yes:X	No:

Test (Na and lgR):

Contact time:	Vc1	Vc2	Na (mean of Vc1 & Vc2 x10)	lgNa	lgR (lgN_0-lgNa)
1: 30 s	0-1	0-1	<140	<2.15	>5.33

Staphylococcus aureus*:*

Validation and Controls:

Validation Suspension (Nv_0)			Experimental Conditions Control (A)			Neutraliser or Filtration Control (B)			Method Validation (C)		
Vc1	77	Mean 7.65 x 10^1	Vc1	86	Mean 8.2 x 10^1	Vc1	53	Mean 4.9 x 10^1	Vc1	79	Mean 7.45 x 10^1
Vc2	76		Vc2	78		Vc2	45		Vc2	70	
Is the mean of Nv_0 between 30 and 160:			Is the mean of A ≥ 0.5 x the mean of Nv_0			Is the mean of B ≥ 0.5 x the mean of Nv_0			Is the mean of C ≥ 0.5 x the mean of Nv_0		
Yes:X	No:		Yes:X	No:		Yes:X	No:		Yes:X	No:	

Test Suspension: (N & N_0):

N:

Dilution:		Vc1	Vc2	Mean	
				cfu	lgN
1)	10^{--7}	30	41	2.76 x 10^8	8.44
2)	10^{-6}	270	266		

N_0:

N_0 (N/10) =	2.76 x 10^7	lg N_0 =	7.44
Is lg N_0 between 7.17 and 7.70 (required inoculum)		Yes:X	No:

Test (Na and lgR):

Contact time:	Vc1	Vc2	Na (mean of Vc1 & Vc2 x10)	lgNa	lgR (lgN_0-lgNa)
1: 30 s	0-1	0-1	<140	<2.15	>5.29

E.coli:

Validation and Controls:

Validation Suspension (Nv_0)			Experimental Conditions Control (A)			Neutraliser or Filtration Control (B)			Method Validation (C)		
Vc1	83	Mean 8.75 x 10^1	Vc1	90	Mean 9.4 x 10^1	Vc1	83	Mean 8.25 x 10^1	Vc1	69	Mean 7.15 x 10^1
Vc2	92		Vc2	98		Vc2	82		Vc2	74	
Is the mean of Nv_0 between 30 and 160:			Is the mean of A ≥ 0.5 x the mean of Nv_0			Is the mean of B ≥ 0.5 x the mean of Nv_0			Is the mean of C ≥ 0.5 x the mean of Nv_0		
Yes:X	No:		Yes:X	No:		Yes:X	No:		Yes:X	No:	

Test Suspension: (N & N_0):

N:

Dilution:		Vc1	Vc2	Mean	
				cfu	lgN
1)	10^{-7}	28	43	3.09 x 10^8	8.49
2)	10^{-6}	279	329		

N_0:

N_0 (N/10) =	3.09 x 10^7	lg N_0 =	7.49
Is lg N_0 between 7.17 and 7.70 (required inoculum)		Yes:X	No:

Test (Na and lgR):

Contact time:	Vc1	Vc2	Na (mean of Vc1 & Vc2 x10)	lgNa	lgR (lgN_0-lgNa)
1: 30 s	0-1	0-1	<140	<2.15	>5.34

Enterococcus hirae:

Validation and Controls:

Validation Suspension (Nv_0)			Experimental Conditions Control (A)			Neutraliser or Filtration Control (B)			Method Validation (C)		
Vc1	70	Mean 7.55 x 10^1	Vc1	48	Mean 5.15 x 10^1	Vc1	47	Mean 4.35 x 10^1	Vc1	49	Mean 4.6 x 10^1
Vc2	81		Vc2	55		Vc2	40		Vc2	43	
Is the mean of Nv_0 between 30 and 160:			Is the mean of A ≥ 0.5 x the mean of Nv_0			Is the mean of B ≥ 0.5 x the mean of Nv_0			Is the mean of C ≥ 0.5 x the mean of Nv_0		
Yes:X	No:		Yes:X	No:		Yes:X	No:		Yes:X	No:	

Test Suspension: (N & N_0):

N:

Dilution:		Vc1	Vc2	Mean	
				cfu	lgN
1)	10^{-7}	28	21	2.56 x 10^8	8.41
2)	10^{-6}	274	240		

N_0:

N_0 (N/10) =	2.56 x 10^7	lg N_0 =	7.41
Is lg N_0 between 7.17 and 7.70 (required inoculum)		Yes:X	No:

Test (Na and lgR):

Contact time:	Vc1	Vc2	Na (mean of Vc1 & Vc2 x10)	lgNa	lgR (lgN_0-lgNa)
1: 30 s	0-1	0-1	<140	<2.15	>5.26

E.coli* K12*:

Validation and Controls:

Validation Suspension (Nv_0)			Experimental Conditions Control (A)			Neutraliser or Filtration Control (B)			Method Validation (C)		
Vc1	69	Mean 6.2 x 10^1	Vc1	66	Mean 6.45 x 10^1	Vc1	51	Mean 5.45 x 10^1	Vc1	57	Mean 5.05 x 10^1
Vc2	55		Vc2	63		Vc2	58		Vc2	64	
Is the mean of Nv_0 between 30 and 160:			Is the mean of A ≥ 0.5 x the mean of Nv_0			Is the mean of B ≥ 0.5 x the mean of Nv_0			Is the mean of C ≥ 0.5 x the mean of Nv_0		
Yes:X	No:		Yes:X	No:		Yes:X	No:		Yes:X	No:	

Test Suspension: (N & N_0):

N:

Dilution:		Vc1	Vc2	Mean	
				cfu	lgN
1)	10^{-7}	31	24	2.60 x 10^8	8.42
2)	10^{-6}	256	262		

N_0:

N_0 (N/10) =	2.60 x 10^7	lg N_0 =	7.42
Is lg N_0 between 7.17 and 7.70 (required inoculum)		Yes:X	No:

Test (Na and lgR):

Contact time:	Vc1	Vc2	Na (mean of Vc1 & Vc2 x10)	lgNa	lgR (lgN_0-lgNa)
1: 30 s	0-1	0-1	<140	<2.15	>5.27

Test Report: BS EN 14476:2013 + A2:2019 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 Laboratory	**BluTest Laboratories Ltd** 5 Robroyston Oval, Nova Business Park, Glasgow, G33 1AP

Identification of sample

Name of the product	Silkscreen
Batch number	HD1204419
Client	Core Environmental Plc
Client Address	Unit 4, 18-20 Millbrook Road East, Southampton. SO15 1HY
Project Code	BT-AGR-01
Date of Delivery	25 March 2020
Storage conditions	Ambient
Active substances	Chlorhexidine Digluconate, Didecyldimethylammonium chloride
Appearance	Clear Liquid
Condition upon receipt	Undamaged
Manufacturer	Safe Microbial Control Limited

Test Method and its validation

Method	1 part interfering substance + 1 part virus suspension + 8 parts biocide were mixed and incubated at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, interference control, neutralisation control and a formaldehyde internal standard.
Neutralisation	Dilution-neutralisation/gel filtration Eagles Minimum Essential Medium + 5.0% v/v foetal bovine serum at 4°C

Experimental Conditions

Period of analysis	06 April 2020 to 11 April 2020
Product diluents used	Sterile distilled water
Product test concentrations	10.0% v/v; 50.0%; 80.0% v/v
Appearance product dilutions	No changes noted- stable
Appearance in test mixture	No changes noted- stable
Contact times (minutes)	2 ± 10s
Test temperature	20°C ± 1°C
Interfering substances	0.3g/l bovine albumin
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification and passage (P) of virus	***Vaccinia virus*** **VR-1549 Elstree strain (P 10)**
Identification and passage (P) of cells	Vero Cells (P 44) (*Vaccinia Virus*)

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Company Registration Number: SC364409 VAT Registration Number: GB 979 1131 96 UKAS Number: 4597

PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with three concentrations of test product solution and a 2 minute contact time. Virus is exposed to disinfectant in 24-well plates, then neutralised, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus. *Vaccinia virus* VR-1549 Elstree strain / Vero cells are assayed in parallel in each test. $TCID_{50}$ is determined by the method of Karber[1].

Cytotoxicity control
The test product solution is measured for its effects on the host cells used to propagate the virus, to determine the sensitivity of the assay.

Interference control
The effect of the cells after treatment of the test product solution are verified to ensure the cells can show susceptibility for virus infection. This is compared against cells that have not been treated with test product.

Disinfectant suppression control VS1
Virus is added to the highest concentration of test product solution and then the mixture immediately removed and neutralised. The neutralised virus titre is then determined to assess the efficiency of the neutralisation procedure.

Disinfectant suppression control VS2
Internal control which adds virus to neutralised test product solution to assess the efficiency of the neutralisation procedure.

No column Control
Internal control on the highest contact time to assess any impact of the Microspin™ S 400 HR columns.

Virus recovery control
Virus titre is determined for virus in contact with sterile distilled water at t=0, t = 2 and at t =15. The virus titre after 2 minutes is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre. The virus titre at 15 minutes is compared to the reference virus inactivation control.

Reference virus inactivation control
Virus is exposed to 0.7% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 5 and 15 minutes, in order to assess that the test virus has retained reproducible biocide resistance. In addition, the formaldehyde cytotoxicity of neutralised formaldehyde is determined, to measure assay sensitivity.

1Kärber, G.: Beitrag zur Kollektiven Behandlung Pharmakologischer Reihenversuche. Arch. Exp. Path. Pharmak. 162 (1931): 480-487.

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Vaccinia virus (VR-1549) Elstree strain Test Results

EN14476:2013 + A2:2019 Suspension test for the efficacy of Silkscreen, Batch HD1204419, BT-AGR-01 from Core Environmental Plc against Vaccinia virus VR-1549 under Clean conditions						
Test Results						
Concentration	**10.0% (v/v)**		**50.0% (v/v)**		**80.0% (v/v)**	
Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
t = 2 minutes	0.00	**3.16E+01**	0.00	**3.16E+01**	1.00	**3.16E+02**
Raw Data	000000	**3.16E+01**	000000	**3.16E+01**	600000	**3.16E+02**
log		**1.50**		**1.50**		**2.50**
log difference		**4.00**		**4.00**		**3.00**

EN14476:2013 + A2:2019 Suspension test for the efficacy of Silkscreen, Batch HD1204419, BT-AGR-01 from Core Environmental Plc against Vaccinia virus VR-1549 under Clean conditions									
Summary Table									
Product:	Interfering substance	Concentration	Level of cytotoxicity	lg $TCID_{50}$					>4 lg reduction after 'X' Min
				0 min	2 min	15 min	30 min	60 min	
Silkscreen	0.3g/l BSA	80.0% (v/v)	2.50	2.50	2.50	n.a.	n.a.	n.a.	>2 mins
		50.0% (v/v)	2.50	n.a.	1.50	n.a.	n.a.	n.a.	<2 mins
		10.0% (v/v)	2.50	n.a.	1.50	n.a.	n.a.	n.a.	<2 mins
Virus Control	DIRTY			5.50	5.50	5.50	5.50	5.50	n.a.
							5 min	15 min	
Formaldehyde	PBS	0.7% (w/v)	3.50				3.83	3.50	>15 mins

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Vaccinia virus (VR-1549) Elstree strain Control Data

EN14476:2013 + A2:2019 Suspension test for the efficacy of Silkscreen, Batch HD1204419, BT-AGR-01 from Core Environmental Plc against Vaccinia virus VR-1549 under Clean conditions

Controls

Virus Recovery 0 min		Virus Recovery 2 min		Virus Recovery 15 min		Cytotoxicity		Disinfectant Suppression VS		Disinfectant Suppression VS2	
raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
4.00	**3.16E+05**	4.00	**3.16E+05**	4.00	**3.16E+05**	1.00	**3.16E+02**	1.00	**3.16E+02**	3.67	**1.47E+05**
666600	**3.16E+05**	666600	**3.16E+05**	666600	**3.16E+05**	600000	**3.16E+02**	600000	**3.16E+02**	666400	**1.47E+05**
	5.50		**5.50**		**5.50**		**2.50**		**2.50**		**5.17**
									3.00		**0.33**

Formaldehyde reference inactivation controls

Cytotoxicity		Exposure time	0.7% Formaldehyde			
			5 mins		15 mins	
raw data	$TCID_{50}$/ml		raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
2.00	**3.16E+03**		2.33	**6.81E+03**	2.00	**3.16E+03**
660000	**3.16E+03**		662000	**6.81E+03**	660000	**3.16E+03**
	3.50	log		**3.83**		**3.50**
		log difference		**1.67**		**2.00**

No column Control	
2 mins	
raw data	$TCID_{50}$/ml
4.17	**4.64E+05**
666610	**4.64E+05**
	5.67

Interference control	Virus dilution					
	-3	-4	-5	-6	-7	-8
PBS Control	1	1	1	0.67	0	0
	3.16E+02	3.16E+02	3.16E+02	1.48E+02	3.16E+01	3.16E+01
	2.50	**2.50**	**2.50**	**2.17**	**1.50**	**1.50**
Raw Data	**6**	**6**	**6**	**4**	**0**	**0**
Product	1	1	1	0.33	0	0
	3.16E+02	3.16E+02	3.16E+02	6.76E+01	3.16E+01	3.16E+01
	2.50	**2.50**	**2.50**	**1.83**	**1.50**	**1.50**
Raw Data	**6**	**6**	**6**	**2**	**0**	**0**
Log Difference	**0.00**	**0.00**	**0.00**	**0.34**	**0.00**	**0.00**
Product Cyt Dilution	-2	-2	-2	-2	-2	-2
PBS Dilution	Neat	Neat	Neat	Neat	Neat	Neat

Stock Virus ($TCID_{50}$)
5.50
1.00E+07
6666630000

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CONCLUSION

Verification of the methodology

A test is only valid if the following criteria are fulfilled:

a) The titre of the test suspension of at least 10^8 TCID50 /ml is sufficiently high to at least enable a titre reduction of 4 lg to verify the method.

b) Detectable titre reduction is at least 4 $\log_{10}$.

c) Difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test is between:
   - Between 0.75 and 3.5 after 5 min and between 2.0 and 4.0 after 15 min for Vaccinia virus

d) Cytotoxicity of the product solution does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4 $\log_{10}$ reduction of the virus.

e) The interference control result does not show a difference of < 1.0 $\log_{10}$ of virus titre for test product treated cells in comparison to the non-treated cells.

e) Neutralisation validation. This is called the disinfectant suppression test in this protocol. The disinfectant was neutralised by column chromatography through an Illustra Microspin S-400 HR column to achieve the best possible neutralisation available for this test. The difference for virus is greater than 0.5 $\log_{10}$ indicating rapid irreversible virucidal activity of the disinfectant by dilution at a concentration of 80.0% v/v for VS1. This neutralisation validation has been verified by VS2, which shows the product has been successfully neutralised.

According to EN 14476:2013 + A2:2019, **Silkscreen POSSESSES VIRUCIDAL** activity at concentrations of **10.0% v/v** and **50.0% v/v** of the working concentration as tested after **2 MINUTES** at **20°C** under **CLEAN** conditions (0.3 g/l bovine albumin) against *Vaccinia virus* VR-1549 Elstree strain / Vero cells.

The cytotoxicity of the product prevented a pass result being observed at 80.0%.

This product therefore is effective against all enveloped viruses as defined in EN 14476:2013 + A2:2019 Annex A*. This therefore includes all coronaviruses and SARS-CoV-2.

Authorised signatory

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
Date: 15 April 2020

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*EN 14476 2013 + A2 2019 Annex A (informative – Enveloped viruses)

Poxviridae
Herpesviridae
Filoviridae (e.g. Ebola, Marburg)
Flavivirus
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Influenza Virus
Paramyxoviridae
Rubella Virus
Measles Virus
Rabies Virus
Coronavirus (e.g. SARS, MERS)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Hepatitis B virus (HBV)

Reference: Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses. Academic Press, San Diego, 2000

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Test Report for Handrub/Sanitiser Products
BS EN 13727:2012+A2:2015

Company Name:	Core Environmental PLC
Contact Name:	Stuart Wright
Contact Email:	s.wright@core-environmentalplc.com
Purchase Order No:	6416
Report Date:	18/01/2021
Melbec Ref Number:	18123
No. of Samples:	1
Name of Test Product:	Superscreen
Batch Number:	20108

Test Report for Handrub/Sanitiser Products
BS EN 13727:2012+A2:2015

Sample Details:

Manufacture / Supplier:.....	Safe Microbial Control
Product storage conditions:.....	Ambient
Appearance of the product (as supplied):.....	Clear colourless liquid
Appearance of the product (after dilution):.....	Clear colourless liquid
Appearance of product with interfering substance and test organism:	Slightly opaque liquid
Active substance and concentration:.....	Chlorhexidine DDAC
Product dilutions/concentrations:.....	RTU, 50% and 10%
Diluent used to dilute product:.....	Sterile Deionised Water
Incubation temperature:	36 degrees

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

Date product received: 19/06/20 Test Date: 14/07/21

Experimental Conditions:

Interfering substance:	Bovine Albumin (dirty 3.0g/l) plus 3ml/l erythrocytes
Test temperature:	18 to 25 ˚C
Contact time:	30 Seconds
Test organisms:	Pseudomonas aeruginosa ATCC 15442
	Staphylococcus aureus ATCC 6538
	Escherichia coli K12 NCTC 10538
	Enterococcus hirae ATCC 10541

Requirements of the Standard:

The test product shall demonstrate at least a 5 decimal logarithm (lg) reduction when tested in accordance with this standard under simulated clean or dirty conditions.

Conclusion:

For the product Superscreen, [20108] the log reduction requirements as specified in EN 13727 (5 lg within the relevant contact time) were met in dirty conditions and a contact time of 30 seconds.

Testing carried out by:

Name: Danika Weatherburn
Position: Laboratory Manager

Report authorised by:

Name: Dawn Mellors
Position: Technical Director
Date: 18/01/2021

Test Results:

Neutralisation Method Used:

Membrane filtration

Rinsing Liquid Used: N7

Pseudomonas aeruginosa ATCC 15442

Validation and controls												Melbec Ref No	18123
Validation suspension (*NvB*) x 10^3			Validation suspension (Nv_0)			Experimental conditions control (***A***)			Neutralizer control (***B***)			Method validation (***C***) Product conc:		RTU
Vc 1	N/A	$\bar{x}$ =	*Vc* 1	117	$\bar{x}$ =	*Vc* 1	85	$\bar{x}$ =	*Vc* 1	85	$\bar{x}$ =	*Vc* 1	61	$\bar{x}$ =
Vc 2	N/A	N/A	*Vc* 2	105	111	*Vc* 2	85	85	*Vc* 2	70	77.5	*Vc* 2	54	57.5
$3.0x10^4 \leq \bar{x}$ of *NvB* $\leq 1.6x10^5$? **N/A**			30 ≤ $\bar{x}$ of Nv_0 ≤ 160? **Yes**			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of Nv_0? **Yes**			$\bar{x}$ of B is ≥ $5.0x10^{-4}$ x $\bar{x}$ of *NvB* ? **Yes**			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of Nv_0 ? **Yes**		

Test suspension and test

Test suspension (*N* and N_0):	***N***	*Vc* 1	*Vc* 2	X m 4.70E+08 ; lg *N* = 8.67
	10^{-6}	>330	>330	$N_0 = N/10$; lg N_0= 7.67
	10^{-7}	49	45	7.17 ≤ lgN_0 ≤ 7.70? Yes
				$\bar{x}$ quotient = >5 and <15? N/A

Conc. of the active (%)	*Vc* 1	*Vc* 2	*Na* = $\bar{x}$ *x10*	lg*Na*	lg*R* N_0 = 7.67		Contact time	Result
RTU	<14	<14	1.40E+02	<2.15		>5.53	30 Seconds	**Pass**
50%	<14	<14	1.40E+02	<2.15		>5.53	30 Seconds	**Pass**
10%	<14	<14	1.40E+02	<2.15		>5.53	30 Seconds	**Pass**

Staphylococcus aureus ATCC 6538

Validation and controls												Melbec Ref No	18123
Validation suspension (*NvB)* x 10^3			Validation suspension (Nv_0)			Experimental conditions control (***A***)			Neutralizer control (***B***)			Method validation (***C***) Product conc:	RTU
Vc 1	N/A	$\bar{x}$ =	*Vc* 1	78	$\bar{x}$ =	*Vc* 1	70	$\bar{x}$ =	*Vc* 1	78	$\bar{x}$ =	*Vc* 1	76	$\bar{x}$ =
Vc 2	N/A	#DIV/0!	*Vc* 2	46	62	*Vc* 2	40	55	*Vc* 2	54	66	*Vc* 2	70	73
$3.0x10^4 \leq \bar{X}$ of *NvB* $\leq 1.6x10^5$? **N/A**			30 ≤ $\bar{X}$ of $Nv_0 \leq 160$? **Yes**			$\bar{X}$ of A is ≥ 0.5 x $\bar{X}$ of Nv_0? **Yes**			$\bar{X}$ of B is ≥ $5.0x10^{-4}$ x $\bar{X}$ of *NvB* ? **Yes**			$\bar{X}$ of C is ≥ 0.5 x $\bar{X}$ of Nv_0 ? **Yes**		

Test suspension and test

Test suspension (*N* and N_0):	***N***	*Vc* 1	*Vc* 2	X wm 2.40E+08	; lg *N* = 8.38
	10^{-6}	231	225	$N_0 = N/10$	; lg N_0= 7.38
	10^{-7}	42	30	7.17 ≤ lgN_0 ≤ 7.70?	Yes
				$\bar{x}$ quotient = >5 and <15?	6.33

Conc. of the active (%)	*Vc* 1	*Vc* 2	*Na* = $\bar{x}$ *x10*	lg*Na*	lg*R* N_0 = 7.38		Contact time	Result
RTU	<14	<14	1.40E+02	<2.15		>5.23	30 Seconds	**Pass**
50%	<14	<14	1.40E+02	<2.15		>5.23	30 Seconds	**Pass**
10%	<14	<14	1.40E+02	<2.15		>5.23	30 Seconds	**Pass**

Test Report for Handrub/Sanitiser Products
BS EN 13727:2012+A2:2015

Escherichia coli K12 NCTC 10538

Validation and controls												Melbec Ref No	18123
Validation suspension (*NvB)* x 10^3			Validation suspension (Nv_0)			Experimental conditions control (***A***)			Neutralizer control (***B***)			Method validation (***C***) Product conc:	RTU
Vc 1	N/A	$\bar{x}$ =	*Vc* 1	84	$\bar{x}$ =	*Vc* 1	63	$\bar{x}$ =	*Vc* 1	75	$\bar{x}$ =	*Vc* 1	76	$\bar{x}$ =
Vc 2	N/A	#DIV/0!	*Vc* 2	79	81.5	*Vc* 2	57	60	*Vc* 2	64	69.5	*Vc* 2	75	75.5
$3.0x10^4 \leq \bar{X}$ of *NvB* $\leq 1.6x10^5$? **N/A**			30 ≤ $\bar{X}$ of Nv_0 ≤ 160? **Yes**			$\bar{X}$ of A is ≥ 0.5 x $\bar{X}$ of Nv_0? **Yes**			$\bar{X}$ of B is ≥ $5.0x10^{-4}$ x $\bar{X}$ of *NvB* ? **Yes**			$\bar{X}$ of C is ≥ 0.5 x $\bar{X}$ of Nv_0 ? **Yes**		

Test suspension and test

Test suspension (*N* and N_0):	***N***	*Vc* 1	*Vc* 2	X wm 3.10E+08 ; lg *N* = 8.49
	10^{-6}	315	294	$N_0 = N/10$; lg N_0= 7.49
	10^{-7}	36	36	7.17 ≤ lgN_0 ≤ 7.70? Yes
				$\bar{x}$ quotient = >5 and <15? 8.46

Conc. of the active (%)	*Vc* 1	*Vc* 2	*Na* = $\bar{x}$ *x10*	lg*Na*	lg*R* N_0 = 7.49		Contact time	Result
RTU	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**
50%	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**
10%	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**

Test Report for Handrub/Sanitiser Products
BS EN 13727:2012+A2:2015

Enterococcus hirae ATCC 10541

Validation and controls												Melbec Ref No	18123
Validation suspension (*NvB*) x 10^3			Validation suspension (Nv_0)			Experimental conditions control (***A***)			Neutralizer control (***B***)			Method validation (***C***) Product conc:		RTU
Vc 1	N/A	$\bar{x}$ =	*Vc* 1	74	$\bar{x}$ =	*Vc* 1	56	$\bar{x}$ =	*Vc* 1	62	$\bar{x}$ =	*Vc* 1	71	$\bar{x}$ =
Vc 2	N/A	#DIV/0!	*Vc* 2	74	74	*Vc* 2	47	51.5	*Vc* 2	48	55	*Vc* 2	60	65.5
$3.0x10^4 \leq \bar{x}$ of *NvB* $\leq 1.6x10^5$? **N/A**			30 ≤ $\bar{x}$ of Nv_0 ≤ 160? **Yes**			$\bar{x}$ of A is ≥ 0.5 x $\bar{x}$ of Nv_0? **Yes**			$\bar{x}$ of B is ≥ $5.0x10^{-4}$ x $\bar{x}$ of *NvB* ? **Yes**			$\bar{x}$ of C is ≥ 0.5 x $\bar{x}$ of Nv_0 ? **Yes**		

Test suspension and test

Test suspension (*N* and N_0):	***N***	*Vc* 1	*Vc* 2	X wm 3.07E+08 ; lg *N* = 8.49
	10^{-6}	308	303	$N_0 = N/10$; lg N_0= 7.49
	10^{-7}	33	32	7.17 ≤ lgN_0 ≤ 7.70? Yes
				$\bar{x}$ quotient = >5 and <15? 9.40

Conc. of the active (%)	*Vc* 1	*Vc* 2	*Na* = $\bar{x}$ *x10*	lg*Na*	lg*R* N_0 = 7.49		Contact time	Result
RTU	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**
50%	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**
10%	<14	<14	1.40E+02	<2.15		>5.34	30 Seconds	**Pass**