alliedhygiene	Sanimed 70% IPA Surface Wipes Allied Code B81080007	Allied Hygiene Systems Ltd 5 Centurion Way Erith, Kent DA18 4AF T: 020 8312 1999 F: 020 8320 8333 admin@alliedhygiene.com www.alliedhygiene.com

DESCRIPTION	A disposable wet wipe designed for the effective disinfection of all surfaces, preventing cross contamination in all healthcare areas.
FEATURES	Tested and approved to European norms EN1276/ EN14348/EN13727 for bactericidal efficacy in medical environments and has effective kill rates against all potentially lethal micro-organisms including MRSA, HIV, C-Difficile, Enterococcus Hirae. Medimax 70% IPA wipes have been tested and conform additionally to EN13624 fungicidal activity and EN14476 (Viral Activity)
USAGE	Also ideal for organic food production as the IPA wipe leaves no residue.

APPEARANCE	2ltr. White pot / White Lid
SOLUTION	70% IPA
SHEET SIZE	200mm x 200mm
PER ROLL	200sheets
PER CASE	10 tubs
CASE PER PALLET	50 Cases
ODOUR	Slight pleasant
COLOUR	White cloth clear liquid
MSDS	70% IPA Mix Wipe

COMPOSITION	100% Aquaspun Polypropylene

TEST ITEM	UNIT	MINIMUM	TARGET	MAXIMUM
WEIGHT	gsm	*22*	23	*24*
THICKNESS	0.mm	*0.14*	0.17	*0.20*
CD - STRENGTH DRY	grams to breaking point	*<200*	200	-
CD - STRENGTH WET		*<200*	200	-
MD - STRENGTH DRY	grams to breaking point	*990*	1175	-
MD - STRENGTH WET		*850*	1050	-
ELONGATION MD	%	*3*	5	*7*
ABSORBANCY	%	*520*	600	-
RUB MD	600 mesh	*250*	278	-
COLOUR	Range	WHITE		
FIBRES MD	%	*0*	1	*2*
COLOUR FAST	PASS / FAIL	-	PASS	-
MESH	30 small 1 large	-	30	-

APPROVED BY	**Paul Newman Quality Manager**	**DATE** 5th April 2019

Test Report: EN 16615:2015

Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2)

Identification of the test laboratory:	Abbott Analytical Ltd Unit 2, Hickmans Road, Birkenhead, CH41 1JH, United Kingdom
Identification of the client:	Allied Hygiene Systems Ltd 5 Centurion Way, Erith, DA18 4AF, United Kingdom
Identification of the sample:	19B/028
Name of the product:	70% IPA
Batch number/reference and expiry date (if available):	N/A
Date of delivery:	21 February 2019
Storage conditions:	Room temperature in darkness
Product diluent recommended by the manufacturer for use:	Not disclosed
Active substance(s) and their concentrations (s) (optional):	Not disclosed
Appearance of the product:	White ready-to-use wipes

Notes:

1) The test results in this report relate only to the sample(s) tested.
2) This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical Ltd.

Test method and its validation:

Method:	Dilution-neutralisation
Neutraliser:	30.0 g/l Polysorbate 80 + 3.0 g/l Lecithin + 1.0 g/l L-histidine + 1.0 g/l L-cysteine (Neutraliser A)
Neutraliser validation:	Validated in accordance with EN 16615:2015 (5.5.2)

Experimental conditions:

Period of analysis:	12 June 2019 to 14 June 2019
Product test concentration(s):	Ready-to-use wipes
Number of layers of wipes used:	5
Diluent used for product test solution(s):	N/A
Contact time(s):	2 min ± 10 s
Test temperature(s):	20°C ± 2.5°C
Interfering substance:	0.3 g/l bovine albumin (clean conditions)
Temperature of incubation:	30°C ± 1°C
Identification of the fungal strain(s) used:	*Candida albicans* (DSM 1386)

Deviations:

1) Wipes provided were ready-to-use pre-moistened wipes used according to the manufacturers' instructions.

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 16615:2015 (5.4.2) or EN 16615:2015 (5.5.1).

Requirements:

The product shall demonstrate at least a 4 decimal log (lg) reduction against every test organism on test field 1. The mean of the accumulation on test fields 2 to 4 shall be less than or equal to 50 cfu for every test organism.

Conclusion:

According to EN 16615:2015, 70% IPA wipes possess yeasticidal activity when tested as ready-to-use wipes (using 5 layers) with a contact time of 2 minutes at 20°C under clean conditions against the referenced strain of *Candida albicans*.

Report prepared by:

Signed: 

Name: Tony Watson

Position: General Manager

Date: 14 June 2019

Approved by:

Signed: 

Name: Gareth Bayliss

Position: Laboratory Manager

Date: 14 June 2019

Results: EN 16615:2015

Test organism:	*Candida albicans*		(DSM 1386)
Date of test:	12 June 2019		
Test temperature:	20°C ± 2.5°C	Incubation temperature:	30°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	A	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Neutraliser or filtration control (*B*)			Method validation (*C*) Product conc.: *RTU*		
*Vc*1	*43*	$\varkappa$ =	*Vc*1	*40*	$\varkappa$ =	*Vc*1	*39*	$\varkappa$ =
*Vc*2	*41*	42	*Vc*2	*37*	38.5	*Vc*2	*43*	41
30 ≤ $\varkappa$ of Nv_o ≤ 160 ? ☒ yes ☐ no			$\varkappa$ of *B* ≥ 0.5 x $\varkappa$ of Nv_o ? ☒ yes ☐ no			$\varkappa$ of *C* ≥ 0.5 x $\varkappa$ of Nv_o ? ☒ yes ☐ no		

Test suspension (*N*):

N	*Vc*1	*Vc*2	$\varkappa$ wm = 4.65 x 10^8	lg *N* = 8.67
10^{-6}	*>330*	*>330*	$N_o = N / 20$;	lg N_o = 7.37
10^{-7}	*49*	*44*	6.88 ≤ lg N_o ≤ 7.40 ?	☒ yes ☐ no

Drying control (Dc_0):

Dc_0	*Vc*1	*Vc*2	$\varkappa$ wm x 5 = 9.02×10^6
10^{-4}	*179*	*181*	lg Dc_0 = 6.96
10^{-5}	*18*	*19*	5.88 ≤ lg N_o ≤ 7.40 ? ☒ yes ☐ no

Drying control (Dc_t):

Dc_t	*Vc*1	*Vc*2	$\varkappa$ wm x 5 = 8.73×10^6
10^{-4}	*176*	*174*	lg Dc_t = 6.94
10^{-5}	*17*	*17*	5.88 ≤ lg N_o ≤ 7.40 ? ☒ yes ☐ no

Test fields (T_1 to T_4):

1:

Conc. of the product	Contact time	T_1		*Na* ($\bar{\varkappa}$ x 5)	lg *Na*	lg *R* (lg Dc_t - lg *Na*)
		*Vc*1	*Vc*2			
RTU	*2 min*	*5*	*6*	<70	<1.85	>5.09

2 to 4:

Conc. of the product	Contact time	T_2		T_3		T_4		$VT_{2\text{ to }4}$ ($\bar{\varkappa}$ x 5)
		*Vc*1	*Vc*2	*Vc*1	*Vc*2	*Vc*1	*Vc*2	
RTU	*2 min*	*0*	*0*	*0*	*0*	*0*	*0*	0
$VT_{2\text{ to }4}$ ≤ 50 cfu/25 cm^2 ? ☒ yes ☐ no								

Water control fields (NwT_2 to NwT_4):

2 to 4:

Contact time	Dilution step	NwT_2		NwT_3		NwT_4		$VNwT_{2\text{ to }4}$ ($\bar{\varkappa}$ x 5)
		*Vc*1	*Vc*2	*Vc*1	*Vc*2	*Vc*1	*Vc*2	
2 min	10^0	*>330*	*>330*	*>330*	*>330*	*>330*	*>330*	8258
	10^{-1}	*191*	*187*	*159*	*149*	*153*	*152*	
$VNwT_{2\text{ to }4}$ ≥ 10 cfu/25 cm^2 ? ☒ yes ☐ no								

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Company number: 10314066

Explanations:

Vc	count per ml (one plate or more)
$\overline{Vc}$	average of *Vc*1 and *Vc*2 (1 + 2 duplicate)
$\overline{Vc}$ wm	weighted mean of $\overline{Vc}$
N	number of cells per ml in the test suspension
Dc_o	number of cells per 25 cm^2 on drying control immediately after the drying time
Dc_t	number of cells per 25 cm^2 on drying control after the drying time plus the contact time
Na	number of cells per 25 cm^2 on test field 1 at the end of the contact time
$VT_{2\ to\ 4}$	number of cells per 25 cm^2 on test fields 2 to 4 at the end of the contact time
$VNwT_{2\ to\ 4}$	number of cells per 25 cm^2 on water control fields 2 to 4 at the end of the contact time
R	reduction (lg *R* = lg Dc_t - lg *Na*)
Nv	number of cells per ml in the validation suspension
Nv_o	number of cells in the validation mixtures at the beginning of the contact time (Nv_o = *Nv* / 10)
B	number of survivors per ml in the neutraliser or filtration control mixture after 5 minutes
C	number of survivors per ml in the method validation mixture after 30 minutes

MS ISO/IEC 17025
TESTING
SAMM NO. 823

Test Report No.: VX-TR-20-0753
Copy No.: 1

DETERMINATION OF THE VIRUCIDAL ACTIVITY (EN 14476) OF SANIMED 70 % IPA WIPE

Lab No.:	VX-109-20-0001
Sample Name:	Sanimed 70 % IPA Wipe
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)
Client:	Allied Hygiene Systems Ltd 5 Centurion Way, Erith, Kent, DA18 4AF, United Kingdom
Sample Receipt Date:	25 September 2020
Report Date:	01 December 2020

Kuala Lumpur, 01 December 2020

Dr Peter Cheong
Head of Microbiology Laboratories

Viroxy Sdn. Bhd. (1193371-A)
6th Floor · Menara RKT · 36 Jalan Raja Abdullah · 50300 Kuala Lumpur · Malaysia
Phone: +60 (0)3 2630 8888 · Fax: +60 (0)3 2630 8085 · info.kl@viroxylabs.com
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Materials and Method

Quantitative suspension test for the evaluation of virucidal activity in the medical area according to EN 14476:2013+A1:2015 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Sample name:	Sanimed 70 % IPA Wipe
2.2	Batch no.:	180820
2.3	Product appearance:	Clear, colourless solution
2.4	Manufacturer:	Allied Hygiene Systems Ltd 5 Centurion Way, Erith, Kent, DA18 4AF, United Kingdom
2.5	Active substances per 100 g:	70 % IPA
2.6	Sample receipt date:	25 September 2020
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water

3. Experimental conditions

3.1	Testing period:	12 November – 23 November 2020
3.2	Test organism(s):	*Human coronavirus*, strain 229E, ATCC VR-740
3.3	Concentration/contact time:	100.00 %*/ 1, 3 and 5 minutes
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Incubation period:	5 days, 36 °C ± 1 °C

4. Test method and its validation

4.1 Testing method: Quantal test

4.2 Inactivation method: Immediate dilution
Molecular sieving using MicroSpin™ S 400 HR (for formaldehyde only)

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

5. Test results

The results are stated in Tables A and B.

6. Conclusion

Sanimed 70 % IPA Wipe showed the required virus reduction of ≥4.0 $\log_{10}$ against test strain *Human coronavirus* ATCC VR-740 in accordance with EN 14476:2013+A1:2015 (E) at 100.00 %* concentration after 1, 3 and 5 minutes under the stated condition. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

Kuala Lumpur, 01 December 2020

Dr Peter Cheong
Head of Microbiology Laboratories

7. Note

Virucidal activity – the capability of a product to produce a reduction in the number of viable viruses belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = V_C/N_a$ = the reduction in viability, or $\lg R = \lg V_C - \lg N_a$

* 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.

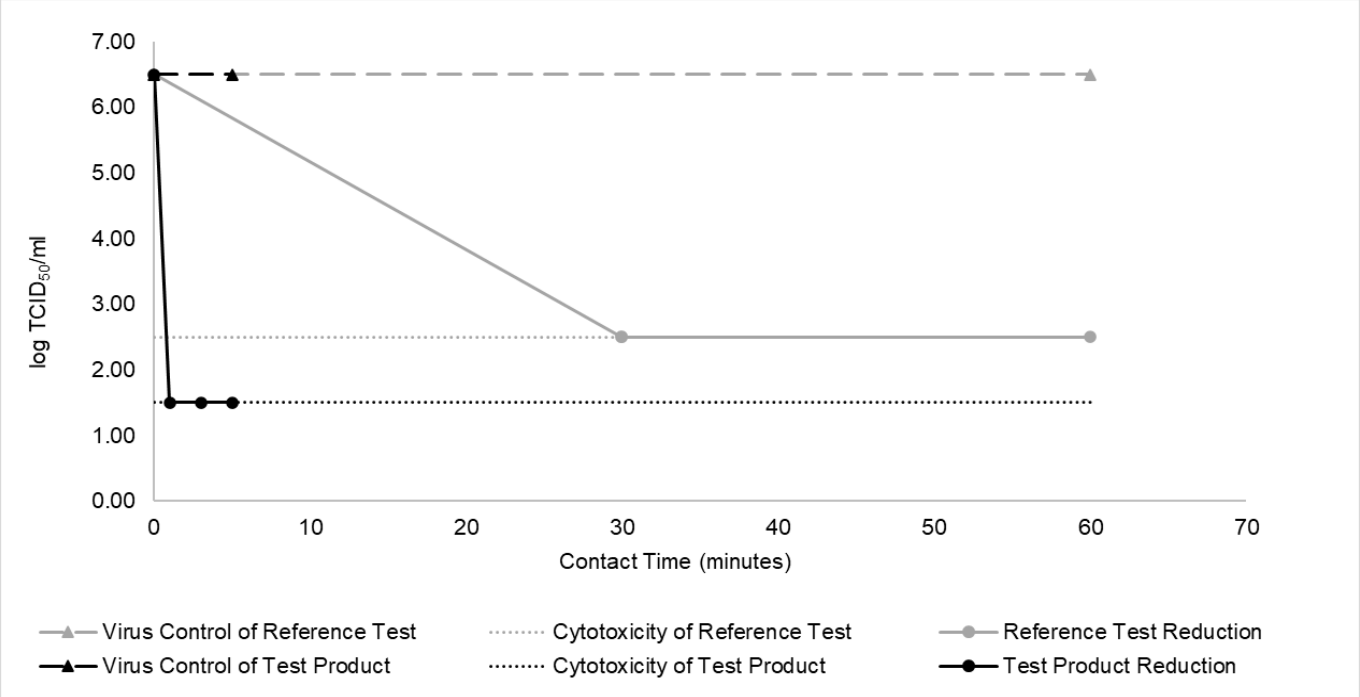
Table A: Evaluation of the virucidal activity of Sanimed 70 % IPA Wipe on test strains according to EN 14476

Product: Sanimed 70 % IPA Wipe
Loading: 0.30 g/L bovine albumin solution

Test strain: *Human coronavirus* ATCC VR-740

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 6.50 ± 0.00 V_{C2}: 6.50 ± 0.00	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* / 1	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥5.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.00 ± 0.00**	lg R: **≥5.00 ± 0.00**
100.00* / 3	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥5.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.00 ± 0.00**	lg R: **≥5.00 ± 0.00**
100.00* / 5	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥5.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.00 ± 0.00**	lg R: **≥5.00 ± 0.00**



* 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.

Table B: Control tests and method validation for Table A

Test strain	Cell susceptibility control	Suppression efficiency control	Reference test for virus inactivation
Human coronavirus ATCC VR-740	A: 6.00 ± 0.38 A_{PBS}: 6.50 ± 0.00	B: 6.25 ± 0.33 V_C: 6.50 ± 0.00	$C_{30:}$ ≥4.00 ± 0.00 $C_{60:}$ ≥4.00 ± 0.00

Note

$TCID_{50}$: The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication.

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_a: log_{10} $TCID_{50}$ per ml in the test mixture at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution.

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vaccinia virus)

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

Test strain	Test concentration (%) / contact time (minute)	Log reduction ($TCID_{50}$/ml)	Associated risk†
Human coronavirus ATCC VR-740	100.00* / 1	**≥5.00 ± 0.00**	minimal risk of false acceptance
	100.00* / 3	**≥5.00 ± 0.00**	minimal risk of false acceptance
	100.00* / 5	**≥5.00 ± 0.00**	minimal risk of false acceptance

* 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.

Allied Hygiene Systems Ltd
5 Centurion Way,
Erith, Kent,
DA18 4AF,
United Kingdom

Efficacy of Sanimed 70 % IPA Wipe against *Human coronavirus,* strain 229E, ATCC VR-740, in a quantitative suspension test at 20 °C according to EN 14476:2013+A1:2015 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-20-0753 dated 01 December 2020.

The virucidal activity of the disinfectant Sanimed 70 % IPA Wipe of Allied Hygiene Systems Ltd against *Human coronavirus* ATCC VR-740 was investigated by a quantitative suspension test according to EN 14476:2013+A1:2015 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal activity if the virus titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

Sanimed 70 % IPA Wipe was examined at 20 °C at the concentration of 100.00 %** for the exposure time of 1, 3 and 5 minutes. After the exposure times, the viral reduction exceeded 4 $\log_{10}$-steps in all assays. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance. Therefore, a virucidal activity against for *Human coronavirus* ATCC VR-740 was measured as follows:

Clean condition	100.00 %**	1 minute
Clean condition	100.00 %**	3 minutes
Clean condition	100.00 %**	5 minutes

Kuala Lumpur, 01 December 2020

Dr Peter Cheong
Head of Microbiological Laboratories

Maizatul Ismail
Microbiologist

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

** 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.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-20-0753 dated 01 December 2020 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 01 December 2020

Maizatul Ismail
Microbiologist

* 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	Sanimed 70% IPA Wipe			**Batch No.**	180820		
Product Diluent	Distilled water			**Lab No.**	VX-109-20-0001		
Test Organism	Human coronavirus, strain 229E, ATCC VR-740			**Passage No.**	4		
Cell Line	MRC-5 cells, ATCC CCL-171			**Passage No.**	11		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution		
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard		
First Assay Test Date	12/11/2020	**Second Assay Test Date**	16/11/2020	**Analyzed By**	WTA	**Verified By**	PCH

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 3 3 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	Pass?
	100.00 %	1:10	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 0 0 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 0 0	n.d.	n.d.	6.00 ± 0.38	Yes

	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	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 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 0	n.d.	n.d.	6.25 ± 0.33	Pass?
	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 3 3 3 4 3 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	Yes

	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	

Appendix 2 Raw data

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)	100.00%	1	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	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	100.00%	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	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	
	100.00%	5	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	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
	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 3 3 3 4 3 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	
		5	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 3 4 3 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)	-	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)	100.00%	1	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	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	100.00%	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	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	
	100.00%	5	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	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
	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 3 3 3 4 3 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	
		5	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 3 4 3 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)	-	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%	1	≤1.50 ± 0.00	≥5.00 ± 0.00	≤1.50 ± 0.00	≥5.00 ± 0.00	≥5.00 ± 0.00
	100.00%	3	≤1.50 ± 0.00	≥5.00 ± 0.00	≤1.50 ± 0.00	≥5.00 ± 0.00	≥5.00 ± 0.00
	100.00%	5	≤1.50 ± 0.00	≥5.00 ± 0.00	≤1.50 ± 0.00	≥5.00 ± 0.00	≥5.00 ± 0.00

Note

$TCID_{50}$: The dilution of the virus suspension that induces a CPE in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication. '0' denotes no CPE and '1' (approximately 25 % of cells) to '4' (all cells) denotes the degree of CPE per cell culture units.

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_a: log_{10} $TCID_{50}$ per ml in the test mixture at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution. 't' denotes the presence of cytotoxicity per cell culture units.

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vaccinia virus)

Appendix 3 Summary of test description

1. Virus and cells

1.1. *Human coronavirus,* strain 229E, ATCC VR-740

1.1.1. Passage no.: 4

1.1.2. Cell line: MRC-5 cells, ATCC CCL-171

1.1.3. Cell line passage no.: 11

1.1.4. Culture medium: EMEM

2. Materials and reagents

2.1. Eagle's Minimal Essential Medium (EMEM, Sigma, catalogue no. M3024)

2.2. Fetal Bovine Serum (FBS, Sigma, catalogue no. F7524)

2.3. Formaldehyde (Merck, catalogue no. 1.0.4003.2500)

2.4. Dulbecco's Phosphate Buffered Saline (PBS, Sigma, catalogue no. P3813)

2.5. Bovine albumin fraction V (Merck, catalogue no. K49238418733)

3. Apparatus and glassware

3.1. CO_2 incubator (Memmert, model ICO 105)

3.2. Cooling water bath (Memmert, model WNB7 with CDP115)

3.3. Inverted microscope (Optika, IM-2)

3.4. Vortex® mixer (Biosan model Biosan V-1 Plus)

3.5. Microtitre plate (NEST)

3.6. Tissue culture flask (JET Biofil)

4. Test procedure

4.1. Preparation of test virus suspension

4.1.1. Cell monolayers shall be >90 % confluent before inoculation. Cell lines are selected in accordance with their sensitivity to the test organisms.

4.1.2. The test organisms and their stock cultures shall be prepared and kept in accordance with EN 12353:2013 (E).

4.1.3. The stock virus suspension is multiplied in an appropriate cell line that produces high titres of infectious viruses for 1 hour at 36 °C with intermittent tilting every 15 minutes.

4.1.4. The cells are subjected to 3 freeze/thaw cycles once cytopathic effect (CPE) is observed in 80 % of the cell population.

4.1.5. Separate the cells debris is by centrifugation at 400 g_N for 15 minutes.

4.1.6. Aliquot the supernatant containing the test virus suspension and store at -80 °C.

4.2. Test Na – Determination of virucidal concentrations

4.2.1. Pipette 1 ml of interfering substance into a container of suitable capacity for appropriate mixing.

4.2.2. Add 1 ml of the virus test suspension to the container, carefully avoiding the upper part of the sides. Mix well.

4.2.3. Add 8 ml of the product test solution to the container.

4.2.4. Mix, start a stopwatch at once, and place the container in a water bath controlled at the chosen test temperature.

4.2.5. Immediately at the end of the chosen contact time, mix, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml ice-cold maintenance medium and put into an ice bath.

4.2.6. Within 30 minutes, prepare a series of ten-fold dilutions of this mixture (text mixture and maintenance medium).

4.2.7. Transfer 0.1 ml of each dilution into six or eight wells of a microtitre plate containing a confluent (>90 %) cell monolayer without any medium.

4.2.8. The last row of six or eight wells will receive 0.1 ml of culture medium and will serve as the cell control.

4.2.9. After 1 hour of incubation at 37 °C, 0.1 ml of cell culture medium is added to each well.

4.2.10. After incubation, the virus titre is calculated. The reduction of virus infectivity is determined from differences of $\log_{10}$ virus titres before and after treatment with the product.

4.3. Cytotoxicity effect – determination of the morphological alteration of cells caused by the product test solution

4.3.1. Mix 1 part of hard water and 1 part of interfering substances with 8 parts of the product test solution.

4.3.2. Serial dilutions are prepared in the culture medium and are inoculated into cell monolayers.

4.3.3. This test is done in parallel with Section 4.2.

4.3.4. Any microscopic changes in the cells are recorded when reading the tests for CPE.

4.3.5. If the cytotoxicity is so great that the residual infectivity titre is smaller than the required $\log_{10}$ $TCID_{50}$, special techniques have to be used, such as molecular sieving or ultrafiltration. Follow the instructions of the manufacturer.

4.4. **Cell susceptibility control A – Verification of the susceptibility of the cells for virus infection is not influenced negatively by the treatment with the product test solution**

4.4.1. Comparative virus titrations are performed on cells that have or have not been treated with product test solution to check the reduction of the sensitivity to viruses.

4.4.2. 0.1 ml of the lowest apparently non-cytotoxic dilution (no microscopic alteration) of the product test solution or PBS and 0.1 ml of culture medium are distributed onto each of 6 established cell cultures in 96-well microtitre plates.

4.4.3. After 1 hour of incubation at 37 °C, the supernatant is discarded.

4.4.4. The virus is diluted from 10^{-1} to 10^{-10} and titrated on the treated or untreated cells.

4.4.5. Verify according to Section 4.8.

4.5. **Suppression efficiency control B – Immediate dilution method validation**

4.5.1. Immediately after preparation of the test mixture in Section 4.2, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml of ice-cold maintenance medium.

4.5.2. Mix again and start the clock. Incubate the mixture in the ice bath for 30 minutes ± 10 seconds.

4.5.3. Immediately prepare dilutions up to 10^{-8} and titrate the virus.

4.5.4. This control is performed in parallel to the test.

4.5.5. Verify according to Section 4.8.

4.6. **Reference test for virus inactivation C – Validation of the test system**

4.6.1. 2 ml of the test suspension shall be mixed with 8 ml of PBS and 10 ml of 1.4 % (w/v) formaldehyde.

4.6.2. Contact times are 30 and 60 minutes.

4.6.3. Immediately at the end of the contact time, mix and pipette 0.2 ml of the test mixture into a tube containing 1.8 ml ice-cold maintenance medium followed by a further 10-fold dilution.

4.6.4. Leave the mixture in the ice bath.

4.6.5. Dilutions up to 10^{-6} are prepared by pipetting the diluted test mixture into another tube containing ice-cold maintenance medium in the ice bath.

4.6.6. In exceptional cases, smaller volumes of the reagents and of the test suspension could be used, ensuring that the relative proportions are maintained.

4.6.7. The cytotoxic control of the formaldehyde shall be performed according to Section 4.3 whereby 8 ml of 1.4 % (w/v) formaldehyde is used instead of the product.

4.6.8. The mixture is further diluted to 10^{-5} in an ice bath.

4.6.9. Verify according to Section 4.8.

4.7. **Titration of the virus control**

4.7.1. The infectivity of the test suspension shall be determined under test conditions at the beginning of the contact time and at the maximum contact time used in the test.

4.7.2. Section 4.2 is repeated by substituting the product test solution with hard water or water for ready-to-use products.

4.7.3. Verify according to Section 4.8.

4.8. **Verification of methodology**

4.8.1. The titre of the test suspension (virus control) of at least 10^8 $TCID_{50}$/mL is sufficiently high to at least enable a titre reduction of 4 log to verify the method. The detectable titre reduction shall be at least 4 log.

4.8.2. Cytotoxicity of the product test solution does 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-log reduction of the virus.

4.8.3. Comparative virus titration on cells cultures treated with test mixture dilutions and in parallel with PBS (cell susceptibility control) result in a difference of <1 log of virus titre.

4.8.4. The difference to the test suspension in the control of efficiency for suppression of products' activity shall be ≤0.5 log.

4.8.5. The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test is:

4.8.5.1. Between -0.5 and -2.5 after 30 minutes and between -2 and -4.5 after 60 minutes for poliovirus

4.8.5.2. Between -3 and -5 after 30 minutes and between -3.5 and -5.5 after 60 minutes for adenovirus

4.8.5.3. Between 0.0 and -2.0 after 30 minutes and between -0.5 and -2.5 after 60 minutes for parvovirus

4.8.5.4. Between -0.75 and -3.5 after 20 and 30 minutes and between -2.0 and ≥-4.0 after 120 and 30 minutes for vaccinia virus.

5. Literature

5.1. 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)

5.2. EN 14885:2015 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

5.3. EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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Certificate of Analysis

Sample(s):	One sample of 70% IPA Formula on Substrate		
Received from:	Allied Paper Products Ltd. 5 Centurion Way, Erith, DA18 4AF		
Date received:	9 December 2011	**Date tested:**	5 January 2012
Certificate no:	11M.018F1.ALH	**Certificate date:**	30 January 2012
Sample ref:	11M/018	**Page:**	1 of 2
Analysis required:	EN 1275, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)		

Product stored at:	Room temperature
Active substance:	Not declared
Test conditions:	Dirty
Interfering substance:	3.0g/l bovine albumin
Product test concentration:	Neat liquor squeezed from wipes (80% in test suspension)
Product diluent used during test:	N/A
Contact time:	1 minute
Test temperature:	20°C ± 0.5°C
Neutralising solution:	30g/l polysorbate 80, 3g/l lecithin, 1g/l histidine, 1g/l cysteine
Incubation temperature:	30°C ± 1°C
Identification of fungal/yeast strain(s) used:	*Aspergillus niger* NCPF 2275 *Candida albicans* NCPF 3179

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Test results:

Test Organism	*Aspergillus niger*		*Candida albicans*	
Validation Suspension	Vc1 188	Vc2 206	Vc1 232	Vc2 216
(Nv_o)	ẍ = 197		ẍ = 224	
Experimental Control	Vc1 166	Vc2 174	Vc1 222	Vc2 200
(A)	ẍ = 170	≥ 0.5Nv_o	ẍ = 211	≥ 0.5Nv_o
Neutraliser Control	Vc1 182	Vc2 158	Vc1 204	Vc2 218
(B)	ẍ = 170	≥ 0.5Nv_o	ẍ = 211	≥ 0.5Nv_o
Method Validation	Vc1 179	Vc2 152	Vc1 190	Vc2 212
(C)	ẍ = 166	≥ 0.5Nv_o	ẍ = 201	≥ 0.5Nv_o
Test Suspension 10^{-5}	Vc1 212	Vc2 196	Vc1 205	Vc2 224
10^{-6}	Vc1 19	Vc2 24	Vc1 18	Vc2 28
(N)	ẅ = 2.05 x 10^7		ẅ = 2.16 x 10^7	
	lg N = 7.31		lg N = 7.33	
(N_o = 0.1N)	lg N_o = 6.31		lg N_o = 6.33	
Results	Vc1 5	Vc2 8	Vc1 0	Vc2 0
(Na)	10ẍ < 140		10ẍ < 140	
	lg Na < 2.15		lg Na < 2.15	
(R)	lg R > 4.17		lg R > 4.19	
Pass: lg R ≥ 4	PASS		PASS	

Vc = plate count per ml
ẍ = average of Vc1 and Vc2
ẅ = weighted mean of ẍ
R = reduction (lg R = lg N_o – lg Na)

Requirements & Conclusion:

The liquor from this batch of 70% IPA Formula on Substrate, when used neat, passes the requirements of EN 1275 for fungicidal/yeasticidal activity in 1 minute at 20°C under dirty conditions.

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Certificate of Analysis

Sample(s):	One sample of 70% IPA Formula on Substrate		
Received from:	Allied Paper Products Ltd. 5 Centurion Way, Erith, DA18 4AF		
Date received:	9 December 2011	**Date tested:**	19 December 2011
Certificate no:	11M.018B.ALH	**Certificate date:**	21 December 2011
Sample ref:	11M/018	**Page:**	1 of 2
Analysis required:	EN 1276, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)		

Product stored at:	Room temperature
Active substance:	Not declared
Test conditions:	Dirty
Interfering substance:	3.0g/l bovine albumin
Product test concentration:	Neat liquor squeezed from wipes (80% in test suspension)
Product diluent used during test:	N/A
Contact time:	30 seconds
Test temperature:	20°C ± 0.5°C
Neutralising solution:	30g/l polysorbate 80, 3g/l lecithin, 1g/l histidine, 1g/l cysteine
Incubation temperature:	37°C ± 1°C
Identification of bacterial strain(s) used:	*Pseudomonas aeruginosa* NCIMB 10421 *Escherichia coli* NCTC 10418 *Staphylococcus aureus* NCTC 10788 *Enterococcus hirae* NCIMB 8192

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Test results:

Test Organism	*Pseudomonas aeruginosa*		*Escherichia coli*		*Staphylococcus aureus*		*Enterococcus hirae*	
Validation Suspension	Vc1 122	Vc2 158	Vc1 152	Vc2 174	Vc1 133	Vc2 150	Vc1 146	Vc2 162
(Nv_o)	$\ddot{x}$ = 140		$\ddot{x}$ = 163		$\ddot{x}$ = 142		$\ddot{x}$ = 154	
Experimental Control	Vc1 112	Vc2 164	Vc1 126	Vc2 184	Vc1 142	Vc2 120	Vc1 134	Vc2 180
(A)	$\ddot{x}$ = 138	≥ $0.5Nv_o$	$\ddot{x}$ = 155	≥ $0.5Nv_o$	$\ddot{x}$ = 131	≥ $0.5Nv_o$	$\ddot{x}$ = 157	≥ $0.5Nv_o$
Neutraliser Control	Vc1 144	Vc2 104	Vc1 138	Vc2 144	Vc1 139	Vc2 93	Vc1 126	Vc2 166
(B)	$\ddot{x}$ = 124	≥ $0.5Nv_o$	$\ddot{x}$ = 141	≥ $0.5Nv_o$	$\ddot{x}$ = 116	≥ $0.5Nv_o$	$\ddot{x}$ = 146	≥ $0.5Nv_o$
Method Validation	Vc1 151	Vc2 125	Vc1 162	Vc2 128	Vc1 118	Vc2 152	Vc1 148	Vc2 124
(C)	$\ddot{x}$ = 138	≥ $0.5Nv_o$	$\ddot{x}$ = 145	≥ $0.5Nv_o$	$\ddot{x}$ = 135	≥ $0.5Nv_o$	$\ddot{x}$ = 136	≥ $0.5Nv_o$
Test Suspension 10^{-6}	Vc1 242	Vc2 256	Vc1 284	Vc2 316	Vc1 270	Vc2 242	Vc1 218	Vc2 234
10^{-7}	Vc1 26	Vc2 33	Vc1 26	Vc2 35	Vc1 29	Vc2 25	Vc1 24	Vc2 28
(N)	$\ddot{w}$ = 2.53×10^8		$\ddot{w}$ = 3.00×10^8		$\ddot{w}$ = 2.57×10^8		$\ddot{w}$ = 2.29×10^8	
	lg N = 8.40		lg N = 8.48		lg N = 8.41		lg N = 8.36	
(N_o = 0.1N)	lg N_o = 7.40		lg N_o = 7.48		lg N_o = 7.41		lg N_o = 7.36	
Results	Vc1 19	Vc2 23	Vc1 11	Vc2 7	Vc1 4	Vc2 0	Vc1 5	Vc2 8
(Na)	10$\ddot{x}$ = 210		10$\ddot{x}$ < 140		10$\ddot{x}$ < 140		10$\ddot{x}$ < 140	
	lg Na = 2.32		lg Na < 2.15		lg Na < 2.15		lg Na < 2.15	
(R)	lg R = 5.08		lg R > 5.33		lg R > 5.26		lg R > 5.21	
Pass: lg R ≥ 5	PASS		PASS		PASS		PASS	

Vc = plate count per ml

$\ddot{x}$ = average of Vc1 and Vc2

$\ddot{w}$ = weighted mean of $\ddot{x}$

R = reduction (lg R = lg N_o - lg Na)

Requirements & Conclusion:

The liquor from this batch of 70% IPA Formula on Substrate, when used neat, passes the requirements of EN 1276 for bactericidal activity in 30 seconds at 20°C under dirty conditions against all of the reference organisms detailed.

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13th March 2009

Certificate of Analysis

Samples:	One sample of 70 / 30 IPA solution received from Allied Paper Products Ltd., 5 Centurion Way, Erith, Kent. DA18 4AF 5th March 2009
Certificate No:	09C.027m.APP
Page:	1 of 1
Sample Ref:	9c / 027
Analysis Required:	EN 13624 Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants used in the medical field.
Samples Tested:	24th November 2008

Product stored at room temperature in the dark.

Experimental conditions:

Product test concentrations	- Neat as received
Contact time	- 15 min
Test Temperature	- 20°C ± 0.5°C
Interferring substance	- 3.0g/l Bovine albumin
Neutralising solution	- 3% Tween 80, 3% Saponin, 0.1% Histidine, 0.1% Cysteine
Temperature of incubation	- 30°C ± 1°C
Identification of mould strains used	- Aspergillus niger NCTC 2275 Candida albicans NCTC 3179

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13th March 2009

Certificate No: 09c.027m.APP

Test Results

Validation test	Candida albicans	Aspergillus niger
Fungal suspension	Vc 222, 248 Nv 2.35×10^5	Vc 388, 430 Nv 4.09×10^5
Experimental conditions	Vc 264, 316 A 2.90×10^2	Vc 267, 298 A 2.82×10^2
Neutraliser control	Vc 236, 260 B 2.48×10^3	Vc 312, 254 B 2.83×10^2
Dilution-neutralisation control	Vc 310, 252 C 2.81×10^2	Vc 250, 325 C 2.87×10^2
Fungal Test Suspension	10^{-5} 256 344 10^{-6} 42 19 N 3.02×10^7	10^{-5} 172 222 10^{-6} 25 18 N 2.06×10^7
Test results		
Vc Na R	12 1200 2.52×10^5	25 2500 8.24×10^4
Log reduction	5.40	4.91

Vc = Viable Count.
N = Number of cfu/ml of the fungal test suspension.
Nv = Number of cfu in fungal suspension.
R = Reduction in viability.
Na = Number of cfu/ml in the test mixture

Conclusion: According to EN13624 this batch of 70 / 30 IPA solution when used neat as received possesses satisfactory fungicidal activity in 15 minutes at 20°C under dirty conditions (3.0g/l bovine albumin / 3.0ml sheep erythrocytes) for the reference organisms detailed.

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13th March 2009

Certificate of Analysis

Samples:	One sample of 70 / 30 IPA solution received from Allied Paper Products Ltd., 5 Centurion Way, Erith, Kent. DA18 4AF 5th March 2009
Certificate No:	09C.027med.APP
Page:	1 of 2
Sample Ref:	9c / 027
Analysis Required:	EN 13727 Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in the medical field.
Samples Tested:	9th March 2009

Product stored at room temperature and shaken well before use.

Experimental conditions:

Product test concentrations	-	Neat as received
Contact time	-	5 min
Test Temperature	-	20°C ± 0.5°C
Interferring substance	-	3.0g/l Bovine albumin 3.0ml/l Sheep erythrocytes
Neutralising solution	-	3% Tween 80, 3% Saponin, 0.1% Histidine, 0.1% Cysteine
Temperature of incubation	-	37°C ± 1°C
Identification of bacterial strains used	-	Pseudomonas aeruginosa ATCC 15442 Escherichia coli NCTC 10418 Staphylococcus aureus NCTC 10788 Enterococcus hirae ATCC 8043

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13th March 2009

Certificate No: 09c.027med.APP

Test Results

Validation test	Pseudomonas aeruginosa	Escherichia coli	Staphylococcus aureus	Enterococcus hirae
Fungal suspension	Vc 292, 250 Nv 2.71×10^3	Vc 354, 438 Nv 3.96×10^3	Vc 433 459 Nv 4.46×10^3	Vc 322, 278 Nv 3.00×10^3
Experimental conditions	Vc 300, 346 Nv 3.23×10^3	Vc 416, 372 Nv 3.94×10^3	Vc 504, 476 Nv 4.90×10^3	Vc 444, 412 Nv 4.28×10^3
Neutraliser control	Vc 444, 458 A 4.51×10^2	Vc 355, 380 A 3.67×10^2	Vc 560, 583 A 5.71×10^2	Vc 400, 376 A 3.88×10^2
Dilution-neutralisation control	Vc 476, 490 B 4.83×10^2	Vc 338, 366 B 3.52×10^2	Vc 558, 577 B 5.67×10^2	Vc 356, 380 B 3.68×10^2
Bacterial Test Suspension	10^{-6} 248 414 10^{-7} 76 58 N 5.00×10^8	10^{-6} 446 392 10^{-7} 33 54 N 4.27×10^8	10^{-6} 696 860 10^{-7} 112 74 N 8.54×10^8	10^{-6} 372 336 10^{-7} 56 41 N 4.19×10^8
Test results				
Vc	0	0	0	0
Na	<100	<100	<100	<100
R	$>5.00 \times 10^6$	$>4.27 \times 10^6$	$>8.54 \times 10^6$	$>4.19 \times 10^6$
Log reduction	>6.70	>6.63	>6.93	>6.62

Vc = Viable Count.
N = Number of cfu/ml of the bacterial test suspension.
Nv = Number of cfu in bacterial suspension.
R = Reduction in viability.
Na = Number of cfu/ml in the test mixture

Conclusion: According to EN13727 this batch of 70 / 30 IPA solution when used neat as received possesses satisfactory bactericidal activity in 5 minutes at 20°C under dirty conditions (3.0g/l bovine albumin plus 3.0ml/l sheep erythrocytes) for the reference organisms detailed.

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Abbott Analytical

Consulting Scientists to the Disinfectant Industry

1st December 2008

Certificate of Analysis

Samples:	One sample of 70% IPA solution received from Allied Paper Products Ltd., 5 Centurion Way, Erith, Kent. DA18 4AF 20th November 2008
Certificate No:	08L.066.APP
Page:	1 of 1
Sample Ref:	81 / 066
Analysis Required:	EN 14348 Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants used in the medical area.
Samples Tested:	24th november 2008

Product stored at room temperature in the dark.

Experimental conditions:

Product test concentrations	- Neat as received
Contact time	- 60 min
Test Temperature	- 20°C ± 0.5°C
Interferring substance	- 3.0g/l Bovine albumin 3.0ml/l Sheep erythrocytes
Neutralising solution	- 3% Tween 80, 3% Saponin, 0.1% Histidine, 0.1% Cysteine
Temperature of incubation	- 30°C ± 1°C
Identification of bacterial strains used	- Mycobacterium terrae ATCC 15755 Mycobacterium avium ATCC 15769

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Test Results

Validation test	Mycobacterium terrae	Mycobacterium avium
Bacterial suspension	Vc 134, 170 Nv 1.52×10^3	Vc 288, 230 Nv 2.59×10^3
Experimental conditions	Vc 155, 223 A 1.89×10^2	Vc 267, 198 A 2.32×10^2
Neutraliser control	Vc 168, 230 B 1.99×10^2	Vc 212, 154 B 1.83×10^2
Dilution-neutralisation control	Vc 120, 186 C 1.53×10^2	Vc 150, 225 C 1.87×10^2
Bacterial Test Suspension	10^{-6} 160 214 10^{-7} 36 26 N 2.48×10^8	10^{-6} 222 260 10^{-7} 35 38 N 3.03×10^8
Test results		
Vc	216	254
Na	21600	25400
R	1.15×10^4	1.19×10^4

Vc = Viable Count.
N = Number of cfu/ml of the bacterial test suspension.
Nv = Number of cfu in bacterial suspension.
R = Reduction in viability.
Na = Number of cfu/ml in the test mixture

Conclusion: According to EN14348 this batch of 70% IPA solution when used neat as received possesses satisfactory mycobactericidal activity in 60 minutes at 20°C under dirty conditions (3.0g/l bovine albumin, 3.0ml sheep erythrocytes) for the reference organisms detailed.

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Certificate of Analysis

Product name:	Sanisafe 70% IPA Wipes		
Batch or ref no:			
Manufacturer or supplier:	Allied Hygiene Systems Ltd 5 Centurion Way, Erith, DA18 4AF		
Sample ref:	16F/023	Date received:	13 June 2016
Date tested:	15 June 2016	Certificate date:	17 June 2016
Certificate no:	16F.023SB.ALH	Page:	1 of 6

Analysis required:
BS **EN 14561**:2006 Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area.

Storage conditions: Room temperature in darkness

Appearance of product (solution): Clear colourless liquid

Active substance(s) and their concentration(s): Not disclosed

Notes

The test results in this report relate only to the sample(s) tested.
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Registered address: Kemp House, 160 City Road,
London, EC1V 2NX, United Kingdom

A company registered in England and Wales
Company number 10031406

Experimental conditions

Concentration(s) of product tested:	Neat solution squeezed from wipes
Product diluent:	N/A
Test organism(s):	Pseudomonas aeruginosa (NCTC 13359) Escherichia coli (NCTC 10418) Staphylococcus aureus (NCTC 10788) Enterococcus hirae (NCTC 13383)
Contact time(s):	5 min ± 10s
Test temperature:	20°C ± 1°C
Test conditions:	Medical dirty
Interfering substance:	3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes
Method:	Dilution-neutralisation
Neutralising solution:	30g/l Polysorbate 80 + 3g/l Lecithin + 1g/l L-histidine + 1g/l L-cysteine
Incubation temperature:	37°C ± 1°C

Conclusion

When tested neat the solution from this sample of Sanisafe 70% Wipes meets the requirements of EN 14561:2006 for bactericidal activity in 5 minutes at 20°C, under medical dirty conditions, against the referenced strains of Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae.

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Results: Pseudomonas aeruginosa (NCTC 13359)

Validation and controls:

Bacterial test suspension (N)		Neutralizer toxicity control (NC)		Method validation (NT)	
Vc1	Vc2	Vc1	Vc2	Vc1	Vc2
10^{-6} >330	>330	10	10^{-4} 96	102	10
10^{-7} 45	39	10	10^{-5} 11	11	10
$\bar{x}$(wm) = 1.05 x 10^{7}			$\bar{x}$(wm) = 9.90 x 10^{6}		$\bar{x}$(wm) = 9.60 x 10^{6}
lg = 7.02			lg = 7.00		lg = 6.98
6.57 ≤ lg N ≤ 7.10 ?			$\bar{x}$ (NC) ≥ 0.5 x $\bar{x}$ (Nc)?		$\bar{x}$ (NT) ≥ 0.5 x $\bar{x}$ (Nc)?
☒ yes ☐ no			☒ yes ☐ no		☒ yes ☐ no
Control of weighted mean counts (N)			Quotient = N/A Between 5 and 15 ?		
					☐ yes ☐ no

Water control:

Nc	Vc1	Vc2	
10^{-4}	165	169	$\bar{x}$(wm) = 1.66 x 10^{7}
	11	15	lg Nc =7.22
10^{-5} Nts	10		lg Nc ≥ 6.27 ?
	8		☒ yes ☐ no

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}$(wm) x10 lg R =Status lg Nd =(lg Nc – lg Nd)	
Neat 5 min	10^{0}	0	0	5.07	PASS< 2.15>
	10^{-1}	0	0		
	10^{-2} Nts	0	0		
		6			

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Results: Escherichia coli (NCTC 10418)

Validation and controls:

Bacterial test suspension (N)	Neutralizer toxicity control (NC)	Method validation (NT)
Vc1 Vc2	Vc1 Vc2	Vc1 Vc2
10^{-6} 330 315 10	10^{-4} 106 108 10	10^{-4} 98 94 10
10^{-7} 39 29 10	10^{-5} 14 15 10	10^{-5} 13 11 10
$\bar{x}$(wm) = 8.10 x 10^{6}	$\bar{x}$(wm) = 1.10 x 10^{7}	$\bar{x}$(wm) = 9.60 x 10^{6}
lg = 6.91	lg = 7.04	lg = 6.98
6.57 ≤ lg N ≤ 7.10 ?	$\bar{x}$ (NC) ≥ 0.5 x $\bar{x}$ (Nc)?	$\bar{x}$ (NT) ≥ 0.5 x $\bar{x}$ (Nc)?
☒ yes ☐ no	☒ yes ☐ no	☒ yes ☐ no
Control of weighted mean counts (N)	Quotient = 9.49 Between 5 and 15 ?	
		☒ yes ☐ no

Water control:

Nc	Vc1	Vc2	
10^{-4}	164 22	169 17	$\bar{x}$(wm) = 1.69 x 10^{7}
10^{-5} Nts	8		lg Nc =7.23
			lg Nc ≥ 6.27 ?
			☒ yes ☐ no

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}$(wm) x10 lg R =Status lg Nd =(lg Nc − lg Nd)	
Neat 5 min	10^{0}				PASS< 2.15>
	10^{-1}	0	0	5.08	
	10^{-2}	0	0		
	Nts	0	0		
		2			

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Results: Staphylococcus aureus (NCTC 10788)

Validation and controls:

Bacterial test suspension (N) Vc1 Vc2	Neutralizer toxicity control (NC) Vc1 Vc2	Method validation (NT) Vc1 Vc2
10^{-6} 319 321 10	10^{-4} 104 108 10	10^{-4} 96 88 10
10^{-7} 41 38 10	10^{-5} 12 15 10	10^{-5} 10 10 10
$\bar{x}$(wm) = 8.17 x 10^{6}	$\bar{x}$(wm) = 1.08 x 10^{7}	$\bar{x}$(wm) = 9.20 x 10^{6}
lg = 6.91	lg = 7.03	lg = 6.96
6.57 ≤ lg N ≤ 7.10 ?	$\bar{x}$ (NC) ≥ 0.5 x $\bar{x}$ (Nc)?	$\bar{x}$ (NT) ≥ 0.5 x $\bar{x}$ (Nc)?
☒ yes ☐ no	☒ yes ☐ no	☒ yes ☐ no
Control of weighted mean counts (N)	Quotient = 8.10 Between 5 and 15 ?	
		☒ yes ☐ no

Water control:

Nc	Vc1	Vc2	$\bar{x}$(wm) = 1.34 x 10^{7} lg Nc =7.13 lg Nc ≥ 6.27 ?
10^{-4}	109 32	114 39	
10^{-5} Nts	9		☒ yes ☐ no

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}$(wm) x10 lg R =Status lg Nd =(lg Nc – lg Nd)	
Neat 5 min	10^{0}				PASS< 2.15>
	10^{-1}	0	0	4.98	
	10^{-2}	0	0		
	Nts	0	0		
		1			

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Results: Enterococcus hirae (NCTC 13383)

Validation and controls:

Bacterial test suspension (N) Vc1 Vc2	Neutralizer toxicity control (NC) Vc1 Vc2	Method validation (NT) Vc1 Vc2
10^{-6} 300 321 10	10^{-4} 294 10	10^{-4} 86 10
10^{-7} 42 34 10	10^{-5} 16 11 10	10^{-5} 14 10 10
$\bar{x}$(wm) = 7.92 x 10^{6}	$\bar{x}$(wm) = 1.01 x 10^{7}	$\bar{x}$(wm) = 9.52 x 10^{6}
lg = 6.90	lg = 7.00	lg = 6.98
6.57 ≤ lg N ≤ 7.10 ? ☒ yes ☐ no	$\bar{x}$ (NC) ≥ 0.5 x $\bar{x}$ (Nc)? ☒ yes ☐ no	$\bar{x}$ (NT) ≥ 0.5 x $\bar{x}$ (Nc)? ☒ yes ☐ no
Control of weighted mean counts (N)	Quotient = 8.17 Between 5 and 15 ?	
		☒ yes ☐ no

Water control:

Nc	Vc1	Vc2	
10^{-4}	68 7	101 9	$\bar{x}$(wm) = 8.45 x 10^{6} lg Nc =6.93 lg Nc ≥ 6.27 ? ☒ yes ☐ no
10^{-5} Nts	7		

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}$(wm) x10 lg R =Status lg Nd =(lg Nc − lg Nd)	
Neat 5 min	10^{0}				PASS< 2.15>
	10^{-1}	0	0	4.78	
	10^{-2}	0	0		
	Nts	0	0		
		8			

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