Clarisan®

Independent test and performance reports



Premium cleaning/ hygiene and infection-control products

HEALTHCARE **SCHOOLS** **CARE HOMES** **FOOD PROCESSING**

Putting more product choice in your hands

Contents

Section 1.0 Introduction

- The Clarisan test report pack has been produced to provide independent assessment of product performance in respect to microbiocidal activity, environmental impact and cleaning capabilities.

- The testing institutions and test protocols selected were chosen to ensure the application of the most stringent and comprehensive testing regimes.

- The microbiocidal tests selected for this report pack are for those organisms which we believe typically represent the high risk elements in the medical, food and industrial environments.

- We have carried out a large number of tests and should you have a specific requirement not covered by the data included in this pack, please advise us and we would be happy to review our records and provide any available repots.

- Our companies product testing philosophy has not only been instrumental in the successful development of our leading edge product range, but also provides our clients with the important reassurance of its superior performance as confirmed by the independent results.

- Should you have any queries in respect to the data contained in these reports, please do not hesitate to get in contact with the team.

2.0 Microbiological Tests: Bio Solution (Non-Alcohol)

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Test Report: Modified EN 14476:2005 Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1) under clean conditions for Human Influenza virus A (H1N1)

Test Laboratory	**BluTest Laboratories Ltd** Robertson Incubator (Level 4) Robertson Building 56 Dumbarton Road Glasgow UK - G11 6NU
Identification of sample	
Name of the product	**CLARISAN SURFACE DISINFECTANT**
Batch number	N/A
Client	**CMS Group Ltd,** Cedar Court, Griffon Road, Quarry Hill Industrial Park, Ilkeston, Derbyshire, DE7 4RF
Project Code	BT-SCC-01
Date of Delivery	22 June 2012
Storage conditions	Stored closed in original packaging only
Active substances	Glutaraldehyde
Test Method and its validation	
Method	I 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, neutralization control and a formaldehyde internal standard.
Neutralization	Dilution-neutralization/gel filtration Modified Eagles medium + 0.125% BSA
Experimental Conditions	
Period of analysis	10 – 13 July 2012
Product diluent used	Sterile distilled water
Product test concentrations	80.00%V/V
Appearance product dilutions	Clear
Contact times (minutes)	1± 10s; 5 ± 10s; 15 ± 10s; 60 ± 10s
Test temperature	20°C ± 1°C
Interfering substances	0.03% V/V BSA
Stability of mixture	Stable
Temperature of incubation	35°C ± 1°C + 5% CO_2
Identification of virus	**Influenza A (H1N1)** (TC Adapted) (ATCC- VR-1469)/MDCK cells

2.1 Clarisan Test Report - Influenza

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with one test per concentration of disinfectant and 1, 5, 15 and 60 minute contact times. Virus is exposed to disinfectant in 24-well plates, then neutralized, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus. $TCID_{50}$ 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 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 hard water at t=0 and at t = 60 (or the longest contact time). The virus titre after 60 minutes (or the longest contact time) is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre.

Reference virus inactivation control
Virus is in contact with 0.07% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 1, 5, 15 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.

2.1 Clarisan Test Report - Influenza

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Suspension test results for the efficacy of CLARISAN SURFACE DISINFECTANT from CMS Group LTD against INFLUENZA VIRUS A (H1N1) under CLEAN CONDITIONS

Exposure Time	Virus Recovery 0 min		Virus Recovery t min		Cytotoxicity		Disinfectant Suppression		80.0% (v/v)	
	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
t = 60	4.17	4.68E+05	4.17	4.68E+05	1.00	3.16E+02	2.83	2.14E+04	1.00	3.16E+02
		4.68E+05		4.68E+05		3.16E+02		2.14E+04		3.16E+02
log		5.67		5.67		2.50		4.33		2.50
log difference								1.34		3.17
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 15	4.17	4.68E+05	4.17	4.68E+05					1.00	3.16E+02
		4.68E+05		4.68E+05						3.16E+02
log		5.67		5.67						2.50
log difference										3.17
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 5	4.17	4.68E+05	4.17	4.68E+05					1.50	1.00E+03
		4.68E+05		4.68E+05						1.00E+03
log		5.67		5.67						3.00
log difference										2.67
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 1	4.17	4.68E+05	4.17	4.68E+05					1.83	2.14E+03
		4.68E+05		4.68E+05						2.14E+03
log		5.67		5.67						3.33
log difference										2.34

2.1 Clarisan Test Report - Influenza

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Suspension test results for the efficacy of CLARISAN SURFACE DISINFECTANT from CMS Group LTD against INFLUENZA VIRUS A (H1N1) under CLEAN CONDITIONS

Product: CLARISAN	Interfering substance	Concentration	Level of cytotoxicity	lg TCID50					>3 lg reduction after .. Min
				0 min	1 min	5 min	15min	60 min	
	0.3g/l BSA	80.0% (v/v)	2.50	5.67	3.33	3.00	2.50	2.50	15 min
Formaldehyde		0.07% (v/v)	2.50	5.67	3.33	2.83	2.50	2.50	>60
Virus Control		n.a.	n.a.	5.67	n.a.	n.a.	n.a.	5.67	n.a.

2.1 Clarisan Test Report - Influenza

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Control Data for INFLUENZA VIRUS A (H1N1)

Stock Virus ($TCID_{50}$)	5.83	2.14E+07

Formaldehyde reference inactivation control

Exposure time	Virus recovery 0 min		Virus recovery 60 min		Cytotoxicity		0.07% (v/v)							
							5		15		30		60	
	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	raw data	$TCID_{50}$/ml
60 min	4.17	4.68E+05	4.17	4.68E+05	1.00	3.16E+02	1.83	2.14E+03	1.33	6.76E+02	1.00	3.16E+02	1.00	3.16E+02
		4.68E+05		4.68E+05		3.16E+02		2.14E+03		6.76E+02		3.16E+02		3.16E+02
log		5.67		5.67		2.50		3.33		2.83		2.50		2.50
log difference								2.34		2.84		3.17		3.17

No Column Control

Virus Recovery	
raw data	$TCID_{50}$/ml
4.50	1.00E+06
	1.00E+06
	6.00

Interference control

	Cytoxicity dilution			
Virus dilution	-1	-2	-3	Mock
-5	0	3	3	3
-6	0	2	3	3
-7	0	1	2	2

2.1 Clarisan Test Report - Influenza

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

CONCLUSION

Verification of the methodology

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

A test is only valid if the following criteria are fulfilled:
a) Test virus suspension has $TCID_{50}$ 10^6/ml, or possesses at least a concentration which allows the determination of a 3 log_{10} reduction of the virus titre; this was achieved (this a modification for influenza A virus, because this virus cannot always achieve a titre to demonstrate a 4 log_{10} reduction)
b) Detectable titre reduction is at least 3 log_{10} (this is a modification for influenza A virus).
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 – 2 and – 4.5 after 60 min; The reference substance used is 0.07% formaldehyde for influenza virus compared to 0.7% V/V for the standard, because influenza is a more sensitive virus to biocidal action
d) Cytotoxicity of the product solution and dilutions of disinfectant to sub-acute levels (interference control), did not affect the demonstration of low efficacy of the test agent.
e) Neutralisation validation. This is called the disinfectant suppression test in this protocol. This was slightly elevated at 1.34 log_{10} reduction and demonstrated effective neutralization of the biocide.
f) When tested under dirty conditions, the product is tested in parallel in the presence and absence of erythrocytes.

According to Modified EN 14476: 2005, CLARISAN SURFACE DISINFECTANT from CMS Group LTD against INFLUENZA VIRUS A (H1N1) possesses virucidal activity in 15 minutes contact (PASS = >3.0 log $_{10}$ reduction) against Influenza Virus A (ATCC VR-1469) at 20ºC UNDER CLEAN CONDITIONS at a concentration of 80.00% V/V.

Signed

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
2 August 2012

UKAS TESTING
4597

"A Statement of the Uncertainty of Measurement can be provided on request"

DISCLAIMER

The results in this test report only pertain to the sample supplied.
BluTest (BT) has performed the testing detailed in this report using reasonable skill and care and has used reasonable endeavours to carry out the testing in accordance with a modified EN 14476 protocol. All forecasts, recommendations and results contained in this report are submitted in good faith. However, other than as expressly set out in this report, no warranty is given (i) in relation to the testing or the use(s) to which any results or deliverables produced in the course of the testing are or may be put by the Client or their fitness or suitability for any particular purpose or under any special conditions notwithstanding that any such purpose or conditions may have been made known to BT or (ii) that the intended results or deliverables from the testing can be achieved or (iii) that the Client can freely make use of the results or the deliverables without infringing any third party intellectual property rights and the Client will be deemed to have satisfied itself in this regard. BT shall have no liability (which is hereby excluded to the fullest extent permissible by law) in respect of any loss, liability or damage, including without limitation any indirect and/or consequential loss such as loss of profit or loss of business, market or goodwill, that the Client may suffer directly or indirectly as a result of or in connection with: (i) the performance of the testing; (ii) the use of any materials, samples or other information provided by the Client for use in the testing; and (iii) the Client's reliance upon or use of any results or deliverables provided as part of the testing.

2.2 Clarisan Test Report - Hepatitis

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Test Report: EN 14476 2005. Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension using Hepatitis C Virus (Bovine Viral Diarrhoea Virus Surrogate)

Test Laboratory	**BluTest Laboratories Ltd** Robertson Incubator (Level 4) Robertson Building 56 Dumbarton Road Glasgow UK - G11 6NU
Identification of sample	
Name of the product	**CLARISAN SURFACE DISINFECTANT**
Batch number	N/A
Client	**CMS Group Ltd,** Cedar Court, Griffon Road, Quarry Hill Industrial Park, Ilkeston, Derbyshire, DE7 4RF
Project Code	BT-SCC-01
Date of Delivery	22 June 2012
Storage conditions	Stored closed in original packaging only
Active substances	Glutaraldehyde
Test Method and its validation	
Method	I 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, neutralization control and a formaldehyde internal standard.
Neutralization	Dilution-neutralization/gel filtration; EMEM + 10% FBS (Australian origin)
Experimental Conditions	
Period of analysis	12 to 17 September 2012
Product diluent used	Sterile distilled water
Product test concentrations	80.00% V/V
Appearance product dilutions	Clear
Contact time (minutes)	1± 10s; 5 ± 10s; 15 ± 10s; 60 ± 10s
Test temperature	20°C ± 1°C
Interfering substance	0.3g/l bovine serum albumin
Stability of mixture	Stable
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification of virus	Bovine Viral Diarrhoea Virus/EBTr cells

2.2 Clarisan Test Report – Hepatitis Cont'd

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with one test per concentration of disinfectant and 1, 5, 15 and 60 minute contact times. Virus is exposed to disinfectant in 24-well plates, then neutralized, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus. $TCID_{50}$ 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 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 hard water at t=0 and at t = 60 (or the longest contact time). The virus titre after 60 minutes (or the longest contact time) is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre.

Reference virus inactivation control
Virus is in contact with 0.7% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 5, 15, 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.

2.2 Clarisan Test Report – Hepatitis Cont'd

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Suspension test results for the efficacy of CLARISAN SURFACE DISINFECTANT from CMS Group LTD against HEPATITIS C VIRUS (Bovine Viral Diarrhoea Virus surrogate) under CLEAN conditions

Exposure Time	Virus Recovery 0 min		Virus Recovery 60 min		Cytotoxicity		Disinfectant Suppression		80.0% (v/v)	
	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
t = 60	5.00	3.16E+06	4.50	1.00E+06	0.00	3.16E+01	0.00	3.16E+01	0.00	3.16E+01
		3.16E+06		1.00E+06		3.16E+01		3.16E+01		3.16E+01
log		6.50		6.00		1.50		1.50		1.50
log difference								4.50		4.50
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 15	5.00	3.16E+06	4.50	1.00E+06					0.00	3.16E+01
		3.16E+06		1.00E+06						3.16E+01
log		6.50		6.00						1.50
log difference										4.50
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 5	5.00	3.16E+06	4.50	1.00E+06					0.00	3.16E+01
		3.16E+06		1.00E+06						3.16E+01
log		6.50		6.00						1.50
log difference										4.50
	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml					raw data	$TCID_{50}$/ml
t = 1	5.00	3.16E+06	4.50	1.00E+06					0.00	3.16E+01
		3.16E+06		1.00E+06						3.16E+01
log		6.50		6.00						1.50
log difference										4.50

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Table of results of virucidal activity for CLARISAN SURFACE DISINFECTANT from CMS Group LTD against HEPATITIS C VIRUS (Bovine Viral Diarrhoea Virus surrogate) under CLEAN conditions

Product: CLARISAN	Interfering substance	Concentration	Level of cytotoxicity	lg TCID50					>4 lg reduction after .. Min
				0 min	1 min	5 min	15min	60 min	
	0.3g/l BSA	80.0% (v/v)	1.50	6.50	1.50	1.50	1.50	1.50	1 min
Formaldehyde		0.7% (v/v)	2.50	6.50	n.a.	2.50	2.50	2.50	>60
Virus Control		n.a.	n.a.	6.50	n.a.	n.a.	n.a.	6.00	n.a.

2.2 Clarisan Test Report – Hepatitis Cont'd

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Control Data for Bovine viral diarrhoea virus

Stock Virus ($TCID_{50}$)	6.17	4.68E+07

Formaldehyde reference inactivation control

Exposure time	Virus recovery 0 min		Virus recovery 60 min		Cytotoxicity		0.7% (v/v)							
							5		15		30		60	
	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	raw data	$TCID_{50}$/ml
60 min	5.00	3.16E+06	4.50	1.00E+06	1.00	3.16E+02	1.00	3.16E+02	1.00	3.16E+02	1.00	3.16E+02	1.00	3.16E+02
		3.16E+06		1.00E+06		3.16E+02		3.16E+02		3.16E+02		3.16E+02		3.16E+02
log		6.50		6.00		2.50		2.50		2.50		2.50		2.50
log difference								3.50		3.50		3.50		3.50

No Column Control

Virus Recovery	
raw data	$TCID_{50}$/ml
4.67	1.48E+06
	1.48E+06
	6.17

Interference control

Virus dilution	Cytoxicity dilution			
	-1	-2	-3	Mock
-4	3	3	3	3
-5	3	3	3	3
-6	3	2	3	3

2.2 Clarisan Test Report – Hepatitis Cont'd

BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Verification of the methodology

A test is only valid if the following criteria are fulfilled:
a) Test virus suspension has $TCID_{50}$ 10^6/ml, or possesses at least a concentration which allows the determination of a 4 log_{10} reduction of the virus titre; this was achieved.
(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 – 2 and – 4.5 after 60 min;
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 comparative virus titration on cells treated with test mixture dilutions (or without, i.e. only addition of PBS)result in a difference of < 1 log_{10} of virus titre; dilutions of disinfectant to sub-acute levels did not interfere in the generation of viral cytopathic effect (Interference control)
e) Neutralisation validation. This is called the disinfectant suppression test in this protocol. In this case the control is elevated.

Conclusion

According to a modified EN 14476 protocol, **CLARISAN SURFACE DISINFECTANT from CMS Group LTD** at a dilution of 80.00% V/V possesses effective virucidal activity (> 4.0 Log_{10} reduction) in 1 minutes, at 20°C under **CLEAN** conditions (0.3% g/l BSA), for suspensions of Hepatitis C virus (Bovine Viral Diarrhoea Virus surrogate ATCC VR – 1422).

Signed

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
25 September 2012

UKAS TESTING
4597

"A Statement of the Uncertainty of Measurement can be provided on request"

DISCLAIMER

The results in this test report only pertain to the sample supplied.
BluTest (BT) has performed the testing detailed in this report using reasonable skill and care and has used reasonable endeavours to carry out the testing in accordance with an EN 14476 protocol. All forecasts, recommendations and results contained in this report are submitted in good faith. However, other than as expressly set out in this report, no warranty is given (i) in relation to the testing or the use(s) to which any results or deliverables produced in the course of the testing are or may be put by the Client or their fitness or suitability for any particular purpose or under any special conditions notwithstanding that any such purpose or conditions may have been made known to BT or (ii) that the intended results or deliverables from the testing can be achieved or (iii) that the Client can freely make use of the results or the deliverables without infringing any third party intellectual property rights and the Client will be deemed to have satisfied itself in this regard. BT shall have no liability (which is hereby excluded to the fullest extent permissible by law) in respect of any loss, liability or damage, including without limitation any indirect and/or consequential loss such as loss of profit or loss of business, market or goodwill, that the Client may suffer directly or indirectly as a result of or in connection with: (i) the performance of the testing; (ii) the use of any materials, samples or other information provided by the Client for use in the testing; and (iii) the Client's reliance upon or use of any results or deliverables provided as part of the testing.

2.3 Clarisan Test Certificate - Tuberculosis

Scientific Services

Consultant Microbiologists
Animal feed Chemists

Willow Farm,
Stewton,
Louth,
Lincolnshire,
LN11 8SD
Mob: 07770 872461
Tel/Messages: 01507 328552
Fax: 01507 328376

K108671-2

16th July 2012

LABORATORY REPORT

SOURCE: CMS Group

ITEMS: Clarisan Surface Disinfectant

TESTS: BSEN14348:2005
Concentration: Neat
Temperature: 20°C
Contact time: 1, 5 and 15 minutes
Interfering substance: Bovine Albumin 3.0g/l + 3.0g/l Sheep Red Cells
Storage conditions: Room temperature, out of direct sunlight
Active substances: Not given
Product appearance: Colourless fluid
Test Date: 25th June 2012

Recovery: Dilution neutralisation, using:-
Tryptone Soya Broth containing Tween 80 100ml/l, Lecithin 30g/l, Sodium thiosulphate 5g/l, L-histidine 1g/l, L-cystine 1g/l

Test organism:Mycobacterium terrae ATCC 15755

2.3 Clarisan Test Certificate - Tuberculosis

SUMMARY & CONCLUSIONS:

Organism	Control	Product	Log Reduction
Mycobacterium terrae ATCC 15755	1.67x10 E7	1 min 2.85x10 E4 5min <10 (<150) 15min <10 (<150)	2.77 >6.22 (>5.04) >6.22 (>5.04)

All test results below 150 (1.5x10 E2) are required to be reported as <150

The product complies with the criteria of BSEN14348:2005 (log 4 reduction in 60 minutes) after 5 minutes contact against Mycobacterium terrae under the test conditions stated.

KMSelf

K.M.Self, M.B.I.C.Sc.,M.R.S.P.H,.A.M.S.B.

Proprietor: K M Self, M.R.S.P.H.,M.B.I.C.Sc.,A.M.S.B., Member of the Society for General Microbiology, Participating in the National Agricultural Check Sample Service

2.4 Clarisan Test Certificate – Clostridium Difficile Spores

Detailed Results K108671-2

Mycobacterium terrae ATCC 15755

Test Suspension (N + No)

N	Vc_1	Vc_2		
10^{-6}	152	170	Weighted Mean = 1.67x10 E8	log = 8.22
10^{-7}	21	24	No = N/10 = 1.67x10 E7	log = 7.22

Test (Na)

	Vc_1	Vc_2	mean		
1min 10^{-3}	27	30	28.5	Na = mean x10 = 2.85x10 E4	log = 4.45
5min 10^{-1}	<1	<1	<1	<10 (<150)	<1 (<2.18)
15 min 10^{-1}	<1	<1	<1	<10 (<150)	<1 (<2.18)

Log Reduction

1 min: 2.77 5 mins: >6.21 (>5.04) 15mins: >6.21 (>5.04)

Validation & Controls

Validation Suspension (Nvo)

Vc_1	Vc_2	mean
61	62	61.5

Experimental Conditions Control (A)

Vc_1	Vc_2	mean
60	54	57

Neutraliser Toxicity Control (B)

Vc_1	Vc_2	mean
52	56	54

Dilution Neutralisation Control (C)

Vc_1	Vc_2	mean
51	53	52

2.4 Clarisan Test Certificate – Clostridium Difficile Spores

Scientific Services

Willow Farm,
Stewton,
Louth,
Lincolnshire,
LN11 8SD
Mob: 07770 872461
Tel/Messages: 01507 328552
Fax: 01507 328376

Consultant Microbiologists
Animal feed Chemists

K108673-4

2nd July 2012

LABORATORY REPORT

SOURCE: CMS Group

ITEMS: Clarisan Surface Disinfectant and wipes

TESTS: BSEN13704:2002
Concentration: Neat
Temperature: 20˚C
Contact time: 1, 5 & 15 mins
Interfering substance: Bovine Albumin 3.0g/l (dirty)
Storage conditions: Room temperature, out of direct sunlight
Active substances: Not given
Product appearance: Colourless fluid
Test Date: 25th June 2012

Recovery: Dilution neutralisation, using:-
Tryptone Soya Broth containing Tween 80 100ml/l, Lecithin 30g/l, Sodium thiosulphate 5g/l, L-histidine 1g/l, L-cystine 1g/l

Test organisms: Clostridium difficile spores, NCTC 11209

2.4 Clarisan Test Certificate – Clostridium Difficile Spores

SUMMARY & CONCLUSIONS:

Organism	Control	Product	Log Reduction
Clostridium difficile spores NCTC 11209	2.19x10 E7	1 min 4.05x10 E4 5 mins 4.45x10 E2 15 mins <10 (<140)	2.73 4.69 >6.34 (>5.19)

All test results below 140 (1.4x10 E2) are required to be reported as <140

The product complies with the criteria of BSEN13704:2002 (log 3 reduction in 60 minutes) against Clostridium difficile spores, after 5 minutes contact, under the test conditions stated.

KMSelf

K.M.Self, M.B.I.C.Sc.,M.R.S.P.H,.A.M.S.B.

Proprietor: K M Self, M.R.S.P.H.,M.B.I.C.Sc.,A.M.S.B., Member of the Society for General Microbiology, Participating in the National Agricultural Check Sample Service

2.4 Clarisan Test Certificate – Clostridium Difficile Spores

Detailed Results K108673-4

Clostridium difficile spores, NCTC 11209

Test Suspension (N + No)

N	Vc1	Vc2		
10^{-6}	218	221	Weighted Mean = 2.19x10 E8	log = 8.34
10^{-7}	18	24	No = N/10 = 2.19x10 E7	log = 7.34

Test (Na)

	Vc1	Vc2	mean		
1min 10^{-3}	39	42	40.5	Na = mean x10 = 4.05x10 E4	log = 4.61
5 min 10^{-1}	37	52	44.5	4.45x10 E2	2.65
15 min 10^{-1}	<1	<1	<1	<10 (<140)	<1 (<2.15)

Log Reduction

1 min: 2.73 5 mins: 4.69 15 mins: >6.34 (>5.19)

Validation & Controls

Validation Suspension (Nvo)

Vc1	Vc2	mean
55	62	58.5

Experimental Conditions Control (A)

Vc1	Vc2	mean
50	56	53

Neutraliser Toxicity Control (B)

Vc1	Vc2	mean
50	47	48.5

Dilution Neutralisation Control (C)

Vc1	Vc2	mean
51	47	49

So What Does Clarisan Kill?

Clarisan has been proven to be effective against the following:

- Staphylococcus Aureus
- E.coli
- Clostridium Difficile Spores
- Enterococcus Hirae
- Pseudomonas Aeruginosa
- Salmonella Typhimurium
- Listeria Monocytogenes
- MRSA
- H1N1 (swine flu)
- Hepatitis C
- Mycobacterium Terrae (TB)

2.6 Summary of Test Results

Below is a table showing the results of all the tests taken to prove what bacteria, Clarisan is effective against…..

Product	Test	Organisms	Result
Clarisan Hand Sanitising Gel	BSEN1500:2013	Escherichia Coli	Pass
Clarisan Surface Disinfectant	BSEN14348:2005	Mycobacterium Terrae	Pass
	BSEN13704:2002	Clostridium Difficile spores	Pass
Clarisan Surface Cleaner	BSEN13697:2001	Pseudomonas Aeruginosa	Pass
	BSEN13697:2001	Staphylococcus Aureus	Pass
		Escherichia Coli	Pass
		Enterococcus Hirae	Pass
		Salmonella Typhimurium	Pass
		MRSA	Pass
		Listeria Monocytogenes	Pass
		Pseudomonas Aeruginosa	Fail
	BSEN1276:2009	Staphylococcus Aureus	Pass
		Escherichia Coli	Pass
		Pseudomonas Aeruginosa	Pass
		Enterococcus Hirae	Pass
		Salmonella Typhimurium	Pass
		MRSA	Pass
		Listeria Monocytogenes	Pass
Clarisan Alcohol-Free Surface Spray	BSEN1276:2009	MRSA	Pass
		Escherichia Coli	Pass
		Pseudomonas Aeruginosa	Pass
		Enterococcus Hirae	Pass
		Salmonella Typhimurium	Pass
		Listeria Monocytogenes	Pass
	BSEN13704:2002	Clostridium Difficile Spores	Pass

3.0 Clarisan MSDS Non-Alcohol Surface Disinfectant Solution

MATERIAL SAFETY DATA SHEET

1. Identification of the Substance / Preparation and of The Company

Product Name:	Clarisan
Generic Description:	Multi Surface Disinfectant Solution
Company Identification:	Clarisan WePack Ltd Cedar Court Griffon Road Quarry Hill Industrial Park Ilkeston DE7 4RF
Telephone No:	0115 8529000
Fax No:	0115 9309292
E-Mail:	sales@we-pack.co.uk

2. Composition / Information on Ingredients:

Hazardous components: Alkyl dimethyl benzyl ammonium chloride Glutaraldehyde

3. Hazards Identification:

Not classified as Hazardous under the CHIP 3 regulations.
No Hazardous ingredients are present at a level of 1% or more.

4. First Aid Measures:

Inhalation:	Remove to fresh air.
Skin contact:	Wash immediately with soap and water. Immediately remove contaminated clothing/footwear.
Eye Contact:	Immediately rinse with water for at least 15 minutes. Refer to eye specialist.
Ingestion:	Call a doctor immediately. If person is fully conscious ensure they drink plenty of water. Seek immediate medical attention. Do not induce vomiting.

3.0 Clarisan MSDS Non-Alcohol Surface Disinfectant Solution

5. Fire Fighting Measures:

Suitable Extinguishing Media: Non Flammable liquid. Compatible with water, foam, carbon dioxide and dry powder extinguishers.

Fire Fighters Protective Equipment: Avoid contact with skin or eyes.

6. Accidental Release Measures:

Personal precautions: Wear suitable gloves and protective clothing. Hose spillage away with copious quantities of fresh water to foul waste.

Environmental Precautions: The product should be kept out of water courses and streams but if this proves impossible the appropriate authorities should be informed.

Clean up Method: Product should be contained by earth or sand and then removed to a safe place, wash the floor with plenty of water.

7. Handling and Storage:

Handling: Do not get into eyes, on skin or on clothing.

Storage: Store in a cool area, away from food stuffs. Store only in original container. Keep container closed.

8. Personal Protection Equipment:

Inhalation: no specific protective equipment necessary.

9. Physical and Chemical Properties:

Colour: Colourless liquid

Odour: Faint odour.

Solubility in Water (% weight): Soluble in water

PH Value Concentrate: 6.0 – 6.6

SG: 1.04 – 1.06 @ 20°C

3.0 Clarisan MSDS Non-Alcohol Surface Disinfectant Solution

10.Stability and Reactivity:

Decomposition Products:	On thermal decomposition releases: Hydrochloric Acid Nitrogen Oxides Carbon Monoxide and Dioxide
Stability and Reactivity:	Stable under normal conditions of use.

11. Toxicological Information:

Acute Toxicity:	Harmful if swallowed
	Benzalkonium chloride
Component:	LD50 Oral rat: 240mg.kg^{-1}
	Glutaraldehyde 50
Component:	LC50 480 mg in 4 hours (rat)
	LD50 oral mouse: 100mg.kg^{-1}
	LD50 > 2500mg.kg^{-1} acute dermal toxicity (rat)
	LD50 oral male rat: 246 mg.kg^{-1}
Local effects:	Corrosive to skin and mucous membranes

12.Ecological Information:

All surfactants used are ≥ 80%biodegradable in line with EU directives 73/404 EEC

13. Disposal Considerations:

Disposal:	small spillages can be disposed of into the drainage system. Large spillages must be absorbed using sand or earth and sent to a licensed waste disposal contractor.

14.Transport Information:

Not classified as Hazardous by air, road or sea at current dilution rates.

15. Regulatory information:

EEC labelling and classification:

Classification:	none
Symbols:	none
R Phase:	none
S Phase:	none

16. Other Information:

Customers are urged to ensure that the product is entirely suitable for their own purposes. It is the customer's responsibility to ensure that a suitable and sufficient assessment of the risks created by a work activity using this product, is undertaken before it is used. The user must also satisfy himself that the product is entirely suitable for their purpose.

THE INFORMATION GIVEN IS BASED ON OUR CURRENT KNOWLEDGE AND IS INTENDED AS A GENERAL GUIDELINE TO THIS PRODUCT IN USE. IT DOES NOT CONSTITUTE THE USERS OWN ASSESSMENT OF WORKPLACE RISK AS REQUIRED BY OTHER HEALTH AND SAFETY LEGISLATION.

3.1 Clarisan MSDS Non-Alcohol - Foaming Hand Rub

MATERIAL SAFETY DATA SHEET

1. Identification of the Substance / Preparation and of The Company

Product Name: Clarisan Non-Alcohol Foaming Hand Rub

Company:
WePack Ltd
Cedar Court
Griffon Road
Quarry Hill Industrial park
Ilkeston DE7 4RF

Telephone No: 0115 8529000

Fax No: 0115 9309292

Email: sales@we-pack.co.uk

2. Composition / Information on Ingredients:

Hazardous Components: Alkyl dimethylbenzyl ammonium chloride

3. Hazards Identification:

Not classified as Hazardous under the CHIP 3 regulations.
No Hazardous ingredients are present at a level of 1.75%or more.

4. First Aid Measures:

Inhalation: Remove to fresh air

Skin Contact: Wash immediately with soap and water.
Immediately remove contaminated clothing/footwear.

Eye Contact: Immediately rinse with water for at least 15 minutes. Refer to eye specialist.

Ingestion: Call a doctor immediately. If person is fully conscious ensure they drink plenty of water. Seek medical attention.
Do not induce vomiting.

3.1 Clarisan MSDS Non-Alcohol – Bio Foaming Hand Rub

5. Fire Fighting Measures:

Suitable Extinguishing Media:	Non flammable liquid. Compatible with water, foam, carbon dioxide and dry powder extinguishers.
Fire fighters protective equipment:	Avoid contact with skin and eyes.

6. Accidental Release Measures:

Personal Precautions:	Wear suitable gloves and protective clothing. Hose spillage away with copious quantities of fresh water to foul waste.
Environmental Precautions:	The product should be kept out of water courses and stream but if this proves impossible the appropriate authorities should be informed.
Clean Up Method:	Product should be contained by earth or sand and then removed to a safe place, wash the floor with plenty of water.

7. Handling and Storage:

Handling:	Do not get into eyes, on skin or on clothing
Storage:	Store in a cool area, away from food stuffs. Store only in original container. Keep container closed.

8. Exposure Controls/Personal Protection Equipment:

Inhalation:	No specific protective equipment necessary.

9. Physical and Chemical Properties:

Colour:	Colourless liquid
Odour:	Odourless
Solubility in water (%weight):	Soluble in water

10.Stability and Reactivity:

Decomposition products:	On thermal decomposition releases: Hydrochloric Acid Nitrogen Oxides, Carbon Monoxide and Dioxide
Stability and Reactivity:	Stable under normal conditions of use.

3.1 Clarisan MSDS Non-Alcohol – Bio Foaming Hand Rub

11. Toxicological Information:

Acute Toxicity:	Harmful if swallowed.
Benzalkonium Chloride Component:	LD50 Oral rat: 240mg. kg^{-1}

12. Ecological Information:

All surfactants used are ≥ 80%biodegradable in line with EU Directives 73/404 EEC.

13. Disposal Considerations:

Disposal:	Small spillages can be disposed of into the drainage system. Large spillages must be absorbed using sand or earth and sent to a licensed waste disposal contractor.

14. Transport Information:

Not classified as Hazardous by air, road or sea at current dilution rates.

15. Regulatory information:

EEC Labelling and Classification Classification:	None
Symbols:	
R Phase:	None
S Phase:	None

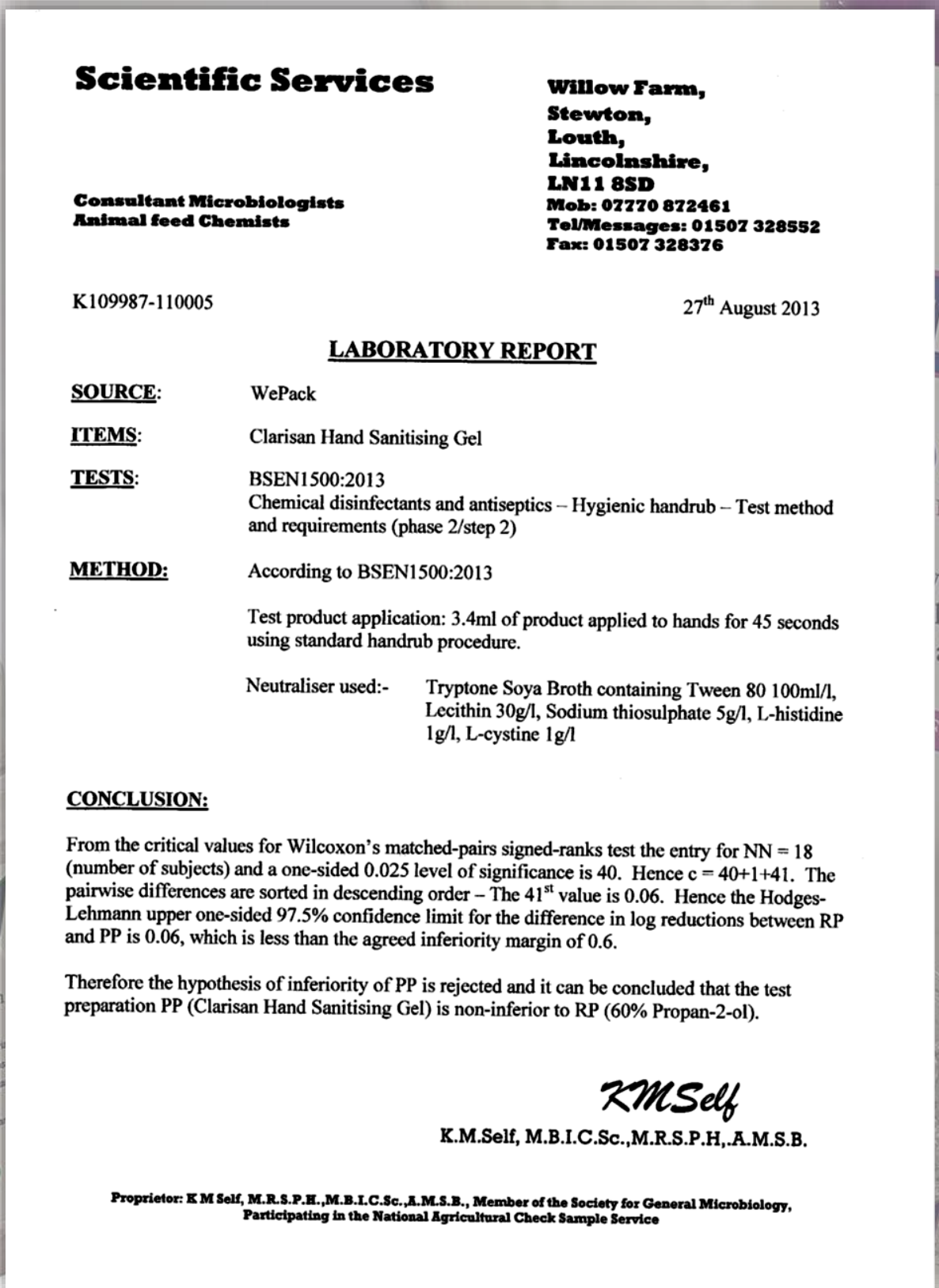
16. Other Information:

Customers are urged to ensure that the product is entirely suitable for their own purposes. It is the customer's responsibility to ensure that a suitable and sufficient assessment of the risks created by a work activity using this product is undertaken before it is used. The user must also satisfy himself that the product is entirely suitable for his purpose.

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

Summary of test result:

With the introduction of BSEN1500 standards for hand sanitising, we undertook, to carry out this test with a very reliable testing laboratory, who regularly work with multinational organisations. The product successfully passed the test and proved more effective than the comparative test substance.



Scientific Services

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Consultant Microbiologists
Animal feed Chemists

K109987-110005

27th August 2013

LABORATORY REPORT

SOURCE: WePack

ITEMS: Clarisan Hand Sanitising Gel

TESTS: BSEN1500:2013
Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2)

METHOD: According to BSEN1500:2013

Test product application: 3.4ml of product applied to hands for 45 seconds using standard handrub procedure.

Neutraliser used:- Tryptone Soya Broth containing Tween 80 100ml/l, Lecithin 30g/l, Sodium thiosulphate 5g/l, L-histidine 1g/l, L-cystine 1g/l

CONCLUSION:

From the critical values for Wilcoxon's matched-pairs signed-ranks test the entry for NN = 18 (number of subjects) and a one-sided 0.025 level of significance is 40. Hence c = 40+1+41. The pairwise differences are sorted in descending order – The 41st value is 0.06. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in log reductions between RP and PP is 0.06, which is less than the agreed inferiority margin of 0.6.

Therefore the hypothesis of inferiority of PP is rejected and it can be concluded that the test preparation PP (Clarisan Hand Sanitising Gel) is non-inferior to RP (60% Propan-2-ol).

KMSelf

K.M.Self, M.B.I.C.Sc.,M.R.S.P.H,.A.M.S.B.

Proprietor: K M Self, M.R.S.P.H.,M.B.I.C.Sc.,A.M.S.B., Member of the Society for General Microbiology, Participating in the National Agricultural Check Sample Service

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

HANDRUB PROCEDURE K109987-110005

PREPARATION: Reference Hygienic Handrub

DATE OF EXPERIMENT: 21st August 2013

TEST ORGANISM: Escherichia coli, NCTC 10538

SUSPENSION: Subject : 1-6, 10-12 4.05x10 E8

Subject : 7-9, 13-18 3.98x10 E3

Subject		No of cfu per plate from dilution 10^x					
		Pre-values		Post-values			
Number	Hand (l/r)	10^{-4}	10^{-5}	10^{0}	10^{-1}	10^{-2}	10^{-3}
1	L	>300	185	>300	>300	62	8
	R	>300	103	>300	>300	41	3
2	L	>300	108	>300	>300	71	10
	R	>300	82	>300	>300	47	5
3	L	>300	57	>300	198*	23*	<1
	R	271*	28*	>300	165*	20*	<1
4	L	>300	62	>300	136*	15*	2
	R	>300	41	>300	150*	16*	1
5	L	>300	56	>300	197*	21*	3
	R	>300	42	>300	45	5	<1
6	L	279*	31*	>300	98	10	2
	R	>300	33	>300	>300	30	5
7	L	>300	68	>300	68	8	<1
	R	>300	95	>300	74	8	<1
8	L	>300	71	>300	204*	26*	3
	R	>300	65	>300	197*	22*	5
9	L	>300	66	>300	>300	38	6
	R	>300	76	>300	>300	40	6

Underlined count used for further computation.
* Use weighted mean
nv = no value

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

HANDRUB PROCEDURE K109987-110005

PREPARATION: Test Product – Clarisan Hand Sanitising Gel

DATE OF EXPERIMENT: 21st August 2013

TEST ORGANISM: Escherichia coli, NCTC 10538

SUSPENSION: Subject: 1-6, 10-12 3.98x10 E8

Subject: 7-9, 13-18 4.05x10 E8

Subject		No of cfu per plate from dilution 10^x					
		Pre-values		Post-values			
Number	Hand (l/r)	10^{-4}	10^{-5}	10^{0}	10^{-1}	10^{-2}	10^{-3}
10	L	>300	68	>300	104	11	2
	R	>300	54	>300	97	12	1
11	L	>300	37	>300	69	8	<1
	R	>300	42	>300	87	10	2
12	L	>300	35	278*	34*	4	<1
	R	>300	40	280*	37*	7	<1
13	L	>300	68	>300	117	13	3
	R	>300	98	>300	181*	20*	5
14	L	>300	101	>300	58	6	<1
	R	>300	87	>300	231*	24*	4
15	L	>300	82	>300	>300	28	4
	R	>300	66	>300	>300	38	6
16	L	297*	31*	>300	86	10	<1
	R	300*	36*	166	14	3	<1
17	L	>300	34	>300	>300	70	10
	R	>300	36	>300	>300	51	9
18	L	>300	66	>300	152	14	2
	R	>300	101	>300	>300	40	6

Underlined count used for further computation.
* Use weighted mean
nv = no value

Validation of the neutraliser and methodology

Validation Suspensions:

Nv = 7.8x10 E2

Nv_o = 7.8x10 E1

Nv_B = 7.8x10 E4

Neutraliser Control:

B = 6.9x10 E1

Method Validation Control:

C = 7.1x10 E1

All results comply with the criteria of BSEN1500:2013 in that they fall within the basic limits set down.

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

K109987-110005

List of computed log values (means of left and right hand) and log reduction factors.

Subject	Chronological sequence	Reference Handrub (RP) (Propan-2-ol 60% v/v)			Handrub with test product		
		log x	log y	log z	log x	log y	log z
1	RP-> PP	8.16	4.71	3.45	7.96	4.59	3.37
2	RP- PP	7.98	4.77	3.21	7.89	4.74	3.15
3	RP- PP	7.47	4.27	3.20	7.43	4.18	3.25
4	RP-> PP	7.71	4.16	3.55	7.62	3.34	4.18
5	RP-> PP	7.69	4.10	3.59	7.30	3.94	3.36
6	RP-> PP	7.46	4.06	3.40	7.35	3.57	3.78
7	PP-> RP	7.91	3.85	4.06	7.85	3.95	3.90
8	PP-> RP	7.83	4.31	3.52	7.83	4.46	3.37
9	PP-> RP	7.85	4.59	3.26	7.74	3.85	3.89
10	RP-> PP	7.61	4.04	3.57	7.79	4.00	3.79
11	RP-> PP	7.81	4.28	3.53	7.60	3.89	3.71
12	RP-> PP	7.77	4.45	3.32	7.57	3.46	4.11

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

K109987-110005

Computation of individual differences of lg Rs of RP-PP

Subject	lg reduction (R)		Difference RP-PP
	Reference procedure (RP)	Product Procedure (PP)	
1	3.45	3.37	0.08
2	3.21	3.15	0.06
3	3.20	3.25	-0.05
4	3.55	4.18	-0.63
5	3.59	3.36	0.23
6	3.40	3.78	-0.38
7	4.06	3.90	0.16
8	3.52	3.37	0.15
9	3.26	3.89	-0.63
10	3.57	3.79	-0.22
11	3.53	3.71	-0.18
12	3.32	4.11	-0.79
13	3.67	3.75	-0.08
14	3.07	3.80	-0.72
15	3.20	3.35	-0.15
16	3.62	3.12	0.50
17	3.32	2.76	0.56
18	3.18	3.68	-0.50

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

K109987-110005

List of computed log values (means of left and right hand) and log reduction factors.

Subject	Chronological sequence	Reference Handrub (RP) (Propan-2-ol 60% v/v)			Handrub with test product		
		log x	log y	log z	log x	log y	log z
13	PP-> RP	7.85	4.18	3.67	7.92	4.17	3.75
14	PP-> RP	7.97	4.90	3.07	7.97	4.17	3.80
15	PP-> RP	7.94	4.74	3.20	7.87	4.52	3.35
16	PP-> RP	7.85	4.23	3.62	7.48	3.36	3.12
17	PP-> RP	7.73	4.41	3.32	7.54	4.78	2.76
18	PP-> RP	7.77	4.59	3.18	7.92	4.24	3.68
$\bar{x}$ S NN	Overall	7.80 0.17 18	4.37 0.29 18	3.43 0.23 18	7.70 0.21 18	4.07 0.44 18	3.57 0.36 18
$\bar{x}$ S NN	RP->PP	7.74 0.21 9	4.32 0.26 9	3.42 0.14 9	7.61 0.22 9	3.97 0.45 9	3.63 0.35 9
$\bar{x}$ S NN	PP->RP	7.87 0.08 9	4.42 0.30 9	3.43 0.30 9	7.79 0.17 9	4.17 0.39 9	3.51 0.37 9

$\bar{x}$ = overall mean
S = standard deviation
NN = No of subjects

log x = log pre-value
log y = log post-value
log z = log reduction factor

4.0 Microbiological Tests: Surgical Gel - British Standard EN1500 Test 4.0

K109987-110005

Sorting of individual differences and computation for Hodges-Lehmann 97.5% upper confidence limits

	Sorted differences	Mean pairwise differences $(d_i+d_{ii})/2$									
		0.56	0.50	0.23	0.16	0.15	0.08	0.06	-0.05	-0.08	-0.15
1	0.56	0.56^{1}									
2	0.50	0.53^{2}	0.50^{3}								
3	0.23	0.40^{4}	0.37^{5}	0.23^{17}							
4	0.16	0.36^{6}	0.33^{8}	0.20^{20}	0.16^{27}						
5	0.15	0.36^{7}	0.33^{9}	0.19^{22}	0.16^{28}	0.15^{30}					
6	0.08	0.32^{10}	0.29^{12}	0.16^{26}	0.12^{32}	0.12^{33}	0.08^{39}				
7	0.06	0.31^{11}	0.28^{13}	0.15^{29}	0.11^{34}	0.11^{35}	0.07^{40}	0.06^{41}			
8	-0.05	0.26^{14}	0.23^{16}	0.09^{37}	0.06^{42}	0.05	0.02	0.01	-0.05		
9	-0.08	0.24^{15}	0.21^{19}	0.08^{38}	0.04	0.04	0.00	-0.01	-0.07	-0.08	
10	-0.15	0.21^{18}	0.18^{23}	0.04	0.01	0.00	-0.04	-0.05	-0.10		
11	-0.18	0.19^{21}	0.16^{25}	0.03	-0.01	-0.02	-0.05	-0.06			
12	-0.22	0.17^{24}	0.14^{31}	0.01	-0.03	-0.04	-0.07				
13	-0.38	0.09^{36}	0.06^{43}	-0.08	-0.11	-0.12					
14	-0.50	0.03	0.00	-0.14	-0.17						
15	-0.63	-0.04	-0.07	-0.20							
16	-0.63	-0.04	-0.07								
17	-0.72	-0.08									
18	-0.79										

The median is between the 9th and 10th value[-0.08 + (-0.15)] / 2 = 0.12. The small exponents represent the ranks.

4.1 Microbiological Tests: Surgical Gel – Eurostar Technology Limited Test Results

This is a Biogurad's test report as we are currently buying the Bioguard gel. However, in the near future, we have other ideas, to make it more effective for WePack.

EUROSTAR TECHNOLOGY LIMITED

Barrier/Restricted Access Technology,with Design,Project Reviews, Sterilisation & Validation Services. Pharmaceutical Plant Design.

Bacteriological Testing Viral Assay/Analysis Toxicology Services. Audits to cGMP/cGLP

TEST REPORT

TITLE: VIRUCIDAL ACTIVITY OF BIOGUARD SURGICAL HAND GEL.

PROTOCOL NO: 23/BIO/28295

OBJECTIVE: TO DETERMINE VIRUCIDAL EFFICACY OF BIOGUARD SURGICAL HAND GEL BY DISINFECTION TESTS:

A) AFNOR VIRUCIDAL DETERMINATION
B) PRACTICAL HAND TREATMENT TESTS USING A BACTERIOPHAGE SPECIES OF VIRUS.

PRODUCT BATCH NO 14295

DATE OF MANUFACTURE: 14TH FEBRUARY 1995

NAME: BIOGURARD SURGICAL HAND GEL

PACKAGE: APPROX. 400 mL DISPOSABLE PLASTIC POUCH.

DATE OF TESTS: 28/29 February and 2/3 March 1995

CONDUCTED BY: C. L. Lambert.

REVIEWED BY: C. L. Lambert

SUMMARY:

A) The AFNOR Virucidal Test indicated that the product was effective against the three standard test species,Poliomyelitis,Orthopox (Vaccinia) and Adenovirus with one minutes exposure time. The test had to be modified as follows:

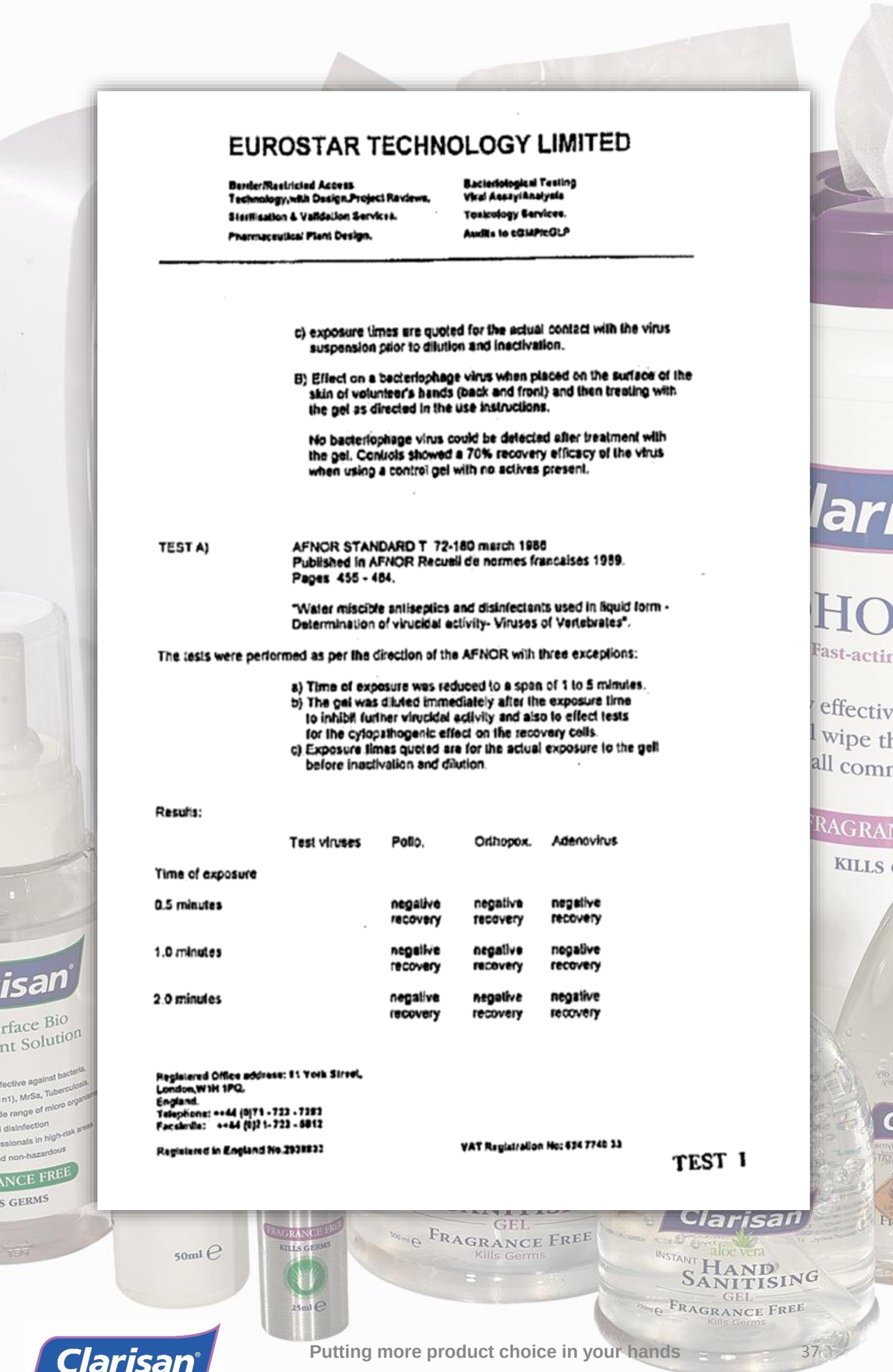
a) Time of exposure was shortened to a span of 1 to 5 minutes
b) The gel was diluted down after exposure with buffer/inactivators to inhibit further virucidal action and to facilitate testing for cytotoxic effects on the recovery cell cultures.

Registered Office address: 81 York Street, London,W1H 1PQ England.
Telephone: ++44 (0)71 - 723 - 7282
Facsimile: ++44 (0)71 - 723 - 0812

Registered in England No.2338933 VAT Registration No: 624 7748 33

TEST 1

4.1 Microbiological Tests: Surgical Gel – Eurostar Technology Limited Test Results



EUROSTAR TECHNOLOGY LIMITED

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c) exposure times are quoted for the actual contact with the virus suspension prior to dilution and inactivation.

B) Effect on a bacteriophage virus when placed on the surface of the skin of volunteer's hands (back and front) and then treating with the gel as directed in the use instructions.

No bacteriophage virus could be detected after treatment with the gel. Controls showed a 70% recovery efficacy of the virus when using a control gel with no actives present.

TEST A) AFNOR STANDARD T 72-180 march 1986
Published in AFNOR Recueil de normes francaises 1989.
Pages 455 - 464.

"Water miscible antiseptics and disinfectants used in liquid form - Determination of virucidal activity- Viruses of Vertebrates".

The tests were performed as per the direction of the AFNOR with three exceptions:

a) Time of exposure was reduced to a span of 1 to 5 minutes.
b) The gel was diluted immediately after the exposure time to inhibit further virucidal activity and also to effect tests for the cytopathogenic effect on the recovery cells.
c) Exposure times quoted are for the actual exposure to the gel before inactivation and dilution.

Results:

Test viruses	Polio.	Orthopox.	Adenovirus
Time of exposure			
0.5 minutes	negative recovery	negative recovery	negative recovery
1.0 minutes	negative recovery	negative recovery	negative recovery
2.0 minutes	negative recovery	negative recovery	negative recovery

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TEST 1

4.1 Microbiological Tests: Surgical Gel – Eurostar Technology Limited Test Results

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Controls 8.89 log 6.12 log 7.12 log.

Comment: The test is based on a calculation of log reduction from the control counts (infectious units per millilitre). In the case of this study we were unable to observe any signs of cytopathic damage to the cell layers inoculated with the treated extracts of the virus plus the gel material. Running tests with the gel minus the active ingredients demonstrated a high level of recovery (see controls above).

It can therefore be concluded that Bioguard Surgical Hand Gel is virucidal within a very short exposure period of time as tested by the modified AFNOR method.

TEST B. HAND DISINFECTION TESTS USING A BACTERIOPHAGE VIRUS.

The test were performed using a modification of the method described by Lilly and Lowbury 1978 (1) where the test organisms were rubbed into the skin prior to any treatment.

Test method for using had gel: Dispense approx. 5 mL into the palm of the hand and proceed to rub over both hands - back and front,paying attaention to the nail beds and inbetwsen the fingers. Continue rubing inot the skin with a hand wringing motion until the skin is completely dry. Average time for this to take place was around 1.0 to 1.5 minutes generally.

The test results were as follows:

Mode of deposition of bacteriophage on skin of the back/front of the hands.	Mean percentage survival after: Cleaning with soap/water	Bioguard Surgical Hand Gel.
Spread and allowed to dry	1.9	0.01
Rubbed in	23.8	0.1

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Facsimile: ++44 (0)1 - 723 - 0812

Registered in England No.2328833 VAT Registration No: 624 7749 33

TEST

4.1 Microbiological Tests: Surgical Gel – Eurostar Technology Limited Test Results

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Bacteriological Testing Viral Assay/Analysis Toxicology Services. Audits to cGMP/cGLP

Comment: When contrasting these results with that reported by Lilly et al there appears to be a similar response on mean percent survival of the bacteriophage as that reported for bacteria by Lilly. Under the conditions of this test it is apparent that Bioguard Surgical Hand Gel is effective in reducing the viability of a bacteriophage virus over the period of 1 to 1.5 minutes on the surface of the skin of the hands when used as directed.

Signed: C. L. Lambert.

Consultant Microbiologist

References:

1. Lilley,H.A. and Lowbury,E.J.L. (1978) "Transient skin flora: their removal by cleaning or disinfecting in relation to their mode of deposition". Journal of Clinical Pathology,31,919-922.

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TEST 1

4.2 Microbiological Tests: Surgical Gel – Selden Test Results

C053

Laboratory Test Results

Microorganism	Classification	Description [No Title]	Test Method	Tested by	Contact time	Conditions	% Kill rate	Dilution
Escherichia coli NCIMB 8879	Gram -ve Bacteria	Common food poisoning bacteria	Modified BSEN 1276	Internal UKAS	10 seconds	Clean	99.999	Neat
						Dirty		
Staphylococcus aureus NCIMB 9518	Gram +ve Bacteria	Bacterial food poisoning and skin infections	Modified BSEN 1276	Internal UKAS	10 seconds	Clean	99.999	Neat
						Dirty		
Pseudomonas aeruginosa NCIMB 10421	Gram -ve Bacteria	Skin infections	Modified BSEN 1276	Internal UKAS	10 seconds	Clean	99.999	Neat
						Dirty		
Enterococcus hirae NCIMB 8192	Gram +ve Bacteria	Common food poisoning bacteria	Modified BSEN 1276	Internal UKAS	10 seconds	Clean	99.999	Neat
						Dirty		
MRSA NCTC 12493	Gram +ve Bacteria	Methicillin resistant strain of *St aureus*	Modified BSEN 1276	Internal UKAS	10 seconds	Clean	99.999	Neat
						Dirty	99.999	Neat
H5N1 Bird Flu	Virus	Human and poultry pathogen	Virucidal Efficacy Test	External	30 seconds		99.9	Neat
Escherichia coli 10083	Gram -ve Bacteria	Common food poisoning bacteria	EN 1500	External UKAS	1 minute		PASS	Neat

MATERIAL SAFETY DATA SHEET

1. Identification of the Substance / Preparation and of The Company

Product Name: Clarisan Surgical Hand Gel

Company: Wepack Ltd
Griffon Road
Quarry Hill Industrial Park
Ilkeston
Derby DE7 4RF

Telephone No: 0115 8529000
Fax No: 0115 9309292
E-Mail: sales@we-pack.co.uk

2. Composition / Information on Ingredients:

A manufactured preparation.

Hazardous ingredients	CAS NO	Content
Isopropanol Alcohol	76-63-0	70%

3. Hazards Identification:

Highly Flammable. Irritating to the eyes,

4. First Aid Measures:

Inhalation: Remove to fresh air.

Eye Contact: Rinse immediately with plenty of water for at least 15 minutes, if soreness persists, seek immediate medical attention.

Skin Contact: Mild irritation may occur if gel comes into contact with broken skin. Rinse the affected area thoroughly with water.

Ingestion: Do not induce vomiting. Remove product from mouth. Give 1-2 glasses of milk/water to drink. Obtain medical attention if a considerable amount has been swallowed.

5.0 Clarisan MSDS Sheet – Alcohol Gel

5. Fire Fighting Measures:

Extinguishing Media: Carbon dioxide. Alcohol resistant foam.

Exposure Hazards: Highly Flammable. Can form explosive air-vapour mixture. Vapour may travel considerable distance to source of ignition and flash back. In combustion emits toxic fumes of carbon dioxide and carbon monoxide.

Protection of Fire Fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent skin contact.

6. Accidental Release Measures:

Wear suitable gloves and protective clothing. Ensure that the area is well ventilated. Avoid contact with ignition source. Allow to evaporate if safe to do so or absorb spillage with sand or earth. Observe all local requirements.

7. Handling and Storage:

Handling: Do not mix with other chemicals.

Storage: Store upright in original closed containers at room temperatures not exceeding 20°C. Keep containers tightly closed. Keep out of the reach of children. Do not expose to direct sunlight.

8. Exposure Controls/Personal Protection Equipment:

Eyes: Wearing of safety glasses is recommended.

Skin: No irritation or reaction expected, none required under normal conditions.

Inhalation: Use in a well ventilated area. Avoid breathing vapours.

9. Physical and Chemical Properties:

Appearance:	Clear Gel
Odour:	Slight Chemical Odour
PH:	N/A
Boiling point:	<30°C

5.0 Clarisan MSDS Sheet – Alcohol Gel

Flash point:	24°C
Flammability (solid/gas):	Highly Flammable
Relative Density:	0.75-0.80/cm^3
Solubility:	100%soluble in water.

10.Stability and Reactivity:

Stable, do not mix with other chemicals.

11. Toxicological Information:

Eyes:	Splashes to the eyes may cause irritation.
Skin:	No irritation or reaction expected.
Ingestion:	May cause gastric irritation.

12.Ecological Information:

All surfactants are >80% biodegradable in line with EU Directives 73/404/EEC and 73/405/EEC as amended.

13.Disposal Considerations:

Small spillages can be disposed of into the drainage system. Large spillages should be absorbed with sand or earth and disposed of via a licensed waste disposal contractor. Observe all local requirements.

14.Transport Information:

Air/Road/Sea:	UN1219
	Isopropanol
	Class: 3
	Packaging group: II
	Symbol: Flammable liquid

15. Regulatory information:

Not classified as hazardous under the CHIP 3 Regulations.

Hazard symbol: Highly Flammable.

5.0 Clarisan MSDS Sheet – Alcohol Gel

Risk phrases: R11 Highly Flammable.

R36 Irritating to the eyes.

Safety phrases: S2 Keep out of reach of children.

S16 Keep away from sources of ignition – no smoking.

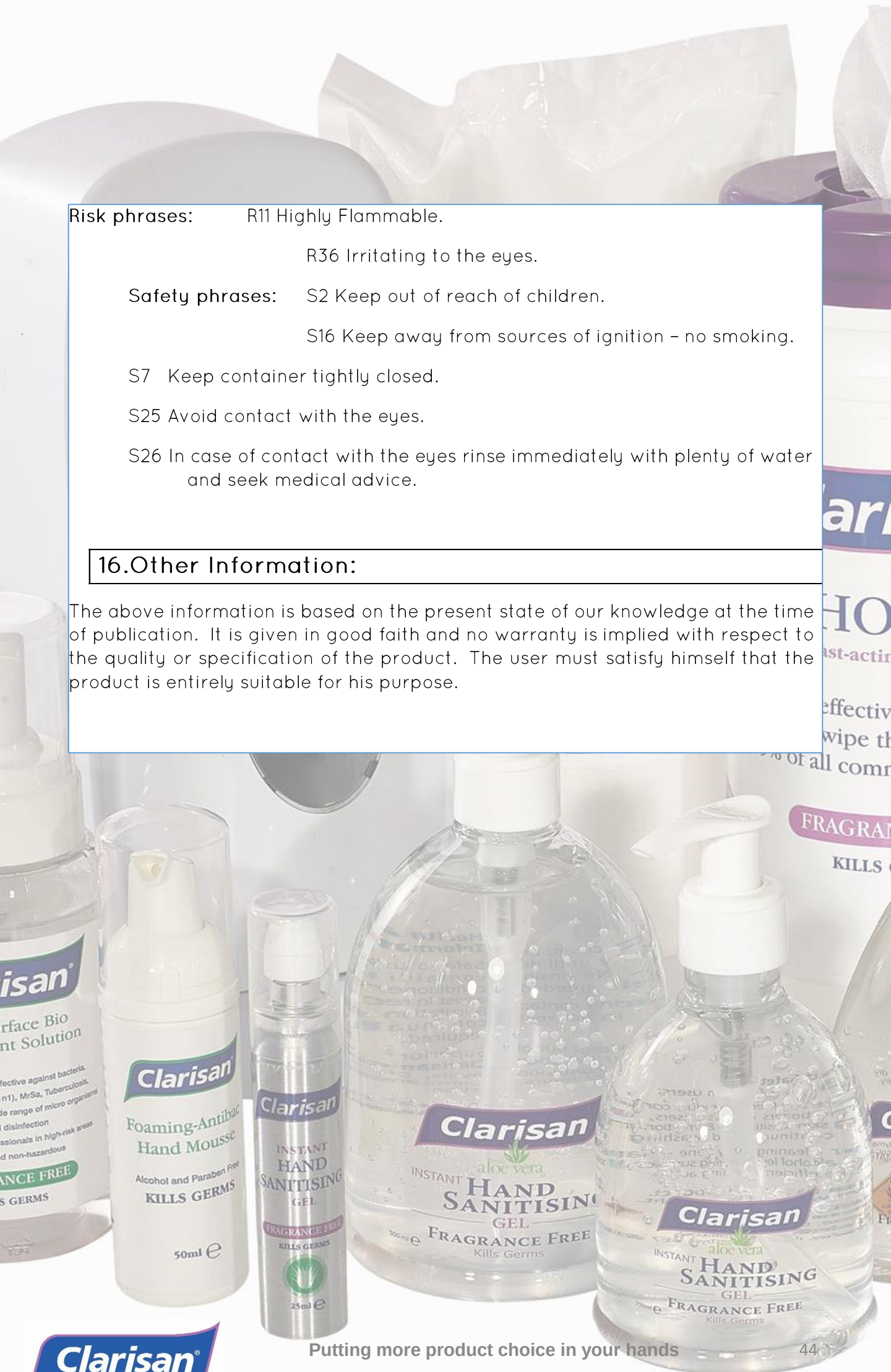
S7 Keep container tightly closed.

S25 Avoid contact with the eyes.

S26 In case of contact with the eyes rinse immediately with plenty of water and seek medical advice.

16.Other Information:

The above information is based on the present state of our knowledge at the time of publication. It is given in good faith and no warranty is implied with respect to the quality or specification of the product. The user must satisfy himself that the product is entirely suitable for his purpose.



MATERIAL SAFETY DATA SHEET

Clarisan Alcohol Wipes
ETPW200

1. Identification of the Substance / Preparation and of The Company

Preparation: Clarisan Alcohol Wipes

Use of Preparation: A wet wipe for use in all food preparation areas and for the wiping of food probes.

Supplier:	Clarisan WePack Ltd Cedar Court Griffon Road Quarry Hill Industrial Estate Ilkeston Derbyshire DE7 4RF
Telephone No:	0115 8529000
Fax No:	0115 9309292
E-Mail:	sales@we-pack.co.uk

2. Composition / Information on Ingredients:

This preparation is not classified as 'Hazardous' according to Directive 1999/45/EC and subsequent amendments.

Hazard Symbols:	F, Xi
Risk Phrases:	R11 – Highly Flammable R36 – Irritating to eyes
Eye Contact:	Not expected to present a hazard to the eyes under normal conditions of use, but direct contact of the impregnating fluid with the eyes would cause irritation.
Inhalation:	Not considered to present an inhalation hazard under normal conditions of use.

3. Hazards Identification:

CAS NO:	Not applicable, preparation is a mixture
EINECS:	Not applicable, preparation is a mixture
Composition:	An aqueous solution of 70% isopropanol, which is listed in Annex II of Regulation (EC) 1451/2007 for product types 1 to 6, impregnated onto a non-woven fabric.

5.1 Clarisan MSDS Sheet – Clarisan Alcohol Wipes

Hazardous Ingredients:

Ingredient	CAS No.	EINECS	%w/w
Symbols	Risks		
Propan-2-ol	67-63-0	200-661-9	70% F, Xi, 11, 36, 67

4. First Aid Measures:

Eye Contact: If the impregnating fluid comes into direct contact with eyes, immediately flush with plenty of water and seek medical advice. If irritation develops, seek medical advice.

5. Fire Fighting Measures:

Suitable Extinguishing Media: Water, spray, foam, carbon dioxide and dry powder

Extinguishing media which must NOT be used: Water Jet

Standard protective equipment should be worn by fire-fighters.

In the event of a large fire, toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self – contained breathing apparatus.

6. Accidental Release Measures:

Personal Precautions: Avoid contact of the impregnating fluid with the eyes.

Methods for cleaning up: Eliminate all sources of ignition, because vapour may travel considerable distance to source of ignition with resultant flash back, and absorb any impregnating fluid onto a suitable inert material, which should be collected mechanically with spilled product for subsequent disposal.

7. Handling and Storage:

Handling: Avoid contact with eyes and do not use near possible sources of ignition

Storage: Store under normal warehouse conditions away from possible sources of ignition and naked flames.

5.1 Clarisan MSDS Sheet – Clarisan Alcohol Wipes

8. Exposure Controls/Personal Protection Equipment:

Exposure Controls:

Ingredient Name	CAS No	STD	LTEL (8hrs)	STEL (15 Min)
Propan-2-ol	67-63-0	OES	980mg/m3	1225mg/m3

Personal Protection: None required under the normal conditions of use.

9. Physical and Chemical Properties:

Appearance: White non-woven fabric impregnated with a colourless solution.
Odour: Ethereal
PH of impregnating fluid: N/A
Boiling point of impregnating fluid: ca 85°C
Flash point of impregnating fluid: <21°C
Flammability: Impregnating liquid is highly flammable
Solubility: Impregnating fluid completely miscible with water.

10. Stability and Reactivity:

This preparation is stable under normal conditions of storage/use and no chemical incompatibility is known.

11. Toxicological Information:

Based on the ingredients present and their concentrations this preparation is, according to the conventional method of Directive 1999/45EC and subsequent amendments, classified as 'Dangerous' according to the health criteria.

Acute Oral: The oral LD50 (rat) value for the impregnating fluid calculated from those of the individual ingredients is >8,300 mg/kg.

12. Ecological Information:

Based on the ingredients present and their concentrations this preparation is, according to the conventional method of directive 1999/45EC and subsequent amendments, classified as not 'Dangerous' to the environment.

13. Disposal Considerations:

Dispose if the preparation according to local and national regulations.

After all the wipes have been removed from a pack, there may be some residual alcoholic impregnating fluid left inside the packaging.

14.Transport Information:

According to the ADR this preparation is listed under UN No 3175 and for which there is a LQ8 Limited Quantities coding. However, since the net weight of the preparation In a pack is less than 3 kg and the gross weight of the packs preparation in the transport case is less than 30 kg, the provisions of ADR are not applicable to the preparation, in the except that the transport case has to be marked with a 100 x 100mm white diamond-shaped area, surrounded by a 2mm wide line, within which 'UN No 3175' is printed with a height of at least 6mm.

15. Regulatory information:

This preparation is classified as 'Hazardous' for labelling purposes.

Labelling for supply:

Hazard Symbols:

F Highly Flammable

Xi Irritant

Risk Phrases: R11 – Highly Flammable
R36 – Irritating to eyes

Safety Phrases: S (2) – Keep out of reach of children
S7 – Keep container tightly closed
S16 – Keep away from sources of ignition – No smoking
S25 – Avoid contact with eyes
S-26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

16.Other Information:

This safety data sheet, which takes into consideration the requirements of Directive 1999/45/EC and subsequent amendments, has been prepared in accordance with Directive (EC) 1907/2006. It is believed to be correct and corresponds to the latest state of scientific/technical knowledge. But all data, instructions, recommendations and/or suggestions are made without guarantee.

Risk phrase listed in Section 3. R11 – Highly Flammable R67 – Vapours may cause drowsiness and dizziness. R36 – Irritating to eyes