

NewGenn Foam Hand Rub



Intuitive Infection Control

NOTE: The current interpretation of the European Medicines Directive dictates that within Europe only people with the appropriate knowledge of infectious diseases should read this document. By definition “appropriate knowledge” is limited to clinical degrees in Medicine, Dentistry and Veterinary Science. NewGenn has made representations to the effect that a qualified practicing Infection Control Nurse will have more appropriate and current knowledge than a surgeon who has had little reason to keep up to date with current infection control strategies. This statement is therefore presented for completeness and recognition of the law.

Presented by:

**NewGenn**

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Contents

Section	Description	Page
1	Summary	3
2	Composition of the product	4
	Material Safety Data Sheets	5
3	Efficacy data	7
	<i>In vitro</i> efficacy data	“
	Viruses	
	Feline Calici Virus (Noro Virus surrogate)	8
	Bacteria	
	EN 1276	
	<i>Staphylococcus aureus</i>	9
	<i>Pseudomonas aeruginosa</i>	“
	<i>Escherichia coli</i>	“
	<i>Enterococcus hirae</i>	“
	MRSA	14
	<i>Staphylococcus epidermidis</i>	19
	<i>Klebsiella pneumoniae</i>	“
	<i>Salmonella enteritidis</i>	“
	<i>Salmonella typhimurium</i>	“
	<i>Salmonella choleraesuis</i>	24
	<i>Listeria monocytogenes</i>	“
	<i>Proteus vulgaris</i>	“
	<i>Campylobacter jejuni</i>	29
	<i>Serratia marcescens</i>	34
	<i>Corynebacterium bovis</i>	39
	<i>Rhodococcus equi</i>	44
	Bacterial Spores	49
	EN 1276	“
	<i>Bacillus subtilis</i>	50
	<i>Clostridium difficile</i>	55
	Fungi	60
	EN 1650	“
	<i>Aspergillus niger</i> (spores)	“
	<i>Candida albicans</i>	“
	<i>In Vivo</i> efficacy data	65
4	Safety assessment	67
	Ingredients	“
	The formulation	“
	Environmental profile	“
5	Clinical and Epidemiological data	68
	Preliminary study on user acceptance compared to alcohol rub	“
6	Conclusion	69
Appendix	The products in the NewGenn range to date	70

Section 1

Summary

NewGenn Foam Hand Rub was created as an alternative to alcohol hand rubs in order to:

1. Provide control against Noro Virus (Winter Vomiting Disease Virus, Norwalk Virus)
2. Build on the fact that those users who state a preference prefer alcohol-free rubs
3. Eliminate the stinging caused by alcohol on damaged hands
4. Provide a Halal accredited rub for those who find alcohols offensive on religious grounds
5. Adhere to CoSHH which requires the replacement of flammable solvents when possible
6. Provide a rub free of flammable solvents for those with respiratory ailments
7. Improve user compliance by bringing a nice cosmetic feel after use
8. Provide a "little and often" alternative to the existing "total but rarely" rubs
9. Provide a foam as an alternative to liquids and gel
10. Be part of an extensive range of chemically compatible infection control products
11. Provide a safe rub which could be used by children and one that would willingly be used by children with skin and respiratory ailments
12. Provide a product that could safely be used in the home, in community care, in transport settings like cruise ships and airlines, in the food sector including restaurants as well as in hospitals.

The material presented in this document is intended to show that this new and innovative product has a clear potential to control infection cycles which will enable a reduction in both healthcare associated infections and community based infections. That will be achieved both by having the product used within the hospital setting and in the community.

Section 2

Composition of the product

Before presenting the exact names of the active ingredients it is important to outline the logic on which the ingredient selection was made.

To achieve the ambitious objectives, it was essential to have:

- Increased user compliance so ingredients derived from plant oils were used
- The cleaning power needed to expose microbes which came from ingredients with detergent action
- Protection for resident flora, an important feature achieved by using long-chain plant oil ingredients that layered over that resident flora
- Action against transient flora re-contaminating the hands by making the hands smooth and therefore more resistant to pathogen adherence
- Greatly reduced likelihood of bacterial resistance development by selecting ingredients which attack the negative charge of the relevant bacteria so before true resistance can occur the microbes would need to undergo an extensive change in fundamental biochemistry
- Very rapid virucidal action against Noro Virus by including ingredients that inactivated the ionic forces between the coat proteins allowing the detergent moieties to enter the viral structure and destroy the nucleic acid.

The liquid in NewGenn Foam Hand Rub is a 2% solution in water of NewGenn High Level Disinfectant concentrate. The list of ingredients in the rub and their respective inclusion rates are:

Ingredient	CAS Number	NewGenn Foam Hand Rub %
Coco alkyl benzene ammonium chloride	121-54-0	<0.07
Didecyldimethyl ammonium chloride	7173-51-5	<0.05
Coco amine oxide	70592-80-2	<0.03
Acidity modifier 1	Secret	<0.05
Acidity modifier 2	Secret	<0.02

The precise identities of the two acidity modifiers are commercially secret but their very low inclusion rates ensure they are safe for users and the environment. Further comment on safety is provided in section 4.

The Material Safety Data Sheet for NewGenn Foam Hand Rub is shown on the following pages.

Safety Data Sheet.

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY

MANUFACTURER / SUPPLIER:

NEWGENN LIMITED

4 Hereward Way Business Park, Harling Road, Roudham, Norfolk, England
Tel: 01953 717757 Fax: 01953 717758 www.newgenn.com

PRODUCT NAME:

NEWGENN Foam Hand Rub

REFERENCE:

SAF139 Issue date: 30 Nov 06 Issue Number: 6
PHYSICAL FORM: Liquid in the container. Foam when dispensed.
PRODUCT TYPE: Hand Sanitiser.
CONTAINERS: Bottles - Plastic.

2. COMPOSITION / INFORMATION ON INGREDIENTS

NAME AND % ACTIVE

Water to 100%
Didecyldimethylammoniumchloride <0.5%
Alkyldimethylbenzylammoniumchloride <0.5%
Alkyl amine oxide <0.5%
pH stabilisers <0.5%

3. HAZARDS IDENTIFICATION

Possibly harmful if swallowed in very large quantities.

4. FIRST-AID MEASURES

EYE: Wash immediately with copious quantities of water. Seek medical advice.
SKIN: Not a known skin irritant.
INGESTION: Remove material from mouth. Drink 1 or 2 glasses of water. Obtain medical attention without delay.
INHALATION: Not appropriate.
EQUIPMENT AT WORK: Eye washing facilities.

5. FIRE-FIGHTING MEASURES

FLAMMABILITY: Not flammable
EXPLOSIVE HAZARDS: None known
SPECIAL PROTECTIVE CLOTHING: Breathing apparatus should be worn when tackling fires involving this product, mainly related to the plastic bottle combustion products.
SUITABLE EXTINGUISHERS: Any can be used.
EXTINGUISHERS WHICH CAN NOT BE USED: None.
HAZARDOUS COMBUSTION PRODUCTS: Toxic and irritant fumes may be given off when this product is heated to combustion.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PROTECTION: None essential but goggles will protect against contact with eyes.
SPILLAGE CLEAN-UP: Observe local legislation. Absorb large spillages with a mop or damp cloth. Wash residues and small quantities away to drains with water.

7. HANDLING AND STORAGE

HANDLING: No special precautions necessary if used correctly. Avoid eye contact and ingestion. Wash hands at the end of the work.
STORAGE: Store in original, closed containers in dry conditions. Avoid temperature extremes.
SHELF LIFE: Four years from date of manufacture.
OPEN LIFE: Not to exceed shelf life.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

None necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear liquid
ODOUR: Odourless

SOLUBILITY IN WATER: Fully miscible
VISCOSITY AT 20°C: As water
pH: 6 – 8
BOILING POINT °C: 100
FLASH POINT: Not Applicable
DANGER OF EXPLOSION: Product is not explosive
DENSITY AT 20°C: 1.0 g/ml

10. STABILITY AND REACTIVITY

Stable if stored and used according to instructions. No dangerous reactions or degradation products known.

11. TOXICOLOGICAL INFORMATION

EYE: Probably slight irritation in 24 hours following exposure.

SKIN AND MUCOUS MEMBRANES: Not a known irritant.

INGESTION: Possibly harmful in very large volumes.

SENSITISATION: No sensitising effect known.

INHALATION: Not applicable.

OTHER TOXICOLOGICAL INFORMATION: Oral LD₅₀ rat: Expected >2000 mg/kg.

12. ECOLOGICAL INFORMATION

May be hazardous to water in very large volumes.

13. DISPOSAL CONSIDERATIONS

Disposal of product and packaging must be according to local regulations.

14. TRANSPORT INFORMATION

Not classified as hazardous for transportation.

15. REGULATORY INFORMATION

In accordance with EC Directives / Ordinance on Hazardous Materials.

Code Letter and hazard designation of product: Product is not hazardous at the dilution provided.

Hazard determining components of labelling: None of the ingredients are hazardous at this low concentration.

Risk phrases: None.

Safety phrases:

26: In case of contact with eyes, rinse immediately with plenty of water and seek immediate medical advice.

45: In case of accident, adverse reaction or if you feel unwell, stop using the product and seek medical advice immediately.

Water hazard class: May be hazardous for water in very large amounts.

16. OTHER INFORMATION

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product feature and shall not establish a legally valid contractual relationship. Use as directed.

End of Safety Data Sheet.

Section 3

In Vitro activity

NewGenn Foam Hand Rub is a 2% solution in water of NewGenn High Level Disinfectant concentrate. Laboratory reports for High Level Disinfectant at dilution rates lower than 2% are therefore relevant.

The virucidal evidence from Akzo Nobel on the following page relates to Feline Calici Virus. The latter is well established as the most appropriate surrogate virus for Noro Virus as the latter does not grow in tissue culture (*Doultree et al. Journal of Hospital Infection (1999) 41: 51-57*). The code name of the product tested by Akzo Nobel relates to a 0.5% dilution of NewGenn High Level Disinfectant which is one quarter of the concentration present in NewGenn Foam Hand Rub. The results presented are therefore valid for this product.

The EN1276 results from the Hospital Infection Research Laboratory in Birmingham relate to TecMark Hand Rub. That was the product name prior to the formation of NewGenn Ltd so again the results are valid for this product as only the name changed and the formulation remained the same.



**Telefax transmittal
cover sheet**

Date
1 October 2002
Number of Pages
(incl. cover sheet)
1

To
Harley Farmer/Andrew Crowe

Company/Department
NewGenn

Fax number
01284 760425

From
Stuart Chalmers

Company/Department
Intervet UK - The Elms

Fax number
01480 466469
Phone number
01480 464242

Dear Harley

Herewith the results (\log_{10}) of the test substances SAIFER 'C' used to inactivate feline calicivirus.

<u>Inactivation time</u> (min)	SAIFER 'C'	Control
	<u>FCV</u>	<u>FCV</u>
0	≤ 2.5	3.6
5	≤ 2.5	
10	≤ 2.5	
30	≤ 2.5	
60	≤ 2.5	3.5

Toxic effect on cells at 10^{-1} dilution meant that no result could be given for a 1:10 dilution of virus. However, no virus was observed at the 1:100 dilution ($3.3 \log_{10}$) or above.

Kind regards

Dr W S K Chalmers
R&D Manager
01/10/02



Intervet UK Ltd.
The Elms
The Thicket
Houghton
Huntingdon
Cambs. PE26 2BQ
Tel: (01480) 464242
Fax: (01480) 461641

EFFICACY TESTS (EN1276)
SAIFER HYGIENE HAND RUB

Note: Now called NewGenn Foam Hand Rub

TECMARK Ltd

HOSPITAL INFECTION RESEARCH LABORATORY
CITY HOSPITAL NHS TRUST
DUDLEY ROAD
BIRMINGHAM B18 7QH

FEBRUARY 2001

MANUFACTURER

TecMark ltd
St John's Innovation Centre
Cowley Road
Cambridge CB4 0WS

TEST PRODUCTS

Saifer Hand Rub

Ingredients - Cocoamido propyl benzene ammonium chloride, di-decyl dimethyl ammonium chloride, amine oxide, acidity modifiers.

Batch number 191200

Lot number 290101

STORAGE CONDITIONS

Room temperature

TEST ORGANISMS

Staphylococcus aureus	NCTC 10788
Pseudomonas aeruginosa	NCTC 6749
Escherichia coli	NCTC 10418
Enterococcus hirae	NCTC 12367

TEST METHOD AND VALIDATION 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 (Phase 2, step 1). Tests for disinfectants for medical establishments not yet ratified.

Product test concentration	Undiluted (i.e. 80% in the test)
Appearance product dilution	Clear solution
Contact times	1 and 5 minutes
Test temperature	20°C
Interfering substance	Bovine albumin 0.03% (clean solutions) 0.3% (dirty solutions)
Inhibition method	Dilution/neutralization
Neutralizer	Tween 80 30g/l, sodium lauryl sulphate 4g/l, lecithin 3g/l

Tests were performed to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms (method described in EN 1276).

SUMMARY OF TEST METHOD

The test method is described in 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 (Phase 2, step 1). Tests for disinfectants for medical establishments are not yet ratified. Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1 ml of the test bacteria with 1 ml of soil (0.3% or 3% albumin and then adding 8ml of disinfectant. After the required contact time, 1 ml is removed and added to 9 ml of recovery/neutralizer fluid which is then plated to detect surviving test bacteria.

RESULTS

BACTERICIDAL ACTIVITY OF SAIFER HAND RUB

USING PHASE 2 STEP 1 SUSPENSION TEST EN 1276

Log₁₀ counts/reduction achieved in 1 minute*

(Tests carried out in duplicate)

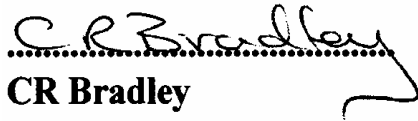
Log ₁₀ reductions achieved							
Test organism	Contact time	Log ₁₀ initial count (challenge)		Clean conditions (0.03% albumin)		Dirty conditions (0.3% albumin)	
		1 min	5 min	1 min	5 min	1 min	5 min
Pseudomonas aeruginosa	Test 1	7.64	7.64	>6.64	>6.64	>6.64	>6.64
	Test 2	7.90	7.90	>6.90	>6.90	>6.90	>6.90
	Mean	7.77	7.77	>6.77	>6.77	>6.77	>6.77
				PASS		PASS	
Staphylococcus aureus	Test 1	7.69	7.69	>6.69	>6.69	>6.69	>6.69
	Test 2	7.88	7.88	>6.88	>6.88	>6.88	>6.88
	Mean	7.78	7.78	>6.78	>6.78	>6.78	>6.78
				PASS		PASS	
Escherichia coli	Test 1	7.85	7.85	>6.85	>6.85	>6.85	>6.85
	Test 2	7.99	7.99	>6.99	>6.99	>6.99	>6.99
	Mean	7.92	7.92	>6.92	>6.92	>6.92	>6.92
				PASS		PASS	
Enterococcus hirae	Test 1	7.99	7.99	>6.99	>6.99	>6.99	>6.99
	Test 2	7.53	7.53	>6.53	>6.53	>6.53	>6.53
	Mean	7.76	7.76	>6.76	>6.76	>6.76	>6.76
				PASS		PASS	

To satisfy the requirements of this test a >5 log₁₀ reduction in test bacteria is required within 5 minutes.

CONCLUSION

When tested in accordance with EN 1276 (1997), undiluted Saifer Hand Rub possesses bactericidal activity at 20°C. A $>5 \log_{10}$ (99.999%) reduction was achieved with all test organisms i.e. *Ps. aeruginosa*, *Staph. aureus* *Esch. coli* and *Ent. hirae* in 1 min and 5 mins under clean (0.03% albumin) and dirty (0.3% albumin) conditions.

To satisfy the requirements of the test, at least a 5 log 10 reduction in specified test organisms is required within 5 minutes when the disinfectant is tested at its intended use dilution. Performance under light (clean) and moderate to heavy (dirty) soiling was assessed and so was efficacy at 1 minute.


.....
CR Bradley
Senior MLSO


.....
JR Babb
Laboratory Manager


.....
Dr AP Fraise
Director

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NR12 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium chloride,
Di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Methicillin Resistant Staphylococcus aureus
ATCC 33591

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1 % (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	10 seconds, 1 minute.
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine O. 1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN1276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Dirty conditions (0.3% albumin)

(Test carried *out* in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Staphylococcus aureus (MRSA)	10 secs	7.26	3.35
	1 min	7.26	5.06

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance after 1 minute.

(> 5 log (10) reduction in 5 minutes required)

A handwritten signature in black ink, appearing to read 'K. Self', written in a cursive style.

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

28th July 2004
K76744

5
End

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NR12 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium
chloride, Di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Staphylococcus epidermidis NCTC 11047

Salmonella enteritidis NCTC 4444

Salmonella typhimurium NCTC 5710

Klebsiella pneumoniae ATCC 4352

Enterococcus hirae ATCC 10541

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1 % (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute.
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3 %, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0. 1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN1276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1 ml of the test bacterium with 1 ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Log (10) counts/reduction achieved in 1 minute

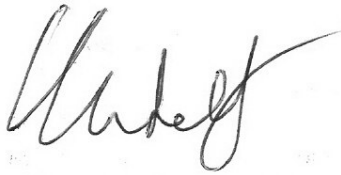
(Test carried out in duplicate)

Log (10) reductions achieved			
Test Organism	Contact time	Log 10 initial count (Challenge) Mean	Dirty conditions (0.3% albumin) Mean
Staphylococcus epidermidis	1 min	7.04	>6.04
Salmonella enteritidis	1 min	7.32	> 6.32
Salmonella typhimurium	1 min	7.58	> 6.58
Klebsiella pneumoniae	1 min	7.28	> 6.28
Enterococcus hirae	1 min	7.08	> 6.08

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance (> 5 log (10) reduction in 5 minutes) against Staphylococcus epidermidis, Salmonella enteritidis, Salmonella typhimurium, Klebsiella pneumoniae and Enterococcus hirae.

A handwritten signature in black ink, appearing to read 'K.M. Self', is centered on the page.

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

2nd August 2004

5
End

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT
NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
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Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
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Bury St. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium chloride,
di-decyl dimethyl ammonium chloride,
acidity modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Escherichia coli 0157 NCTC 12900

Salmonella choleraesuis NCTC 10653

Listeria monocytogenes NCTC 11994

Proteus vulgaris NCIMB 4175

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1 % (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute.
Test Temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3 %, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine O. 1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN1276 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 area (phase 2, step 1)..Copies of EN1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Log (10) counts/reduction achieved in 1 minute

(Test carried out in duplicate)

Log (10) reductions achieved			
Test Organism	Contact time	Log10 initial count (challenge) Mean	Dirty conditions (0.3% albumin) Mean
Salmonella choleraesuis	1 min	7.49	> 6.49
Escherichia coli 0157	1 min	7.32	> 6.32
Listeria monocytogenes	1 min	7.25	> 6.25
Proteus vulgaris	1 min	7.38	> 6.38

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance ($> 5 \log (10)$ reduction in 5 minutes) against *Salmonella choleraesuis*, *Escherichia coli* 0157, *Listeria monocytogenes* and *Proteus vulgaris*.



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

6th August 2004

5
End

EFFICACY TESTS (EN 1276)

NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES

MILL FARM

MILL LANE

TUNSTEAD

NORWICH

NR12 8HP

01692 536303

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium
chloride, di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Campylobacter jejuni NCTC 11951

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1.0% (i.e. 0.8 % in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute, 5 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0. 1 % Histidine 0. 1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN1276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Campylobacter jejuni	1 min	6.99	> 5.99
	5 min	6.99	> 5.99

To satisfy the requirements of this test a >5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance (>5 log (10) reduction in 5 minutes) after 1 minute against *Campylobacter jejuni*.



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

17th December 2004

5
End

EFFICACY TESTS (EN 1276)

NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES

MILL FARM

MILL LANE

TUNSTEAD

NORWICH

NR12 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury S1. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium
chloride, di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Serratia marcescens NCTC 10211

Test Method and Validation ENI276 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 (phase 2, step 1).

Product test concentration	1% (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	1 and 5 minutes.
Test Temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in ENI276)

Summary of test method

The test method is described in ENI276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Serratia marcescens	1 min	7.32	4.91
	5 min	7.32	> 6.32

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance after 5 minutes.

A handwritten signature in black ink, appearing to read 'K.M. Self', is centered on the page.

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

6th September 2004

5
End

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NR12 8IIP
01692536303

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium
chloride, di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms: *Corynebacterium bovis* NCTC 3224

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1.0% (i.e. 0.8 % in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute, 5 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN1276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Log (10) counts/reduction achieved

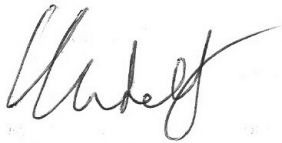
(Test carried out in duplicate)

Log (10) reductions achieved			
Test Organism	Contact time	Log 10 initial count (challenge) Mean	Dirty conditions (0.3% albumin) Mean
Corynebacterium bovis	1 min	6.36	> 5.36
	5 mins	6.36	> 5.36

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance ($> 5 \log (10)$ reduction in 5 minutes) after 1 minute against *Corynebacterium bovis*.

A handwritten signature in black ink, appearing to read 'K. Self', is centered on the page.

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

8th October 2004

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End

EFFICACY TESTS (EN 1276)

NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES

MILL FARM

MILL LANE

TUNSTEAD

NORWICH

NR12 8HP

01692536303

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury S1. Edmunds,
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium
chloride, di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Rhodococcus equi NCTC 1621

Test Method and Validation ENI276 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 (phase 2, step 1).

Product test concentration	1.0% (i.e. 0.8 % in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute, 5 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in ENI276)

Summary of test method

The test method is described in ENI276 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 area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution, which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Rhodococcus equi	1 min	6.80	2.31
	5 min	6.80	> 5.80

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 complies with the criteria for acceptance (> 5 log (10) reduction in 5 minutes) after 5 minutes against Rhodococcus equi.



KM. Self, M.B.I.C.Sc.,M.R.S.H.
Proprietor

8th November 2004

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End

Sporicidal activity.

The following test reports show NewGenn Foam Hand Rub has limited sporicidal activity against both *Bacillus subtilis* and *Clostridium difficile* spores. The test method used was EN1276 which requires a 5 log₁₀ reduction and as expected this mild product fails to achieve that level of decontamination.

However it does achieve a several log₁₀ reduction in minutes which makes it useful against the levels of spores anticipated on visibly clean hands. If hands are contaminated with faeces, and especially faeces from a patient affected with *C. difficile* diarrhea, the care staff will be expected to wash them using an appropriate wash.

Therefore NewGenn Foam Hand Rub is presented as a product that will offer an element of prevention in the transfer of bacterial spores.

EFFICACY TESTS (EN 1276)

NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES

MILL FARM

MILL LANE

TUNSTEAD

NORWICH

NRI2 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR.

Test Products:

NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium chloride,
Di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Bacillus subtilis IPP 5262
(spores)

Test Method and Validation 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 (phase 2, step 1).

Product test concentration	1% (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	5, 10, 15, 30 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in EN 1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation or bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (Phase 2, step 1). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN 1276

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Bacillus subtilis	5 min	7.00	1.89
	10 min	7.00	3.03
	15 min	7.00	3.21
	30 min	7.00	3.46

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1276 does not comply with the criteria for acceptance after 30 minutes.

(> 5 log (10) reduction in 5 minutes required)

A handwritten signature in black ink, appearing to read 'K.M. Self', is centered on the page. The signature is fluid and cursive.

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

28th July 2004
K76740

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End

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT
NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NRI2 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate –
West
Stanton
Bury St Edmunds
Suffolk IP31 2AR

Test Products: NewGenn High Level Disinfectant

Ingredients - Cocoamido propylbenzene ammonium chloride
Di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Clostridium difficile NCTC 11209 (
spores)

Test Method and Validation EN1276 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 (phase 2, step 1).

Product test concentration	1% (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	5, 10, 15, 30 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1% Histidine 0.1%

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1276)

Summary of test method

The test method is described in 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 area (Phase 2, step I). Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1 ml of the test bacterium with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Bactericidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1276

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
Clostridium difficile	5 min	7.32	2.14
	10 min	7.32	2.34
	15 min	7.32	2.53
	30min	7.32	3.04

To satisfy the requirements of this test a > 5 log(10) reduction in test bacteria is required within 5 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN 1276 does not comply with the criteria for acceptance after 30 minutes.

(> 5 log (10) reduction in 5 minutes required)

A handwritten signature in black ink, appearing to read 'KM. Self', is centered on the page.

KM. Self, M.B.I.C.Sc.,M.R.S.H.
Proprietor

28th July 2004
K76746

5
End

EFFICACY TESTS (EN 1650)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NR12 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products:

NewGenn High Level Disinfectant

Ingredients - Cocamido propylbenzene ammonium chloride,
Di-decyl dimethyl ammonium chloride, acidity
modifiers

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms Aspergillus niger ATCC 16404
(spores)

Candida albicans ATCC 10231
(vegetative)

Test Method and Validation EN1650 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1).

Product test concentration	1% in water of standard hardness (i.e. 0.8% in the test)
Appearance of product dilution	Clear solution
Contact time	1 minute and 15 minutes
Test Temperature	20C
Interfering substance	Bovine albumin 0.3% (dirty solutions)
Inhibition method	Dilution neutralisation
Neutraliser	Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 %

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1650)

Summary of test method

The test method is described in EN1650 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (Phase 2, step 1). Copies of EN 1650 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test fungi with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Fungicidal activity of NewGenn High Level Disinfectant

Using Phase 2 step 1 Suspension Test EN1650

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log 10 reductions achieved Mean
Candida albicans	1 min	6.51	> 5.51
	15 min	6.51	> 5.51
Aspergillus niger (spores)	1 min	6.23	1.12
	15 min	6.23	2.19

To satisfy the requirements of this test a > 4 log(10) reduction in test fungi is required within 15 minutes

Conclusion

NewGenn High Level Disinfectant, when tested under dirty conditions as specified in EN1650 complies with the criteria for acceptance (> 4 log (10) reduction in 15 minutes) in 1 minute and 15 minutes against *Candida albicans*, but fails against *Aspergillus niger* spores at 1 minute and 15 minutes.



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

25th June 2004

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End

In vivo activity

NewGenn Foam Hand Rub is a completely new type of hand rub which necessitates a new way of thinking. Any test protocol that requires pre-wash with an anionic wash is inappropriate because the anionic soft soap would partially inactivate this product and lead to a falsely negative result. That makes the European EN1500 protocol inappropriate in this context as it prescribes a pre-wash with soft soap.

The alternative assessment process is the FDA requirement where it is necessary to remove 2 \log_{10} of bacteria on the first application. NewGenn Foam Hand Rub removes 2.45 \log_{10} of bacteria in the EN 1500 protocol despite the obvious neutralizing effect of the anionic pre-wash step. Therefore this product meets those accepted global requirements for which it is suited.

Whenever staunch supporters of EN 1500 choose to refute this logic they are invited to prove the FDA wrong; so far none have accepted the invitation. In a recent debate in the Lancet Journal it was reported that many alcohol gels in use at the time did not pass EN 1500. A letter from Hoffman, Cookson and Teare (*The Lancet* 2002; **360**: 1510) in response cited a paper by Casewell & Phillips, *BMJ* 1977; **2**: 1315-17) reporting that in normal clinical practice there were usually 2 \log_{10} of bacteria on hands. NewGenn Foam Hand Rub eliminates more than that so once again it can be shown to provide all that is needed from a clinical perspective.

EN 1500 is therefore considered to be relevant for alcohol rubs but it has no relevance to rubs based on cationic ingredients. Cationic ingredients bring so many advantages for patients that this academic debate should be seen in the context of allowing infection control to advance. Anyone supporting the EN1500 requirements in the face of many years of data proving alcohol rubs are poorly used are invited to wonder whether their actions are tantamount to endorsing the thousands of avoidable deaths which happen every year from healthcare associated infections.

NewGenn Foam Hand Rub is therefore deemed to have ample *in vitro* activity for the purposes required.

In vivo activity

This is the true indicator for hand rubs. Much has been written in the medical journals over recent decades on how well rubs perform in the laboratory with the result that most people opt for alcohol based rubs. The logic being that alcohol kills so many pathogens that it must be a good thing. Unfortunately tens of thousands of patients die every year from avoidable HAI deaths despite alcohol rubs being available. NewGenn argues that such evidence based research needs to be considered.

There is a huge difference between killing bacteria and preventing infectious microbial disease. The main aspect of that difference relates to whether care-workers actually use the rubs. Many peer-reviewed papers document the evidence-based research of how infrequently people use alcohol rubs. In Britain the National Patient Safety Agency's 'Cleanyourhands' campaign put a huge amount of effort into inducing care-workers to use alcohol rubs. Unfortunately the usage rates did not rise sufficiently as staff just continued their practices of the previous decades. It can therefore be argued that alcohol hand rubs are excellent biocides when considered in both *in vitro* laboratory tests and *in vivo* tests like EN1500, but that is only part of the picture. If staff do not USE the alcohol rubs the products are effectively useless.

To better safeguard the patient it is therefore appropriate to find an alternative to these 'high-kill' products that are rarely used. One way to advance would be a less effective biocide which was far more frequently used. The evidence-based research in the medical literature shows there are usually only 2 log₁₀ bacteria present on hands which means it is only necessary to kill that number with each application of a hand rub. NewGenn Foam Hand Rub achieves more than that, even in a test protocol that inactivates some the of the product's active component.

Improving usage rates has not been achieved by applying pressure, and event the pro-active National Patients Safety Agency campaign failed in this regard.

What would happen if the users were given a positive reward every time they used a hand rub? The easiest reward would be a nice feels on their hands and that is what NewGenn Foam Hand Rub provides.

Section 4

Safety Assessment

Ingredients

All the ingredients in NewGenn Foam Hand Rub were selected as ones known to be safely used in numerous skin products. The quaternary ammonium compounds are also used safely in the food industry and have been for many decades. Therefore all the individual ingredients have high safety profiles.

NewGenn Foam Hand Rub is free of flammable solvents. Under Britain's health and safety CoSHH guidelines employers are required to replace hazardous substances as soon as viable alternatives are available. That time has arrived as alcohol rubs can now be replaced with NewGenn Foam Hand Rub.

The Formulation

The overall product has been used in ward environments for several years during which time numerous staff, cleaners and even patients have sought out NewGenn to purchase the product for use at home.

A significant number of people have also stated that their "dermatitis" has been "cured" by the use of NewGenn's hand products. Whenever statements of that type are made the person is told that NewGenn has not "cured" anything; it has simply removed the chemical insult of their previous products and the skin has cured itself. The growing list of people for whom NewGenn's hand products have apparently brought an improvement in clinical skin conditions is now being discussed with dermatology groups and risk assessment teams.

This same formulation plus a preservative is used as the liquid in NewGenn Wet Wipes which have been successfully and extensively used for two years in a special care baby unit. The infection control team has been very assiduously watching for deleterious effects on babies, staff and equipment and since none have arisen the wipes are still being used in neonatal units.

NewGenn Foam Hand Rub is Halal accredited which provides assistance to Muslims who should avoid alcohol. Some people argue that the use of external alcohol is allowed. However a recent peer-reviewed article in the Journal of Hospital Infection showed the presence of alcohol in the blood following use of an alcohol rub which means alcohol rubs should be considered Haram under Shari'a Law.

Environmental profile

NewGenn Foam Hand Rub is biodegradable under the European and American requirements.

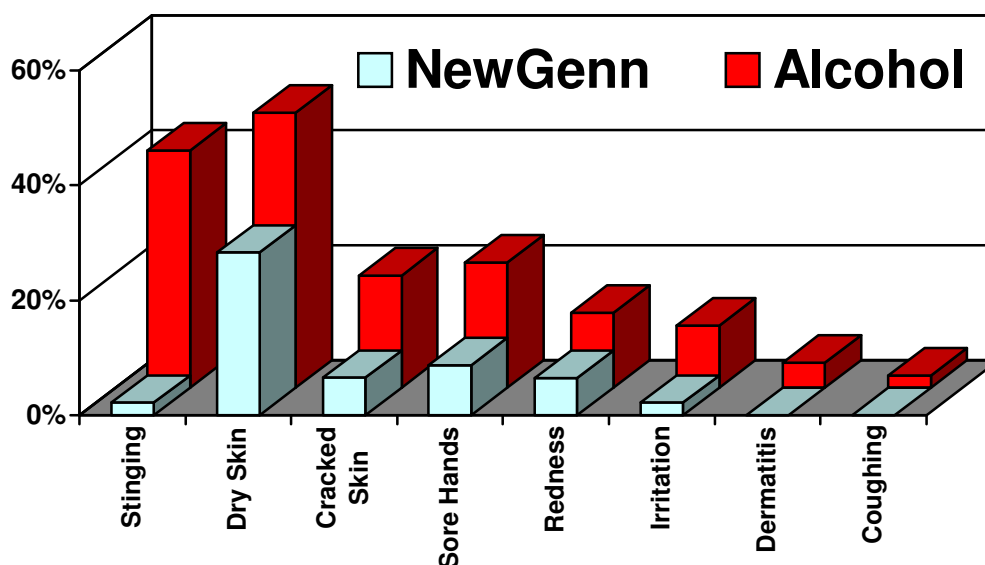
Section 5

Clinical and Epidemiological data

Since no large-scale hospital studies have been conducted full clinical and epidemiological data has yet to be compiled.

A number of British infection control teams have instigated the use of NewGenn Foam Hand Rub in their hospitals to good effect. Unfortunately the current adversarial political arena surrounding hand rubs in Britain is making it uncomfortable for those teams to be open about their progressive decisions and the good results they have achieved. Other infection control teams who wanted to try this new and innovative product in their hospitals now believe it is wiser for them to continue doing what they have always been doing even though they know perfectly well that patients are dying needlessly from infections they feel could and should be prevented. That is another reflection of the political pressure currently surrounding hand rubs. Until that changes rubs like this one will remain relatively obscure and patients will continue to die in unacceptable numbers.

What can be presented here, anonymously, is a two-ward study as it can be so easily repeated in a matter of weeks with the results brought into the public domain. In this study users were asked to indicate how many of the nine clinical symptoms shown they suffered while using alcohol, and then while using NewGenn Foam Hand Rub.



Many of the respondents had the “typical” sore hands associated with chlorhexidine use which accounts for the high percentage who reported stinging when alcohol was applied. In this study, of those who expressed an opinion on the smell of alcohol, 70% did NOT like the alcohol smell compared to 30% who said they liked it.

This study was designed for internal use and only serves as a preliminary indicator of what is likely to be found when a more robust study is performed. Any clinician who wishes to undertake such a study is invited to contact NewGenn.

Section 6

Conclusion

NewGenn Foam Hand Rub achieves all the design objectives presented on page 3.

For decades it has been preferred practice to rely on 'evidence-based research' which usually meant laboratory generated data. Unfortunately the reality of high HAI rates shows that this evidence-based research has failed too many patients. NewGenn would like to introduce a new phrase of 'evidence-based results' which is relates to the incidence of clinical cases. Evidence-based research has concentrated on the ability to kill microbes whereas evidence-based results extends the debate to also include the patient outcomes and directs peoples' minds towards the objective of having no disease.

As with any new approach to any long-established medical problem it will take time to find individual clinicians ready to undertake the relevant studies destined for peer-reviewed journals. NewGenn Foam Hand Rub is therefore expected to have a prolonged entrance into the hospital setting and that has certainly been the case.

While that work is being done the product is actively being used in markets where a more immediate answer to the problems of cross-contamination with bacterial, viral and fungal pathogens is desired. The cruise ship sector has very readily taken the product because of its ability to kill Noro Virus without damaging the hands of passengers. The Veterinary sector uses it because alcohol offends cats and many dogs, making the NewGenn product useful from the perspective of staff safety as offended pets become dangerous to handle. The mother and baby market is accepting the product because there is no flammable solvents and the nice cosmetic feel left on skin. In the food sector people readily use the product since it overcomes the de-fatting of skin so commonly encountered with alcohol rubs. Muslims appreciate the fact that this product has official Halal accreditation under Shari'a Law.

Therefore NewGenn Foam Hand Rub is readily accepted in all sectors other than hospitals, which is ironic as that is where most of the lethal healthcare associated infections occur. This product in NOT intended to mimic alcohol hand rubs or any other rubs which remove 5 logs₁₀ of bacteria from fingertips. There are ample such products, with or without alcohol, and if that is what medical influencers want then that is what they should advocate. However the existence of those products has failed to prevent thousands of deaths from health-care associated infections and some people are seeking a more refined approach.

NewGenn Foam Hand Rub provides that, a product that brings improved user compliance and an alternative that offers the opportunity to control Noro Virus. It is also part of an extended range of products which together offer something those responsible for preventing infections have never had until now.

In conclusion, NewGenn Foam Hand Rub provides a degree of finesse into the topic of hand hygiene. It does what is required from a clinical perspective and it breaks many of the barriers which have arisen in the fifty years during which alcohol rubs have allowed so many people to die avoidable deaths.

Appendix

The products in the NewGenn range to date

NewGenn's infection control products are part of a system comprised of four mini-systems.

Mini-system

Hands

- Foam Hand Rub
- Foam Hand Wash
- Foam Deep Wash
- Wet Wipes

Environmental

- Antimicrobial Cleanser spray
- High Level Disinfectant
- Wet Wipes

Instruments

- Instrument Wash
- Instrument Disinfectant
- Wet Wipes

Patient

- Personal Care Foam
- Wet Wipes

Laundry

- System Sanitise

Air space

- High Level Disinfectant for fogging

More products have been added so NewGenn can become the single-source supplier for cleaning and hygiene products. That includes laundry, kitchens, rooms and people.