

NewGenn Instrument Wash



Intuitive Infection Control

Presented by:

NewGenn

NewGenn Research Limited

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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	66
	Ingredient safety	“
	The formulation	“
	Environmental profile	“
5	Clinical and Epidemiological data	67
6	Conclusion	67
Appendix	The products in the NewGenn range to date	68

Section 1

Summary

NewGenn Instrument Wash is a concentrate used at 1% dilution in water for cleansing medical instruments prior to subsequent disinfection. The product is intended to provide:

1. Rapid cleaning action
2. Compatibility with NewGenn Instrument Disinfectant
3. A mild liquid that will be safe if it comes into contact with an operative's skin
4. Rapid antimicrobial action against a wide range of pathogens to provide a degree of protection of operatives who inadvertently become splashed during the cleaning process
5. A non-toxic, non-corroding and biodegradable multi-purpose product
6. An additional component within an extensive range of chemically compatible infection control products.

The material presented in this document is intended to show that this new and innovative product has a clear potential to help reduce hospital acquired infections in staff.

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.

1. Enthusiastic user compliance was needed so ingredients derived from plant oils were used
2. The cleaning power needed to expose microbes came from ingredients with strong detergent action
3. To ensure chemical compatibility with NewGenn Instrument Disinfectant the same cleansing ingredients were used in both products
4. In order to achieve the broad spectrum antimicrobial activity this product is simply NewGenn High Level Disinfectant under a different label.

The ingredients and their respective inclusion rates in the working 1% solution are:

Ingredient	CAS Number	NewGenn High Level Disinfectant (working solution) %
Coco alkyl benzene ammonium chloride	121-54-0	<0.03
Didecyldimethyl ammonium chloride	7173-51-5	<0.02
Coco amine oxide	70592-80-2	<0.01
Blue dye	3844-45-9	<0.001
Acidity modifier 1	Secret	<0.03
Acidity modifier 2	Secret	<0.01

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 Instrument Wash is shown on the following pages.

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY

MANUFACTURER / SUPPLIER:

NEWGENN RESEARCH LIMITED

5 Shepherds Grove Industrial Estate, Stanton, Bury St Edmunds, Suffolk, England. IP31 2AR
Tel: 01329 253840 Fax: 01359 251836 www.newgenn.com

PRODUCT NAME:

NEWGENN Instrument Wash

REFERENCE:

SAF186 Issue date: 24 April 2006 Issue Number: 4

PHYSICAL FORM: Liquid.

PRODUCT TYPE: Instrument Wash concentrate.

CONTAINERS: Bottles - Plastic.

2. COMPOSITION / INFORMATION ON INGREDIENTS

NAME AND % ACTIVE

Water to 100%

Didecyldimethylammoniumchloride <5.0%

Alkyldimethylbenzylammoniumchloride <5.0%

Alkyl amine oxide <5.0%

pH stabilisers <0.5%

3. HAZARDS IDENTIFICATION

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: Goggles and gloves will protect against contact with eyes and hands.

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: Two 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: Dark blue 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

Efficacy data

In Vitro activity

NewGenn Instrument Wash is supplied as a concentrate and used as a 1% solution in water.

The cleaning capacity is best represented by the fact that it has been used in NHS endoscopy units for several years to the satisfaction of those cleaning the instruments.

The antimicrobial activity is that of NewGenn High Level Disinfectant as the two products are identical in every respect other than name. That basic formulation has remained the same but over recent years the name has changed whenever the company name changed. Therefore some of the data presented here relates to previous names. The data is relevant for this document as the formulation has remained the same.

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 half the concentration present in the user dilution of NewGenn Instrument Wash. The results presented are therefore valid for this product at the 1% working solution.

The EN1276 results from the Hospital Infection Research Laboratory in Birmingham relate to TecMark Hand Rub which was a 0.5% solution of NewGenn High Level Disinfectant. The Birmingham EN1276 results presented are therefore relevant for this product and this document.

The other test reports on bacteria, bacterial spores and fungi were all conducted on 1% NewGenn High Level Disinfectant which is the same as this product at its working dilution.



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)	<u>SAIFER 'C'</u>	<u>Control</u>
	<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. PE28 2BQ
Tel: (01480) 464242
Fax: (01480) 461641

EFFICACY TESTS (EN1276)
SAIFER HYGIENE 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)

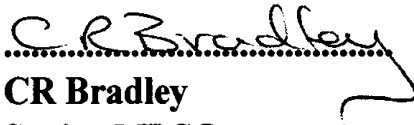
Log ₁₀ reductions achieved							
Test organism	Contact time	Log ₁₀ initial count (challenge)		Clean conditions (0.03% albumin)		Dirty conditions (0.3% albumin)	
		1 min	5 min	1 min	5 min	1 min	5 min
Pseudomonas aeruginosa	Test 1	7.64	7.64	>6.64	>6.64	>6.64	>6.64
	Test 2	7.90	7.90	>6.90	>6.90	>6.90	>6.90
	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 – Cocoamido 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	1.0% (i.e. 0.8 % in the test)
Appearance of product dilution	Clear solution
Contact time	10 seconds, 1 minute
Test temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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)

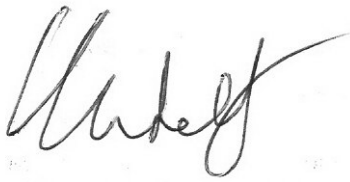
(Test carried out in duplicate)

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.M. 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 HGIH 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 - Cocoamido 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	1.0% (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 conditions)
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 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 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) achieved 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.



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

2nd August 2004

5
End

EFFICACY TESTS (EN 1276)
NEWGENN HGIH 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 Personal Care Product

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

Lot No: 311001

Storage Conditions: Room temperature

Test Organisms: Escherichia coli 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	1.0% (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 conditions)
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 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 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
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 – Cocoamido 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	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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

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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)

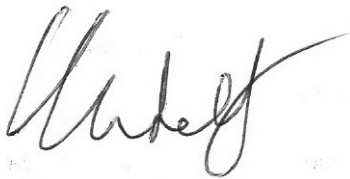
(Test carried out in duplicate)

Test Organism	Contact time	Log 10 initial count (challenge) Mean	Log (10) reductions achieved Mean
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*.

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

17th December 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

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: *Serratia marcescens* NCTC 10211

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 and 5 minutes
Test temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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
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', written in a cursive style.

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

6th September 2004

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End

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

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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 – Cocoamido 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	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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*.



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

8th October 2004

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EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
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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: Rhodococcus equi NCTC 1621

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	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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
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*.

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

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Proprietor

8th October 2004

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Sporicidal activity.

The following test reports show NewGenn Instrument Wash has a degree of sporicidal activity against both *Bacillus subtilis* and *Clostridium difficile* spores and a similar effect on fungal spores of *Aspergillus niger*. The test method used was EN1276 which requires a 5 log₁₀ reduction and as expected this mild product falls short of that high level of decontamination.

Since the instruments cleaned in NewGenn Instrument Wash are usually then disinfected in NewGenn Instrument Disinfectant that does achieve the required 5 log₁₀ reduction in bacterial and fungal spores within minutes it is fairly inconsequential that the instrument wash brings its own sporicidal action. However anything that routinely, safely and cost effectively contributes to the reduction in pathogens within the clinical setting brings a benefit.

Therefore NewGenn Instrument Wash is presented as a product that will augment a prevention philosophy intended to routinely reduce the number of spores in the patient and working environments and therefore help reduce the number of spores transferred.

EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
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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 – Cocoamido 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 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	5, 10, 15, 30 minutes
Test temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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
Bacillus subtilis	5 min	7.32	2.14
	10 min	7.32	2.34
	15 min	7.32	2.53
	30 min	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 EN1276 does not comply with the criteria for acceptance after 30 minutes.
(> 5 log (10) reduction in 5 minutes required)



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Proprietor

28th July 2004
K76746

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EFFICACY TESTS (EN 1276)
NEWGENN HIGH LEVEL DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
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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 – 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	1.0% (i.e. 0.8 % in the test)
Appearance of product dilution	Clear solution
Contact time	5, 10, 15, 30 minutes
Test temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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
Clostridium difficile	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)



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 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 -- Cocoamido 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 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 the	1% in water of standard hardness (i.e. 0.8% in test)
Appearance of product dilution	Clear solution
Contact time	1 minute and 15 minutes
Test temperature	20 C
Interfering substance	Bovine albumin 0.3% (dirty conditions)
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 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 Instrument Disinfectant

Using Phase 2 step 1 Suspension Test EN1650

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

Log (10) reductions achieved

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

The intended use for NewGenn Instrument Wash is to cleanse instruments prior to the latter being disinfected. It is therefore not intended to come into contact with users or patients which makes the need for data on *in vivo* activity redundant.

It does however have an *in vivo* activity as this product is NewGenn High Level Disinfectant under another name, and if the reader wishes to see the relevant data it can be found in the equivalent document for NewGenn High Level Disinfectant.

Section 4

Safety Assessment

Ingredients

All the ingredients in NewGenn Instrument Wash 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 Instrument Wash is free of flammable solvents, halides, enzymes and phenols. Under CoSHH guidelines employers are required to replace hazardous substances as soon as viable alternatives are available. In the view of most Health and Safety personnel who have examined NewGenn Instrument Wash, that time has arrived and washes containing hazardous substances can now be replaced.

The Formulation

The formulation, under various other names, has been used in ward environments for several years without any reports of problems. In fact numerous staff, cleaners and even patients have sought out NewGenn to purchase other products based on this formulation for use at home.

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

Environmental profile

NewGenn Instrument Wash is biodegradable under the European and American requirements.

Section 5

Clinical and Epidemiological data

This product has been used at The Royal Brompton and Harefield NHS Trust for a number of years.

Section 6

Conclusion

NewGenn Instrument Wash achieves all the design objectives presented on page 3.

The primary purpose of the product is to provide a means of cleansing instruments. Secondary benefits are to ensure compatibility with NewGenn Instrument Disinfectant and any other cationic based instrument disinfectant and to provide a degree of protection for users who might be susceptible to infection from spray created during manual cleaning of instruments.

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

Patients

- Personal Care Foam
- Wet Wipes

Laundry

- System Sanitise

Air space

- Biobreez[®]

More products will be added when appropriate on a market-led basis. NewGenn Research is predominantly a research company with the research element is firmly based on a Prevention Philosophy.