STERI-7 HALO

BREAK TREAT PREVENT

it's a revolution

Summary of Evidence

STERI-7 HALO

BREAK TREAT PREVENT

STERI-7 HALO TECHNOLOGY

The active ingredient in all Biomimetics Health Industries formulations is a unique form of Hypochlorous acid. Hypochlorous acid is generated in very low concentrations (ppm – parts per million) by the body to power the human immune system. Although non-toxic, it is the most effective oxidizing agent known to man. STERI-7 HALO formulations replicate this chemistry - and extrapolate its performance. All STERI-7 HALO formulations are rapidly sporicidal, Virucidal, fungicidal and bactericidal. At low concentrations, STERI-7 HALO rapidly kills the most dangerous pathogens, yet is pH neutral and non-toxic to healthy skin. At high concentrations (up to 4,000ppm), STERI-7 HALO is suitable for decontamination applications where a high level of biological load is present or for high volume dosing requirements such as water treatment.

Sporicidal efficacy

UCLH Speed of kill trial:
Quantitative suspension test to assess the efficacy of STERI-7 HALO in the destruction of Clostridium difficile 027 spores. Conducted by Dr Ginny Moore, UCLH. Test organism: Clostridium difficile 027.

Organisms were exposed to 2,000ppm STERI-7 HALO. Method: Test reactions were set up by adding 1 ml spore suspension to 9 ml of the STERI-7 HALO solution - this mixture was stirred regularly. At 15, 30, 60 seconds, 1.30, and 2 minutes, 100ul of the test reactions were removed into 900ul of neutralizer. This sampling aliquot was allowed to stand for approximately 2 minutes after which it was cultured for total viable counts. Counts were run in duplicate. Brazier's Agar plates were used and read after 48 hours incubation at 37°C in an anaerobic environment, and the concentration of viable C. difficile calculated.

Requirement:
As high a log reduction, as quickly as possible.

Results/Conclusion:
"STERI-7 HALO at a concentration of 2000ppm demonstrated a kill rate of between 6 log^{10} and 7 log^{10} (99.9999%) of C. difficile (027) spores within 15 seconds".

>99.9999%
Log reduction within 15 seconds against
C. difficile 027

BS EN13704:
Quantitative suspension test to establish sporicidal activity of chemical disinfectants within the medical area (Phase 2, Step 1 sporicidal test). Conducted by Tina Bradley, Hospital Infection Research Laboratory. Test organism: Bacillus subtilis var niger NCTC 10073. Interfering substances – Clean Conditions: 0.03% w/v bovine albumin (final concentration). Dirty Conditions: 0.3% w/v bovine albumin (final concentration) plus 0.3% v/v washed sheep erythrocytes. Organisms were exposed to 2,000ppm STERI-7 HALO.

Requirement:
3 log^{10} reduction in 60 minutes in clean and dirty conditions. Results: 2,000ppm STERI-7 HALO achieved in excess of 6.70 log^{10} reduction within 1 minute in clean conditions and 4.82 log^{10} reduction within 1 minute in dirty conditions.

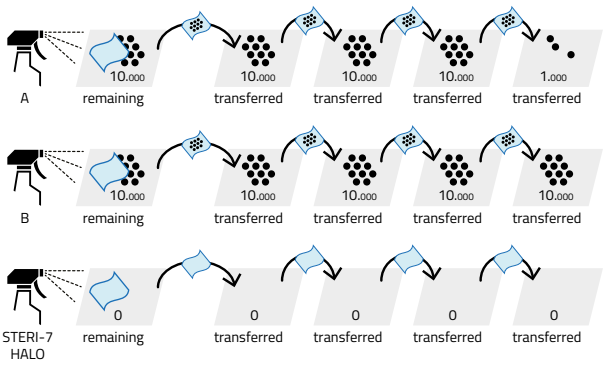
Conclusions:
"Tests carried out with STERI-7 HALO at a concentration of 2,000ppm under clean (0.03% w/v albumin) and dirty (0.3% w/v albumin and 0.3% v/v sheep erythrocytes) conditions demonstrated a >3 log^{10} reduction against spores of Bacillus subtilis at 20°C within 1 minute, and a >6 log^{10} reduction within 1 minute under clean conditions and 5 minutes under dirty conditions. Published EN tests for sporicidal activity i.e. EN 13704 have a requirement for a >3 log^{10} reduction in 60 minutes. This was achieved in clean and dirty conditions within 1 minute".

UCLH wipe transfer study:
Comparison of STERI-7 HALO to the two best performing wipe products in use in the UK NHS. Conducted by Dr Ginny Moore, UCLH, 2011. Clean test surfaces (5x5cm2) were seeded with approximately 107 spores of an outbreak strain of Clostridium difficile 027 and wiped clean with a microfiber cloth. This cloth was then used to wipe four clean test surfaces consecutively. In all cases, cloths were

pre-treated with one of three disinfectants: Product A (Chlorine dioxide based), Product B (Chlorine based) and STERI-7 HALO (chemically generated Hypochlorous Acid) and compared against tap water (control). A suspension test was also performed under BS EN 13704 conditions to test the sporicidal activity of all disinfectants.

Results/ Conclusion:
All three disinfectants satisfied the requirements of the BS EN 13704 standards and were able to reduce the spore counts by more the 3 logs within a 60 minutes contact time. Spore counts fell below the detection limit within seconds when treated with STERI-7 HALO and after 3 and 5 minutes of contact time with Product A and Product B respectively.

Cleaning a surface contaminated with approximately 7 log^{10} C. difficile 027 spores with a microfiber cloth pre-treated with the disinfectants resulted in product A and B leaving 3-4 log^{10} spores remaining on the surface after cleaning – similar to the number of spores remaining when no disinfectant was used. These cloths spread 3-4 log^{10} spores to four sterile surfaces subsequently wiped with the same cloths. The STERI-7 HALO wiper left no spores remaining on the contaminated surface and eliminated the transference of spores to the four subsequently wiped sterile surfaces.



Tests conducted by Dr G. Moore Environmental Laboratory - University College London Hospitals. April 2011

Testing of Sporicidal wipes against C. difficile – Cardiff University:
Comparison of STERI-7 HALO treated wipes to the results of the Siani et al (American Journal of Infection Control 2011), paper conducted by Jean Yves Maillard – Cardiff University. Testing replicated the 3 stage protocol of the 2011 Siani et al paper, comprising:

a) the ability of the wipe to remove the bioburden from the surface,

b) the ability of the wipe to transfer bioburden and

c) the sporicidal activity of the formulation within the wipe. Test organism: Clostridium difficile NCTC 12727. Interfering substances – 3 g/L bovine serum albumin.

Results/ Conclusion:
The STERI-7 HALO impregnated wipe removed more spores of C. difficile than the best performing wipe in the Siani et al paper, achieving 5.28 log^{10} +/- 0.00 in both clean and dirty conditions. It achieved greater sporicidal activity at 10 seconds and 5 minutes than any of the other wipes in the Siani test and it transferred zero spores in dirty conditions. The STERI-7 HALO impregnated wipe performed better than any other wipe previously tested using the Siani methodology.

BS EN13704:
Quantitative suspension test to establish sporicidal activity of chemical disinfectants within the medical area (Phase 2, Step 1 sporicidal test). Conducted by Tina Bradley, Hospital Infection Research Laboratory. Test organism: Clostridium difficile NCTC 11209. Interfering substances – Clean Conditions: 0.03% w/v bovine albumin (final concentration). Dirty Conditions: 0.3% w/v bovine albumin (final concentration) plus 0.3% v/v washed sheep erythrocytes. Organisms were exposed to 2,000ppm STERI-7 HALO.

Requirement:
3 log^{10} reduction in <60 mins. in clean and dirty conditions. Results: 2,000ppm STERI-7 HALO achieved in excess of 5.64 log^{10} reduction within 1 minute in clean and dirty conditions.

Conclusion:
"Tests carried out with STERI-7 HALO at a concentration of 2,000ppm under clean (0.03% w/v albumin) and dirty (0.3% w/v albumin and 0.3% v/v sheep erythrocytes) conditions demonstrated a >5 log^{10} reduction against spores of Clostridium difficile at 20°C within 1 minute.

Virucidal efficacy

BS EN14476:
2005 quantitative test in virucidal suspension for chemical disinfectants and antiseptics. Conducted by Eurofins Biolab SRI. Test organisms: Polio virus Type 1 LSc-2ab and Adenovirus type 5 – ATCC VR-5. Interfering substances 0.03% bovine albumin (clean conditions) and 0.3% bovine albumin and sheep's erythrocytes (dirty conditions) – all final concentrations. Organisms were exposed to 2,000ppm STERI-7 HALO.

Requirement:
4 log10 reduction in <60 minutes in clean conditions.

Results:
2,000ppm STERI-7 HALO achieved in excess of 4 log^{10} reduction within 30 seconds in clean and dirty conditions.

Conclusion:
"STERI-7 HALO causes a reduction >4 log with the test conditions using a 0.03% final concentration of bovine albumin, in compliance with EN14476:2005 +A1:2006".

Yeasticidal and fungicidal efficacy

BS EN 1275 (2005):
Quantitative suspension test of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics – Phase 1. Conducted by Eclipse Scientific. Test organisms: Candida

albicans NCTC 3179 and A. niger NCTC 2275. Interfering substances – none. Organisms were exposed to 400ppm and 600ppm STERI-7 HALO.

Requirement:
4 log^{10} reduction within 15 minutes in clean conditions.

Results:
400ppm and 600ppm STERI-7 HALO achieved in excess of a 4.0 log^{10} reduction within the required contact time.

Conclusion:
"According to BS EN1275:2005 the above referenced batch(s) of product does possess fungicidal activity when tested using the conditions referenced above".

BS EN1650:
2008 Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics (Phase 2, Step 1). Conducted by MGS Laboratories. Test organisms: Candida albicans ATCC 10231. Interfering substances – 0.3 g/l bovine albumin. Organisms were exposed to 100ppm STERI-7 HALO.

Requirement:
4 log^{10} reduction within 15 minutes in clean conditions.

Results:
100ppm STERI-7 HALO achieved > 4.22 log^{10} reduction in 30 seconds.

Conclusion:
"Based on EN 1650 (2008), the STERI-7 HALO product (100ppm), when tested at RTU, possesses yeasticidal activity in 30 seconds, 1 minute and 15 minutes at 20oC under clean conditions for the referenced strain of C. albicans".

Bactericidal efficacy

BS EN1040 2005:
Suspension test for basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1). Conducted by Eclipse Scientific.

Test organisms:
Staphylococcus aureus (NCTC10788) and Pseudomonas aeruginosa (ATCC 15442). Organisms were exposed to 400ppm and 600ppm STERI-7 HALO.

Requirement:
5 log^{10} reduction in 5 minutes in clean conditions.

Results:
Both 400ppm and 600ppm STERI-7 HALO achieved in excess of a 5 log10 reduction within the required contact time.

Conclusion:
"According to BS EN1040 2005: the product possesses bactericidal activity when tested using the conditions referenced above".

BS EN13727 2003:
Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used for instruments in the medical area. (Phase 2, step 1). Conducted by Tina Bradley, Hospital Infection Research Laboratory. Test organisms: Staphylococcus aureus (NCTC 10788), Pseudomonas aeruginosa (NCTC 6749), Enterococcus hirae (NCTC 12367). Interfering substances - Clean Conditions: 0.03% bovine concentration) plus 0.3% sheep erythrocytes. Organisms were exposed to 600ppm STERI-7 HALO.

Requirement:
5 log^{10} reduction in 60 minutes in clean and dirty conditions.

Results:
600ppm STERI-7 HALO achieved >6.85 log10 reduction against Staphylococcus aureus, >5.95 log10 reduction against Pseudomonas aeruginosa and > 6.74 log10 reduction against Enterococcus hirae in less than one minute in clean conditions, and within the required contact time against all test organisms in dirty conditions.

Conclusion:
"When tested in accordance with EN 13727 (2003), 600ppm STERI-7 HALO possesses bactericidal activity at 20oC under clean (0.03% albumin) and dirty (0.3% albumin/ 0.3% sheep erythrocytes) conditions. A >5 Log10 (99.999%) reduction was achieved with all test organisms within the obligatory contact time of 60 minutes. This was achieved within 1 minute under clean conditions for the three test organisms ie Staphylococcus aureus, Pseudomonas aeruginosa and Enterococcus hirae. 600 ppm STERI-7 HALO, therefore, complies with the requirements described in EN 13727".

BS EN1276 2009:
Chemical disinfection and antiseptics – quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Phase Two, Step One. Conducted by MGS Laboratories. Test organisms: Staphylococcus aureus (ATCC 65388) and Pseudomonas aeruginosa (NCIMB 10421). Interfering substances - 0.3 g/l bovine albumin. Organisms were exposed to 100ppm STERI-7 HALO.

Requirement:
5 log^{10} reduction within 5 minutes.

Results:
100ppm STERI-7 HALO achieved > 5 log10 reduction within 30 seconds.

Conclusion:
"Based on EN 1276 2009, the STERI-7 HALO (100ppm) when tested at RTU, possesses bactericidal activity in 30 seconds, 1 minute and 15 minutes at 20oC under clean conditions for the referenced strains of S. aureus and P. aeruginosa".

BS EN1276 1997:
Chemical disinfection and antiseptics – quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Phase Two, Step One. Conducted by Tina Bradley, Hospital Infection Research Laboratory. Test organisms: Enterococcus hirae (NCTC 12367) and Escherichia coli (NCTC 10418). Organisms were exposed to 100ppm STERI-7 HALO.

Requirement:
5 log10 reduction within 5 minutes.

Results:
100ppm STERI-7 HALO achieved > 7 log10 reduction within 30 seconds.

Conclusion:
"When tested in accordance with a modified EN1276 (1997), STERI-7 HALO at 100ppm possesses bactericidal activity at 20oC under clean (0.03% albumin) conditions. A >5 log10 (99.999%) reduction was achieved with both test organisms within 30 seconds under clean conditions".

BS EN1276 2009:
Chemical disinfection and antiseptics – quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1). Conducted by MGS Laboratories. Test organisms: Bacteroides fragilis (NCTC 9343). Organisms were exposed to 200ppm STERI-7 HALO.

Requirement:
5 log10 reduction within 15 minutes.

Results:
200ppm STERI-7 HALO achieved > 5.0 log10 reduction within 30 seconds.

Conclusion:
"Based upon EN1276 (2009) the product when tested at RTU, possesses bactericidal activity at 30 seconds, 1 minute and 15 minutes at albumin (final concentration). Dirty Conditions: 0.3% bovine albumin (final 20 C under clean conditions for the referenced strain of B. fragilis".

BS EN1276 2009:
Chemical disinfection and antiseptics – quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Conducted by Dr Ginny Moore, ULCH. Test organisms: Streptococcus pyogenes GpA ATCC 19615. Interfering substances - clean conditions: phosphate-buffered-saline solution. Dirty conditions: 0.3% w/v bovine serum albumin. Organisms were exposed to 500ppm, 1,000ppm and 1,500ppm of STERI-7 HALO.

Requirement:
5 $\log^{10}$ reduction within 60 minutes in clean conditions only.

Results:
500ppm, 1,000ppm and 1,500ppm STERI-7 HALO achieved in excess of an 8.9 log10 reduction within one minute in both clean and dirty conditions.

Conclusion:
"In a suspension test, STERI-7 HALO hypochlorous acid solution at 500, 1000 and 1500ppm is an effective microbicide against Streptococcus pyogenes GpA under clean and dirty conditions and can achieve an 8.9 log reduction in colony counts within seconds of contact time".

BS EN14348:
Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the medical area including instrument disinfectants (Phase 2, Step 1). Conducted by Tina Bradley, Hospital Infection Research Laboratory. Test organism: Mycobacterium terrae NCTC 10856. Interfering substances – Clean Conditions: 0.03% bovine albumin (final concentration). Dirty Conditions: 0.3% bovine albumin (final concentration) plus 0.3% sheep erythrocytes. Organisms were exposed to 2,000ppm STERI-7 HALO.

Requirement:
4 $\log^{10}$ reduction in < 60 mins. in clean and dirty conditions.

Results:
2,000ppm STERI-7 HALO achieved in excess of 7.08 log10 reduction within 1 minute in both clean and dirty conditions.

Conclusion:
"When tested in accordance with the methodology described in EN 14348 STERI-7 HALO at a concentration of 2,000ppm under clean (0.03% w/v albumin) and dirty (0.3% w/v albumin and 0.3% v/v sheep erythrocytes) conditions demonstrated a >7 log10 reduction against Mycobacterium terrae within 1 minute. STERI-7 HALO therefore fulfils the tuberculocidal requirements described in EN14348 under clean and dirty conditions".

In-vivo performance

BS EN13697: Efficacy as a fogging agent.
Tests at Campden BRI using PDX fogging equipment were conducted to evaluate the efficacy of STERI-7 HALO against a range of micro-organisms using Campden's whole room disinfection model - an industry accepted procedure based upon standardised non-porous surface disinfection test BS EN13697: 2001. Test organisms: Candida albicans, Staphylococcus aureus, Aspergilus niger, Clostridium difficile, Listeria monocytogenes, Mycobacterium terrae, Bacillus subtilis, Bacillus cereus. Test organisms were exposed to 4000ppm STERI-7 HALO delivered into a 43m^3 test chamber, over a period of 60 minutes. Testing conducted by Dr David Crouch (PDX) and Mr Lawrence Staniforth (Camden BRI). All results are quoted for an exposure time of 60 minutes (as per CEN13697 standards). STERI-7 HALO was experimentally proven not to be degraded in any way when used with PDX technology.

Requirement:
3 log^{10} reduction within 15 minutes.

Conclusion:
The table below demonstrates the log reductions achieved.

Average microbial reductions achieved (log10)

Micro- organism	Initial count CFU / ml	Final count CFU / ml	Log reduction
Candida albicans	1.54 x 10	>15	>7.30
Staphylococcus aureus	1.88 x 10	>10	>7.26
Aspergillus niger	2.10 x 10	>15	>5.32
Clostridium difficle	6.30 x 10	>15	>5.80
Listeria monocytogenes	1.06 x 10	>15	>7.02
Mycobacterium terrae	1.10 x 10	>10	>4.86
Bacillus subtilis	2.92 x 10	>15	>7.64
Bacillus cereus	1.12 x 10	>15	>4.88

BS EN13697:
Efficacy compared to alternative fogging chemistries
Additional testing was conducted at Campden BRI using PDX fogging equipment to compare the efficacy of STERI-7 HALO against a range of competitive fogging chemistries. Again Campden's whole room disinfection procedure for non-porous surface disinfection testing (BS EN 13697: 2001), was employed. Test organisms: Staphylococcus aureus, Bacillus subtilis & Bacillus globigii and Clostridium difficile. Organisms were exposed to 4000ppm STERI-7 HALO via delivering 4.3 litres of STERI-7 HALO chemistry into a 43m^3 test chamber, containing the test organisms.

Result:

EN13697 Compliant (Log10 reduction achieved)

Chemistry	Staphylococcus aureus	Bacillus subtilis var. globigii	Clostridium difficile
Peractic Acid	Yes (6.10)	Yes (5.85)	Yes (4.51)
Quat Ammonium	Yes (4.50)	No	No
Ozone	Yes (5.22)	No	No
Hydrogen Peroxide	No	No	Yes (3.74)
Peroxygen Acid Ester	Yes (6.37)	Yes (3.07)	Yes (4.37)
Chlorine Dioxide	No	No	No
Alkaline Paracetic Acid	Yes (5.62)	Yes (5.32)	Yes (4.90)
STERI-7 HALO	Yes (7.26)	Yes (7.46)	Yes (5.8)

Testing at Campden BRI using PDX fogging equipment

All results are quoted for an exposure time of 60 minutes (CEN13697 standards) - however in all cases STERI-7 HALO achieved the maximum microbial reduction within a 15 minute exposure window. Testing conducted by Dr David Crouch (PDX) and Mr Lawrence Staniforth (Camden BRI).

Requirement:
3 log^{10} reduction within 15 minutes.

Conclusion:
4000 ppm STERI-7 HALO achieved greater microbiological reductions against all specified organisms than each of the competitor chemistries evaluated.

The speed of action of STERI-7 HALO when fogged with PDX equipment was demonstrated by the time taken to achieve its maximum biological reduction against C. difficile and Mycobacterium terrae: under 5 minutes. Even at lower concentrations (2000ppm) fogged STERI-7 HALO performs significantly faster than traditional, more toxic, chemistries such as peracetic acid.

Eradication of Legionella and Pseudomonas in drinking/ process water

STERI-7 HALO complies with EC Biocidal Products Directive (BPD) (98/8/EC) for use in both drinking water and process water at up to 5ppm. 'Shock' dosing at 2ppm causes rapid removal of bio-films and subsequent maintenance dosing, typically at less than 1ppm, keeps all counts below detectable limits. Independent microbiological testing has proven STERI-7 HALO to be more effective in the removal of bio-films, Legionella, Pseudomonas and TVC's than chlorine dioxide or copper silver treatments. Government guidelines on the treatment of Legionella (publication L8), are currently being re-written to endorse the use of STERI-7 HALO for water treatment applications.

STERI-7 HALO as an ultrasonic cleaning agent

Testing conducted by Dr. Paul Humphreys at Huddersfield University shows 400ppm STERI-7 HALO to achieve a total kill (6 log^{10} reduction) in under one minute when used as a sanitising agent in an ultrasonic bath. Test protocol: EN13697. Test organism: Bacilus subtilis spores. It is believed likely that further testing will demonstrate the same efficacy can be delivered using lower concentrations of STERI-7 HALO.

Safety

STERI-7 HALO contains no alcohol, is non-flammable, has no COSHH implications and causes no harm to the environment. At low concentrations it offers a skin neutral pH and is non-sensitising to skin or eyes. At higher concentrations it can be used in industrial applications without the use of PPE or having to be transported as a hazardous substance.

Chemicals Hazard Information & packaging (CHIP)

	Symbol	Risk phrase
STERI-7 HALO 4000	Irritant	Eye irritant
STERI-7 HALO 2000	N/A	None
STERI-7 HALO 1000	N/A	None
STERI-7 HALO 800	N/A	None
STERI-7 HALO 700	N/A	None
STERI-7 HALO 600	N/A	None
STERI-7 HALO 500	N/A	None
STERI-7 HALO 250	N/A	None

Toxicology / Mutagenicity
Full independent toxicity human risk assessment conducted on 2,000ppm STERI-7 HALO concluded that STERI-7 HALO at its stated formulation (<1% calcium hypochlorite in water, 2000 ppm afc), is neither a skin nor eye irritant and presents no risk to human health if used as intended. Full bacterial reverse mutagenicity testing has proven STERI-7 HALO 2000 to be completely non-mutagenic. This was conducted by exposing specially selected strains of Salmonella typhimurium and E. coli to STERI-7 HALO 2000 and incubating both bacteria and test substance in the absence and presence of a supplemented homogenate fraction (S9 mix). The substance was then evaluated for base change mutagens: S. typhimurium TA1535 and TA100, and E. coli WP2 uvrA (pKM101) and frameshift mutagens: S. typhimurium TA1537 and TA98. All testing was conducted in compliance with the UK Good Laboratory Practice Regulations (Statutory Instrument No. 3106), the OECD Principals of Good Laboratory Practice ENV/MC/CHEM (98) 17 and EC Commission Directive 2004/10/EC. The mutagenicity study was conducted in compliance with: OECD Guidelines for the Testing of Chemicals (1997). Genetic Toxicology: Bacterial Reverse Mutation Test, Guideline 471. EC Commission Regulation No. 440/2008. Method B.13/14: Mutagenicity - Reverse mutation test using bacteria. OJ L 142/248. US EPA Health Effects Test Guidelines (1998). OPPTS 870.5100 Bacterial reverse mutation test. EPA 712-C-98-247.

Inhalation Toxicity
Evaluations conducted at HSE Buxton to assess low-level chlorine (Cl2) emissions from STERI-7 HALO following its delivery from PDX vapour jet technology into a 34m3 test chamber. Varying concentrations of STERI-7 HALO (100, 1000, 2000 & 4000ppm) were used to assess levels of chlorine gas generated from the fogging process and from treated surfaces. Measurements were taken using a Portasens II monitor containing a connected via Teflon tubing to 6 locations within the chamber and a MultiRAE portable gas monitor with a chlorine sensor. Experiments were conducted over two days (21-22 August 2012).

Results/ conclusion
Ten fumigation runs were conducted. The data from both the Portasens II and the MultiRAE show that under the described experimental conditions there is no evidence of any off gassing of chlorine gas from any of surfaces present in the chamber during testing. The MultiRAE sensor detected 0-0.1ppm chlorine gas after the purge phase from the highest concentration (4000ppm, 2 minutes delivery) however the short term (15 minute) workplace exposure limit for chlorine is 0.5ppm (EH40-2005) therefore even when misting 4000ppm, STERI-7 HALO is safe to use for single room misting applications (e.g. hospital rooms), as rooms would not be occupied during the misting process. STERI-7 HALO therefore presents no occupational health hazard.

STERI-7 HALO Chemistry

All Biomimetics formulations are manufactured via a patent pending chemical process and are available in a range of strengths up to 4000ppm. The chemical composition of STERI-7 HALO is unique and enables the hypochlorous content to exist across a far wider pH band than has previously been possible: compared to traditional active halogen solutions, STERI-7 HALO offers greater purity, stability, efficacy and safety, together with reduced corrosion.

Physical/chemical properties of STERI-7 HALO:

State:	Liquid Colour: Colourless
Odour:	Characteristic odour (chlorine)
pH:	5.5 - 3.0 dependent upon ppm
Description:	Clear-aqueous
CAS No:	Hypochlorus acid: 7790-92-3

Materials Compatibility

Independent corrosion and compatibility testing has been conducted on a wide range of materials including aluminium, anodised aluminium, mild steel, galvanised steel, 304 stainless steel, 316 stainless steel, polypropylene, rubber, HDPE and multiple soft furnishings including vinyl fabrics and floor coverings. After 8 weeks continuous immersion in 5000ppm STERI-7 HALO neither 304 nor 316 stainless steel displayed any sign of corrosion. After 6 weeks immersion, mild steel and aluminium both demonstrated less corrosion than equivalent concentrations of sodium hypochlorite. Testing on soft furnishings conducted by Intertek and Cleaning Research International demonstrated STERI-7 HALO 1,000ppm to cause no change in colour or tear strength on a wide range of fabrics and only one change in shade of colour of one fabric when wet rubbed. Tests used included: Colour Change: BS EN 20105-A02:1995, Dry Rubbing: BS EN 105-X12:2002, Wet Rubbing: BS EN ISO 105-X12:2002 and Tear Strength: BS EN ISO 13937-1: 2000. STERI-7 HALO at 1,000ppm is also accredited with the Wool Safe Mark.

Quality Control

All Biomimetics formulations are manufactured to exacting standards in our dedicated UK facility. The facility is certified with BS EN ISO 13485:2003 accreditation and is approved for the manufacture of Class III Medical Devices in clean room conditions. All batches of product are manufactured using the same process, and are verified for free available Chlorine (ppm), pH and purity. Validation samples are retained for all batches.

Stability

All Biomimetics formulations have been tested for ppm, pH and antimicrobial efficacy in both real time and accelerated conditions in order to ensure they meet applicable guidelines when aged. All standard strengths of product have been demonstrated to be stable and effective for one (1) year.

Sectors of Activity

Biomimetics Health Industries are currently working within the following sectors: water treatment, human and animal healthcare, healthcare infection control, post harvest decontamination, food and beverage processing, life science clean-room and healthcare laundry.

Accreditations

Biomimetics Health Industries Ltd is a member of Global GAP – and complies with the recognised standards of Good Agricultural Practice (G.A.P.) and the Global GAP regulations and compliance criteria.

Biomimetics Health Industries are also working with:

- **The UK Institute for Animal Health** who are currently evaluating the use of STERI-7 HALO for a range of applications within the avian and livestock industry.
- **The Royal Agricultural College,** UK who have proven the benefit of STERI-7 HALO for seed priming, mite eradication and farm security applications.
- **The Volcani Agricultural Research Institute** who have proven the benefit of STERI-7 HALO for post harvest and fresh produce decontamination.

STERI-7 HALO will shortly be submitted for approval by the Department for Environment, Food and Rural Affairs (DEFRA).