ANTIMICROBIAL GLOVE

Solmed Pty Ltd

Gloveon - Protect

Contrary to conventional medical gloves that serve only as a passive barrier between microbes and your hands, GloveOn Protect antimicrobial gloves can play an important role in reducing the spread of infections by using its killing mechanism.

GloveOn Protect is designed to kill microorganisms on the external side of the glove quickly upon contact. The ingredient on the glove is a photosensitiser which generates singlet oxygen when exposed to light. This singlet oxygen oxidises the bacteria's protein and lipid, thus leading to the death of microbes. Ultimately, GloveOn Protect antimicrobial glove helps reduce the risk of transmission from an infection source to a susceptible patient.

GloveOn Protect gloves have antimicrobial properties that can kill up to 99.999% of microbes. Suitable to be used to help prevent healthcare-associated infections and in any situation where cross contamination is a major concern.

FEATURES:

Powder Free

Standard Cuff

Violet Blue Colour

Lab Chemical Tested

Chemo Drugs Tested

Nitrile

Ambidextrous

Fingertip Textured

No Natural Rubber Latex

Antimicrobial Properties

SPECIFICATIONS:

Glove Properties	Measurement (mm)
Length (mm)	≥ 230
Thickness at Palm (centre of Palm)	0.07 ± 0.02
Thickness at Finger (13mm ± 3mm from tip)	0.09 ± 0.02

Physical Properties	Before Ageing	After Ageing
Tensile Strength (MPa)	≥ 18	≥ 16
Elongation (%)	≥ 500	≥ 400

Inspection Levels & AQL	Inspection Level	AQL
Watertightness	G1	1.5
Physical Dimensions	S2	4.0
Tensile Strength	S2	4.0
Visual Inspection (Major)	S4	2.5
Visual Inspection (Minor)	S4	4.0
Particulate Residue	N = 5	≤ 2mg/glove

CHEMOTHERAPY DRUGS AND CONCENTRATION

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05-Test Report PN 104145B)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	Not recommended
Cisplatin, 1.0mg/ml (1,000 ppm)	> 240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	> 240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	> 240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	> 240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	> 240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	> 240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	> 240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	> 240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	> 240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	Not recommended
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	> 240 minutes

BREAKING THE CHAIN OF INFECTION

WHAT ARE HEALTHCARE-ASSOCIATED INFECTIONS (HAIs)?

Healthcare-associated infections are infections that develop as a result of medical care in a hospital or other healthcare facilities, which were neither present nor incubating at the time of transmission. It includes infections acquired by patients in the medical facility but emerging after discharge, as well as occupational infections among staff.

WHAT ARE THE ADVERSE EFFECTS OF HAIs?

Every year HAIs cause unnecessary suffering and higher medical cost for hundreds of millions of patients and their families around the world. These infections prolong hospital stay, increase the risk of post-operative complications and disabilities, increase resistance to antimicrobials and even result in unnecessary deaths and massive financial losses to the healthcare system.

Figure 1. Annual Impact of HAIs in the USA and Europe

Source: Adapted from World Health Organization, Healthcare-Associated Infections Fact Sheet.

HOW DO HAIs OCCUR?

Infections occur when microbes enter the body, breed and cause a reaction to the body. 3 things lead to an infection to the healthcare system:

1. Source - A source is one within which an infectious agent, such as a virus, bacterium or other microbe thrive and reproduce. In healthcare settings, people such as patients, healthcare workers, visitors and family members can be a source of infection. Other source includes the healthcare environment where microbes can live and breed such as on dry and wet surfaces, dust or decaying debris, moist areas and indwelling medical devices
2. Susceptible Person - A susceptible person is someone who is not vaccinated or otherwise immune, or person with a weakened immune system of which once exposed, provides a way for the microbe to enter the body. For an infection to take place, the microbe must first enter a susceptible person's body and attack the tissues, multiply and cause a reaction
3. Transmission -Transmission refers to the route or method by which microbes are transferred from the source to the susceptible person. In healthcare settings, microbes travel via several ways - physical contact (touching), sprays and splashes, inhalation, and sharps injuries, i.e. when a needle, scalpel or other medical instruments penetrate the skin. Among these routes, physical contact is the main mode of transmission in the healthcare setting.[2]

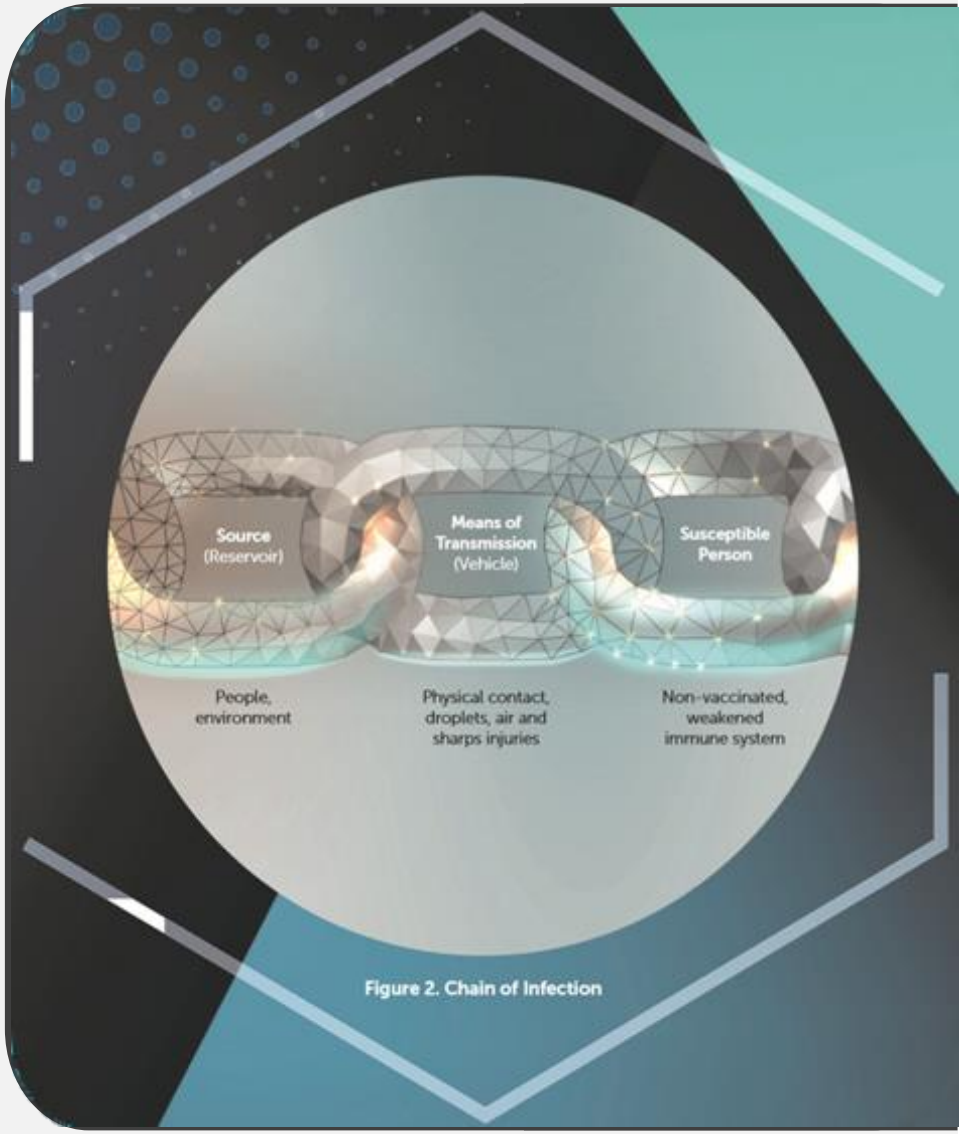
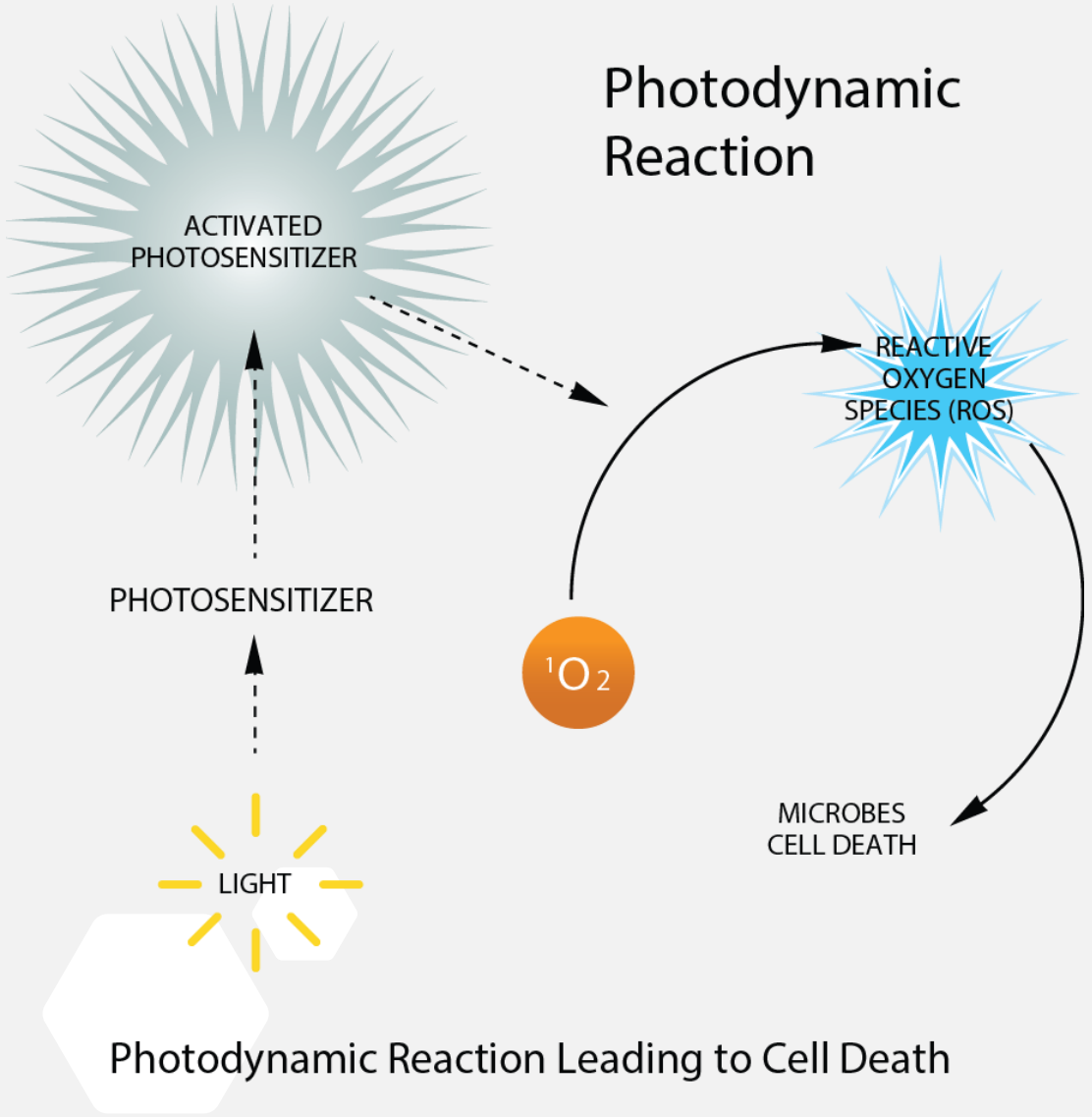


Figure 2. Chain of Infection

AN ACTIVE APPROACH IN PREVENTING HAIs



Photodynamic Reaction Leading to Cell Death

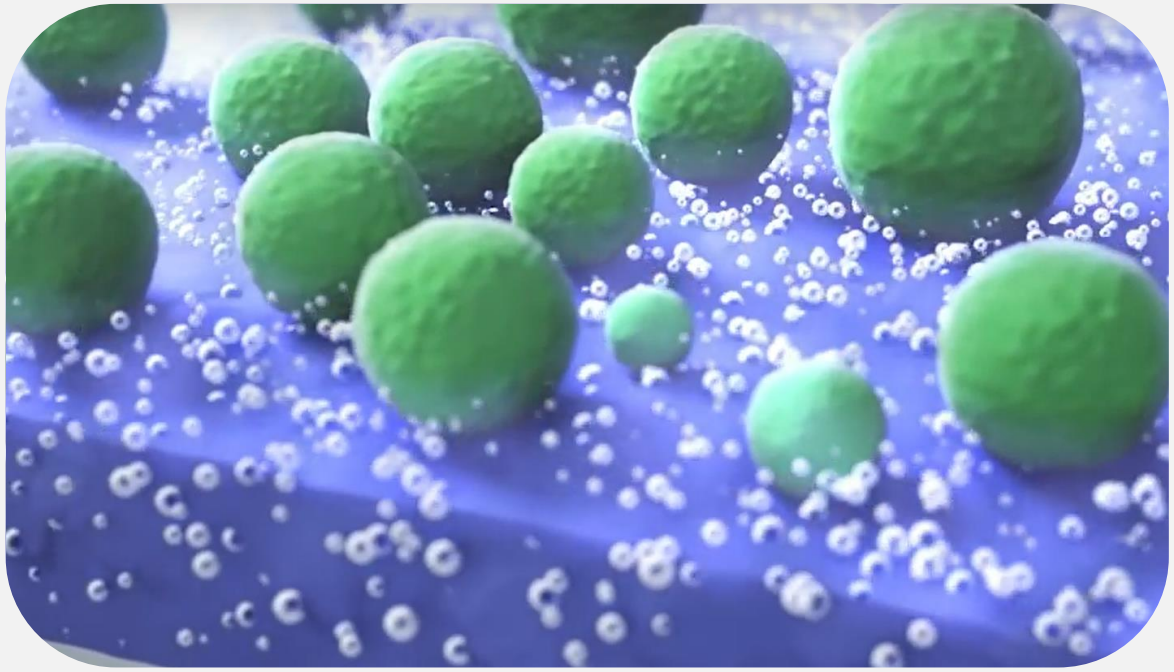
Contrary to conventional medical gloves that serve only as a passive barrier between microbes and your hands, AMG antimicrobial gloves can play an active role in reducing the spread of infections by using its killing mechanism.

The AMG glove is designed to kill microorganisms on the external side of the glove quickly upon contact. The active ingredient on the glove is a photosensitiser which generates singlet oxygen when exposed to light. This singlet oxygen oxidises the bacteria's protein and lipid, thus leading to the death of microbes. As shown in the diagram.

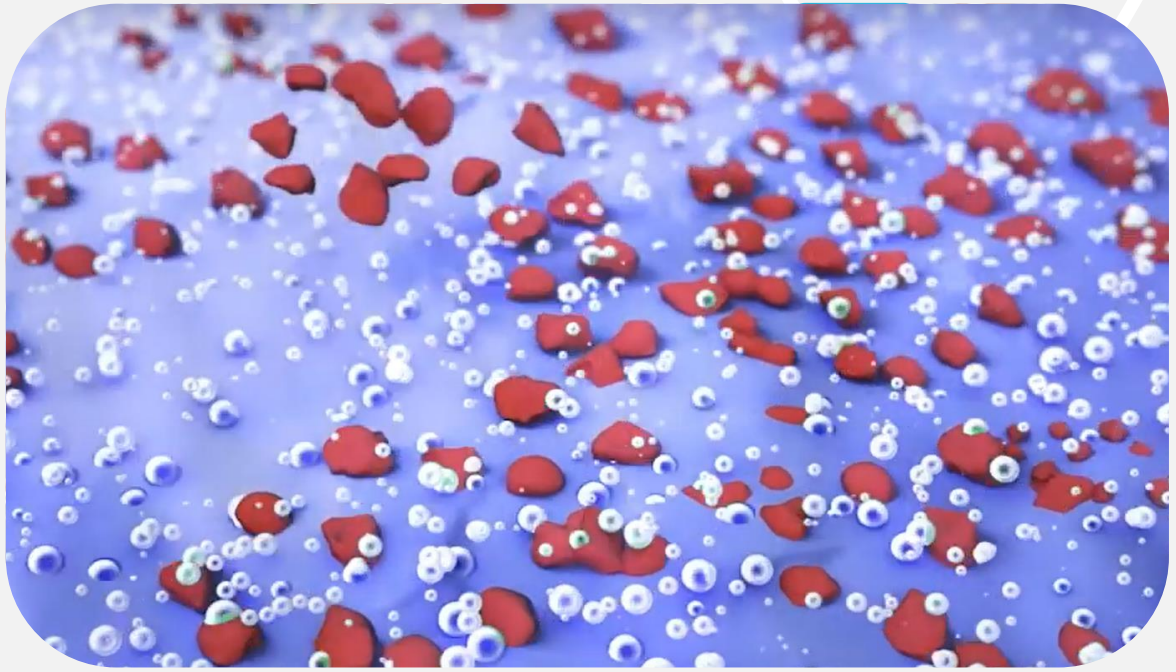
Ultimately, AMG antimicrobial glove helps reduce the risk of transmission from an infection source to a susceptible patient.*

* The use of AMG glove does not replace hand hygiene protocol which is required before donning and removing of gloves.

PHOTODYNAMIC REACTION



REACTIVE OXYGEN SPECIES



MICROBES CELL DEATH

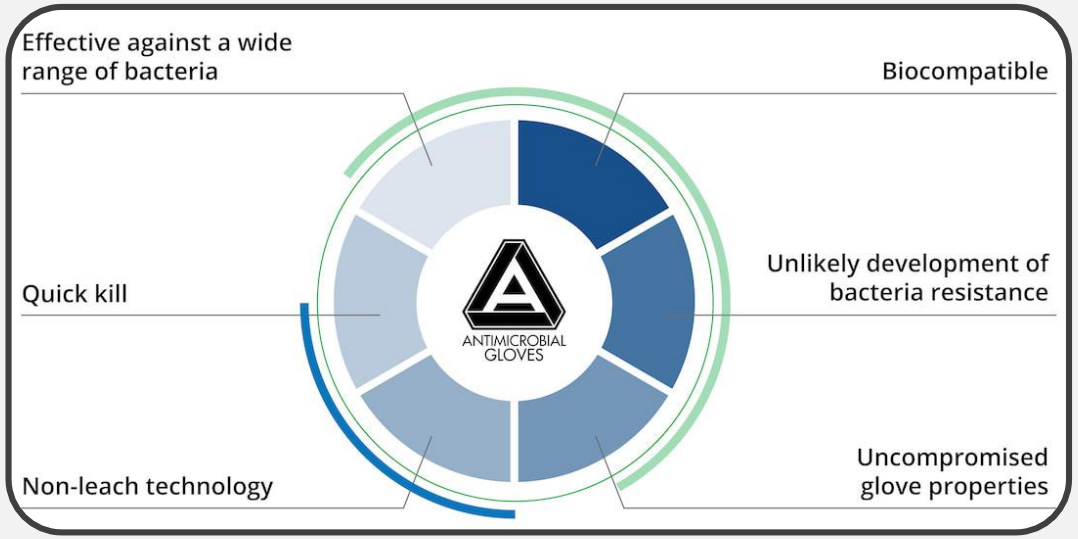
CLICK HERE TO CHECK OUT THE VIDEO FROM HARTALEGA

THE BENEFITS OF AMG

QUICK KILL - Based on ASTM D7909 Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves, AMG is effective in killing superbug MRSA and VRE. Test data has shown that AMG can kill up to 99.999% of selected microbes such as Staphylococcus aureus as quickly as 5 minutes. Further testing was conducted at a shorter contact time with kill rate recorded at 99.989% in 1 minute and 99.998% in 2 minutes.

EFFECTIVE AGAINST A WIDE RANGE OF BACTERIA - Table 1. AMG Antimicrobial Glove Test Results for Bacteria Kill.

** Further testing was conducted on Staphylococcus aureus at shorter contact time. Bacteria kill rate (%) results recorded: 99.989% (1 min), 99.998% (2 mins) & 99.999% (5 mins)



Microbe	Type	Average % Bacteria Killed			
		5 Mins	10 Mins	15 Mins	20 Mins
Enterococcus faecalis (VRE)	Gram-positive	99.982	99.996	-	99.968
Enterococcus faecium	Gram-positive	99.991	99.991	99.996	-
MRSA	Gram-positive	99.988	99.998	99.999	99.997
Staphylococcus aureus**	Gram-positive	99.999	99.993	-	99.994
Streptococcus pyogenes	Gram-positive	99.946	99.970	99.988	99.996
Escherichia coli	Gram-negative	-	-	99.030	-
Klebsiella pneumoniae	Gram-negative	-	96.471	-	97.747

NON-LEACH TECHNOLOGY

AMG is the world's first non-leaching antimicrobial examination glove. The photosensitiser has been tested for non-migration with the following medium:

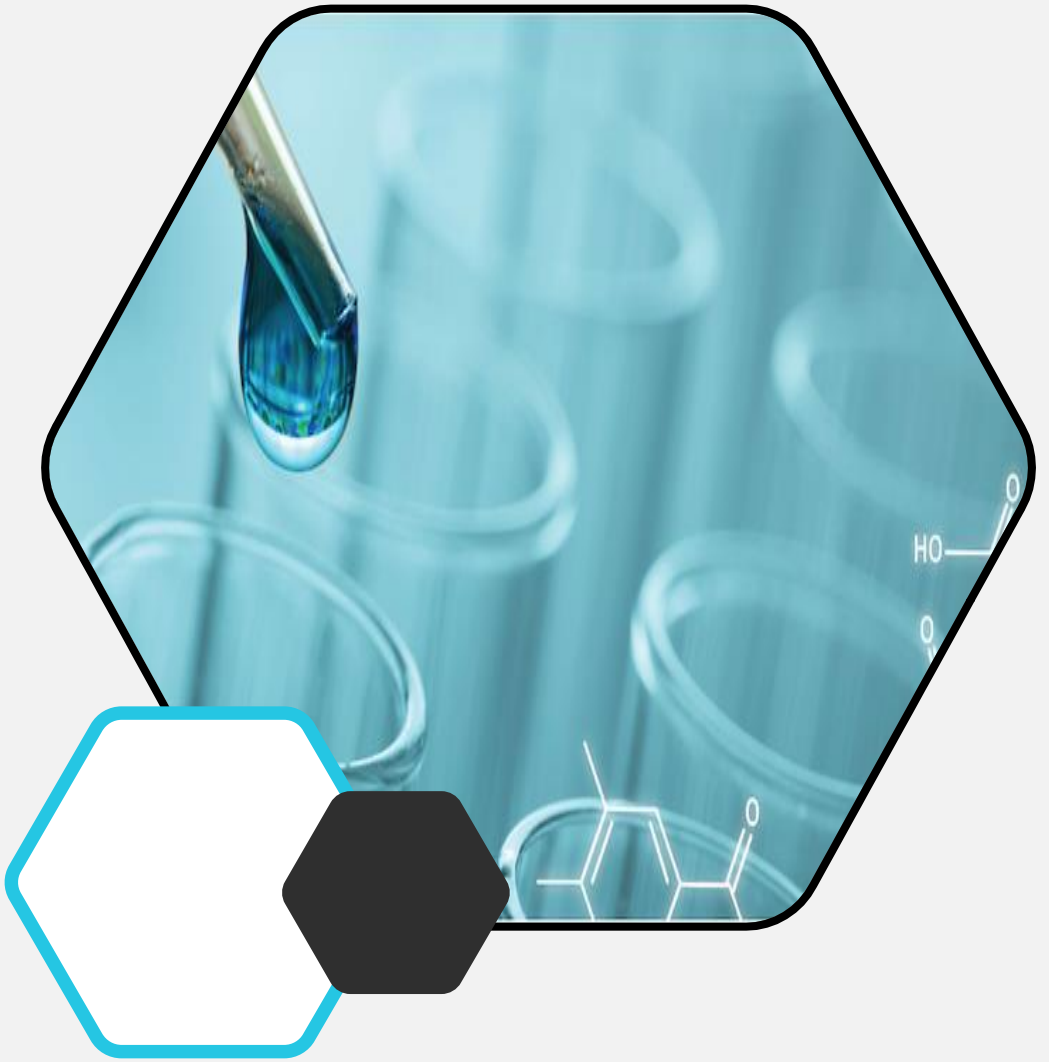
- Water
- Hot Water (45 degrees Celsius)
- Sweat
- Saliva
- Ethanol

All extracts were analysed at Intertek using validated analytical techniques to detect the presence of the photosensitiser. Results concluded that none of the photosensitiser could be found in any of the extracts from neither the inner nor outer glove surface. Although the photosensitiser is proven safe, GloveOn Protect has been designed to further ensure that it does not leach and transfer onto patients.

UNLIKELY DEVELOPMENT OF BACTERIA RESISTANCE

Singlet oxygen technology employed has been assessed as low in regards to bacteria resistance. This is attributed to the non-specific nature of the glove's bacteria-killing mechanism.

Generally, oxidative antimicrobials such as the AMG technology has been viewed as low probability for development of resistance by the EU Scientific committee.[3]



BIOCAMPATIBLE

AMG glove is suitable for different applications as it has been tested safe for use against various contacts such as skin and oral contact. Some of these tests confirm that the AMG glove is:

- **Non-irritating** - It does not cause primary skin irritation like redness (erythema) or slight swelling (edema).
- **Non-sensitising** - It does not contain any substance that will induce skin allergy.
- **Non-toxic** - No toxic effects occurring following oral administration.
- **Non-cytotoxic** - It does not display destructive action on cells.
- **Non-sensitising & low dermatitis potential** - Modified Draize Test shows the gloves do not cause allergic reaction in normal tissue after exposure.

No	Test	Method	Purpose of Testing	Result Summary
1	Modified Draize95 Test	FDA	To determine whether gloves contain residual chemical additives at a level that may induce Type IV allergy.	No Sensitiser Detected
2	Acute Toxicity Oral	ISO 10993-11	To evaluate toxic potential of substance that leaches out of gloves by determining adverse effect occurring within short term exposure via oral route.	No toxic effects
3	Cytotoxicity Test	ISO 10993-5	To determine if gloves contain significant quantities of harmful extractables and their effect on cellular components.	Non-cytotoxic at 10% extract
4	Primary Skin Irritation	ISO 10993-10	To determine whether exposure to gloves may produce skin irritation.	Non-Irritating
5	Dermal Sensitisation Study	ISO 10993-10	To assess potential of gloves to cause delayed hypersensitivity (Type IV) or allergic reaction stimulated by the immune system.	Non-Sensitising
6	Accelerator Extraction Test	Malaysian Rubber Board (MRB) In-House Method	To quantify the amount of extractable accelerators in gloves.	Non-Detectable for accelerators

UNCOMPROMISED GLOVE PROPERTIES

Apart from medical settings, AMG glove has been proven safe for use in different applications and industries. Its safety and effectiveness are proven to ensure it befits its intended use.

Medical - Tested for impermeability and glove strength, AMG glove is effective in preventing contamination between patient and healthcare practitioner, as well as for handling various chemotherapy drugs. All tests conducted are in accordance to recognised international standards such as ASTM D6319, EN 455 and ISO 11193 part 1.

Personal Protective Equipment (PPE) - The glove has been tested to protect users from substances and mixtures that are hazardous to health, and harmful biological agents that may cause very serious consequences or damage to health. Tests conducted are in accordance to the harmonised standard which complies with PPE Regulation. Some countries may require further registration.

Food Handling - The glove has been tested safe for food contact according to the standards of US FDA, BfR XXI German Recommendation and Japan Food Sanitation on various types of simulants representing different types of food that are acidic, alcoholic and fatty in content.

FAQ

1. What is AMG Antimicrobial glove?
2. What is the purpose of AMG antimicrobial glove?
3. Why does AMG gloves provide Active Protection Against HAIs?
4. Does AMG antimicrobial glove replace the need for hand hygiene?
5. What materials are in contact with my skin when using AMG Antimicrobial gloves?

1. AMG is the world's first non-leaching antimicrobial gloves, designed to kill microorganisms on the external side of the glove quickly upon contact.
2. Though conventional gloves provide a barrier between healthcare worker and patient, it does not tackle the problem of transient transmission, where microbes get transmitted from one surface to another. AMG glove is designed to help reduce the spread of HAI, as it is proven to kill up to 99.999% of selected microbes.
3. The use of medical gloves is intended to prevent cross contamination between the patient, the user and its environment. However, conventional gloves can only provide passive protection as contaminated gloves caused by inappropriate storage, inappropriate use and techniques for donning and removing, may in turn become a vehicle for transmission of microbes. Conversely, AMG gloves provide an active approach in HAI prevention as the gloves can continuously and effectively reduce or inhibit microbial colonisation on the glove surface within a short amount of time, thus further reducing the risk of cross contamination
4. Although AMG glove has been found effective against a wide range or microbes, it does not replace the need for hand hygiene. AMG serves as an extra precaution or tool to help mitigate the spread of HAI. Protocols for hand rubbing or hand washing should still be performed before donning and after removing gloves.
5. AMG's technology is introduced on the external side of the glove. The glove user is exposed to the donning side of the glove, which is similar to a standard examination glove. The skin of the glove user is not exposed to this technology.

FAQ

6. What does it mean by non-leaching? Is it safe?

6. We designed the antimicrobial gloves to be non-leaching to ensure the active ingredient does not transfer to the patient. To further ensure the safety of the active ingredient, the gloves were tested for biocompatibility. Below illustrates the tests carried out:
   i. Tested at Intertek UK, the gloves were extracted using water, artificial saliva, artificial sweat and alcohol at room and body temperature. The extracts were analysed by validated analytical techniques to detect the active. No active could be found extracted from the gloves' inner or outer surface.
   ii. ISO 10993 biocompatibility testing has been conducted on the inside and external surface of the gloves. Results confirm that the gloves are non-sensitising, non-irritating, nontoxic (oral) and non-cytotoxic.
   iii. The Modified Draize-95 test was also conducted where both the inner and outer surfaces of the gloves were tested on human skin. The gloves provided no clinical evidence of inducing allergic reactions. With this test result, U.S. FDA allows a "Low Dermatitis Potential" claim for the gloves.

7. How does singlet oxygen work?

7. In this technology a special dye is used. The dye absorbs visible light. The dye is thus raised from a ground state to an excited quantum state, in which an elevation in energy takes place. The energy then transfers to a proximal oxygen molecule found in the air, causing the oxygen molecule to also rise to an excited quantum state. The ground state of oxygen present in air, is a triplet electronic configuration, written as $_3O_2$. Upon sensitisation by the dye molecule, the electronic configuration changes and enters the singlet state, $_1O_2$. This singlet oxygen state is reactive and more oxidative compared to ground state oxygen and therefore, is able to kill microbes such as bacteria by oxidising the cells' protein and lipid. Using the dye as a catalyst, singlet oxygen can be generated continuously as it absorbs light and air.

FAQ

8. What are the advantages of using singlet oxygen antimicrobial system?

8. Singlet oxygen is a non-selective system that can react rapidly against many microbial components. There is not one single protection mechanism that bacteria can protect itself from singlet oxygen.[4] This is in contrast to antibiotics, which needs very specific mechanism to treat a patient. As singlet oxygen is transient, it does not lead to the release of persistent biocides into the environment. AMG will as such transform the standard examination glove from a passive medical device to a medical device with active protection which will actively reduce or inhibit microbial colonisation.

9. Has singlet oxygen technology been used before commercially?

9. Whilst it has not received as much attention as traditional biocides, singlet oxygen has been researched for a wide range of uses for many years and a number of important commercial applications are known.[5,6,7,8,9]
In humans, singlet oxygen generating dyes are used for cancer treatment, known as photodynamic therapy, PDT. It is also used in dental disinfection prior to procedures like root canal treatments, in which the dye is rinsed into the patients' mouths, a light applied and disinfection occurs safely and rapidly. However, probably the most ubiquitous use is in laundry powders, where a singlet oxygen generating dye is washed onto clothing, and subsequently acts as a photobleach. Many readers of this will therefore be unwitting users of singlet oxygen and will be wearing some singlet oxygen generating dye.

10. What is the amount of light needed to activate the AMG Antimicrobial Gloves?

10. Testing of AMG glove has been conducted at general lighting condition at hospitals of 1000 lux and 500 lux. Results show that there was no significant difference in bactericidal efficacy. Further testing at lower light levels are underway.

11. Would differences in lighting type affect the efficacy of AMG Antimicrobial gloves?

11. No. The AMG is activated by any white light source. It is specifically activated by light in the 600 - 700 nm region but all white light sources contain this, otherwise they would be coloured

FAQ

12. Are there literature to show potential of resistance using singlet oxygen antimicrobial system?

12. Experimental studies have been done and reported in the literature about singlet oxygen efficacy and resistance.[10,11] In these, bacteria were killed to a high extent with singlet oxygen, typically 99.9% or 99.99%, leaving only the most robust bacteria. These were then re-cultivated and re-exposed to singlet oxygen. This cycle is repeated 10 or 20 times, and the efficacy of killing is measured. In all cases, it was found that there is no decrease in efficacy and no development in resistance. Many of the mechanisms bacteria use to confer resistance involve processes internal to the cell. In AMG system however, the singlet oxygen is generated purely exogenously to the cell – the dye is separated from the bacteria, it does not leach, and it cannot enter the cells. Other authors in the literature have noted[4,10] that this makes development of resistance especially difficult, because singlet oxygen is short lived and with a short length of diffusion – nothing the bacterial cell does internally will affect the process of oxidation by singlet oxygen. Furthermore, a review of the potential for resistance to biocidal materials was done by the EU expert scientific committee. The report puts biocidal materials into three categories: low risk of resistance developing, medium risk and high risk. These authors put oxidative systems as low risk, some traditional biocide materials such as chlorhexidine and PHMB as medium risk, and silver as high risk.[3]

13. Will the dye be depleted if the AMG Antimicrobial Gloves are continually exposed to light?

13. No. As long as there is light and oxygen, the gloves are active. Heat aged AMG gloves (accelerated aging equivalent to 3 years shelf life) did not show significant difference in bactericidal efficacy compared to fresh AMG gloves. AMG gloves were also exposed to “light” (equivalent to 30 days in an open box environment). Again, there was no significant difference in bactericidal efficacy compared to fresh AMG gloves.

FAQ

14. What are the different classifications of bacteria?

14. Bacteria are classified into Gram-positive or Gram-negative. This classification came from a staining property observed by Hans Gram in 1884. It was observed that some bacteria could be stained with a dye, and others could not. It was later found that bacteria have different cell wall structure. Gram-positive bacteria allow substances to cross the cell wall more easily. The cell wall of Gram-negative bacteria is multi-layered and so it is harder for substances to cross the cell wall.

15. What are some examples of Gram-negative bacteria?

15. Gram-negative bacteria include Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii among others

16. What are some examples of Gram-positive bacteria?

16. Gram-positive bacteria include MRSA, Staphylococcus aureus, Enterococcus faecium, Streptococcus pyogenes, Enterococcus faecalis (VRE) among many others.

17. What type of bacteria survive longer on surfaces, which allow the possibility of infection transfer?

17. Based on a study conducted by Hirai,[12] which measures the survival of different types of bacteria on cotton lint, the results showed that Gram-positive bacteria have longer lifetimes on surfaces, which may have implications that these bacteria are available for transfer to cause HAIs. Gramnegative bacteria are known to die more quickly on surfaces, especially if the surface is dry.

18. How about a clinical environment? Is there a survival difference between Gram-positive and Gram-negative bacteria?

18. The pattern of lower survival of Gram-negative bacteria is also seen in the clinical environment. In Wilson et al study,[13] Grampositive bacteria such as Staph a. were found in numerous locations in the hospital environment, but Gram-negative bacteria such as E. Coli were not found on any surfaces sampled, despite having a number of patients in the ward with E. Coli infections.

FAQ

19. Do biocides kill Gram-positive or Gram-negative bacteria easily?

20. How is the bactericidal efficacy of AMG Antimicrobial gloves measured?

21. What is the intended use and indication for AMG Antimicrobial Gloves in the technical file?

19. All bacteria respond to biocides differently, requiring different contact times and concentrations for inactivation. In general, Gram-negative bacteria are harder to kill with biocides.[14]

20. AMG Antimicrobial Glove will start generating singlet oxygen and start killing bacteria immediately upon exposure to light and oxygen. Based on the requirements of ASTM D7907-14, the contact time in which the bacteria have been exposed the external surface of the glove containing antimicrobial agent needs to be measured at intervals of 5 mins, 10 mins, 20 mins and 30 mins. At the end of each contact time, the glove is transferred into a validated neutraliser to stop the bactericidal activity. This will stop the singlet oxygen killing activity on the microbes, which will in turn allow the calculation of bacteria kill. Additional testing has been conducted at shorter contact times of 1 min and 2 mins on Staphylococcus aureus with bacteria kill rates of 99.898% and 99.998% respectively.

21. The Antimicrobial Nitrile Powder Free Examination Gloves are intended to be used in the framework of medical examinations and diagnostic and therapeutic procedures conducted under non-sterile conditions. Furthermore, the use of the device is intended to help prevent cross contamination. Its indication is stated as “Any medical condition requiring an examination, a diagnostic or therapeutic procedure on the intact skin or mucosa under non-sterile conditions”.

FAQ

22. Do AMG gloves have any efficacy on viruses?

22. We believe AMG can kill viruses apart from bacteria. This is why we choose to name it Antimicrobial instead of the more limited Antibacterial. However, all our tests are based on ASTM D7907 Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves. This test method specified the glove to be tested against 4 specific bacteria. As AMG is a new invention, there is no other standard that we can use to test for viral efficacy. Nevertheless, we are working on adapting D7907 to test for viruses. This work will take a longer time to complete. One of the challenge is that viruses only replicate inside the living cells; once expose to the environment they will be destroyed quickly, therefore making it difficult for us to test. Meanwhile, we have decided to launch AMG with D7907 test data as we believe most HAIs attributable to hand-surface contamination are bacteria. Viruses like Hepatitis and HIV are spread through fecal-oral route or transmission through contaminated syringes, needles or sharps, infected blood transfusions. The more common flu virus is mainly spread to others by droplets made when people with flu, cough, sneeze or talk. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. Less often, a person might get flu by touching a surface or object that has flu virus on it and then touching their own mouth, nose, or possibly their eyes.[15]

23. What is the medical device classification for AMG Antimicrobial Gloves in MDD93/42/EEC?

23. European Union MDD 93/42/EEC Annex IX: Class I (Rule 5) includes “All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device…”. As such, the Antimicrobial Nitrile Powder Free Examination gloves are an invasive device intended for short transient use (I. Definitions, 1.1) for examinations on intact skin and also involve body orifices (I. Definitions, 1.2). All other parts of rule 5 do not apply. Based on rule 5 (III. Classification, section 2, 2.1), the Antimicrobial Nitrile Powder Free Examination Gloves are classified as a medical device class I.

FAQ

24. Does AMG Antimicrobial Gloves require registration by EU Biocidal Regulation?

24. The Biocides Regulation (EU) No. 528/2012 is not applicable for medical devices unless they are intended to be used for other purposes not covered by the medical device directive, in which case the Biocides Regulation shall also apply to that product insofar as those purposes are not addressed by those instruments. In our understanding, this would mean that the biocides regulation is only applicable if the gloves are intended for other non-medical purposes or if the antibacterial feature would not be within the original purpose of the medical device. As the gloves' medical purpose is to prevent infection of the patient and the antimicrobial feature supports this purpose, we believe that the biocides regulation is not applicable.[16]

End Notes

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