Tristel™

TRISTEL DUO OPH
The Data

High-level Disinfectant Foam for Ophthalmology

A complete set of evidence

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ABOUT TRISTEL DUO OPH

The Chemistry

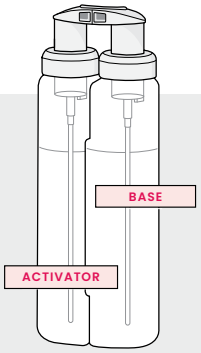
Chlorine dioxide has been Tristel's trusted chemistry **for over 30 years.**

Our proprietary chlorine dioxide chemistry is produced through a chemical reaction between sodium chlorite and citric acid.

Tristel's chlorine dioxide has been marketed in **over 40 countries worldwide** and has been used in an estimated **100 million+ decontamination procedures.**

The Design

Tristel has **pioneered product designs** that combine the precursor solutions with the press of a pump.



Due to this intuitive design, our chlorine dioxide products have the ability to generate active chemistry **at the point of use.**

The Intended Use

Tristel DUO OPH is intended for the **high-level disinfection** of medical devices used in ophthalmology such as diagnostic lenses, tonometer prisms, pachymeters, A-scan and B-scan probes.

Tristel DUO OPH is bactericidal, yeasticidal, fungicidal, virucidal, mycobactericidal, and sporicidal in a uniform contact time of 30 seconds, and has been rigorously validated following globally relevant and well-established test methods.

30 sec

THE ESSENTIAL DATA

EN 14885 compliance

In the United Kingdom and Europe, the European Standard EN 14885 outlines the required testing for disinfectants used in the medical area. **Tristel DUO OPH complies with the relevant EN 14885 test methods according to its intended use.**

Organic matter and soiling are prevalent in healthcare settings, so it is beneficial that the product remains effective, even in dirty environments. These methods **allow two test conditions that simulate the environment in which the product is used:**

Clean – 0.3g/l protein. This condition represents a surface that has been cleaned before disinfection.

Dirty – 3g/l protein + 3ml/l blood. This represents a contaminated surface that has not been cleaned before disinfection.

MICROBIAL HIERARCHY OF RESISTANCE TO DISINFECTANTS

HIGH

MID

LOW

STANDARD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS	CONTACT TIME	RESULT
EN 17126 (P2, S1)	Bacterial spores	*Bacillus subtilis*	Clean	30s	Pass
			Dirty	30s	Pass
		Bacillus cereus	Clean	30s	Pass
			Dirty	30s	Pass
		Clostridioides difficile	Clean	30s	Pass
			Dirty	30s	Pass
EN 17846 (P2, S2)		*Clostridioides difficile*	Clean	30s	Pass
			Dirty	30s	Pass
EN 14348 (P2, S1)	Mycobacteria	*Mycobacterium terrae*	Clean	30s	Pass
			Dirty	30s	Pass
		Mycobacterium avium	Clean	30s	Pass
			Dirty	30s	Pass
EN 14476 (P2, S1)	Viruses	Poliovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Adenovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Murine Norovirus	Clean	30s	Pass
			Dirty	30s	Pass
EN 13624 (P2, S1)	Fungi	*Aspergillus brasiliensis*	Clean	30s	Pass
			Dirty	30s	Pass
EN 13624 (P2, S1)	Yeast	*Candida albicans*	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Yeast	*Candida albicans*	Clean	30s	Pass
			Dirty	30s	Pass
EN 13727 (P2, S1)	Bacteria	*Staphylococcus aureus*	Clean	30s	Pass
			Dirty	30s	Pass
		Pseudomonas aeruginosa	Clean	30s	Pass
			Dirty	30s	Pass
		Enterococcus hirae	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Bacteria	*Staphylococcus aureus*	Clean	30s	Pass
			Dirty	30s	Pass
		Pseudomonas aeruginosa	Clean	30s	Pass
			Dirty	30s	Pass
		Enterococcus hirae	Clean	30s	Pass
			Dirty	30s	Pass

Phase 2, Step 1: P2, S1 and Phase 2, Step 2: P2, S2
According to the acceptance criteria of the European standard: Bacterial spores, mycobacteria, fungi, yeast and viruses: ≥4 log_{10} reduction. Bacteria: ≥5 log_{10} reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm^2

THE WIPING DATA

Demonstrated effectiveness through surface application

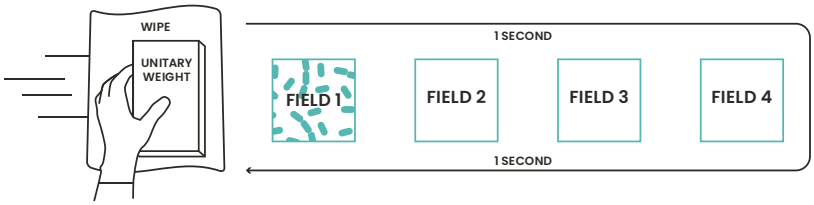
Tristel DUO OPH is a foam designed to be applied onto a device with a dry wipe. It has been rigorously tested using the **4-field test method**. This test was specifically developed to evaluate products that are wiped onto a surface. **The testing covers a range of microorganisms commonly found in healthcare environments, this includes ophthalmic devices and clinical settings.**

STANDARD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS	CONTACT TIME	RESULT
EN 17846 (P2, S2)	Bacterial spores	*Clostridioides difficile*	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Mycobacteria	*Mycobacterium terrae*	Clean	30s	Pass
			Dirty	30s	Pass
		Mycobacterium avium	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Viruses	Adenovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Murine Norovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Bovine coronavirus	Dirty	30s	Pass
EN 16615 (P2, S2)	Fungi	*Aspergillus brasiliensis*	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Yeast	*Candida albicans*	Clean	30s	Pass
			Dirty	30s	Pass
EN 16615 (P2, S2)	Bacteria	*Staphylococcus aureus*	Clean	30s	Pass
			Dirty	30s	Pass
		Enterococcus hirae	Clean	30s	Pass
			Dirty	30s	Pass
		Pseudomonas aeruginosa	Clean	30s	Pass
			Dirty	30s	Pass

Phase 2, Step 2: P2, S2
According to the acceptance criteria of the European standard:
Bacterial spores, mycobacteria, fungi, yeast and viruses: ≥4 log_{10} reduction.
Bacteria: ≥5 log_{10} reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm^2

THE WIPING DATA, CONTINUED

EN 16615 evaluates the effectiveness of a disinfectant when applied with a wipe. In this test, the disinfectant is applied to a wipe, which is then wrapped around a standardised weight and pushed across multiple test fields. These fields include one seeded with the microorganism and an interfering substance. The microbial load on each field is measured after wiping. The test also examines whether microorganisms are transferred between areas, ensuring that contamination is effectively inactivated rather than spread.

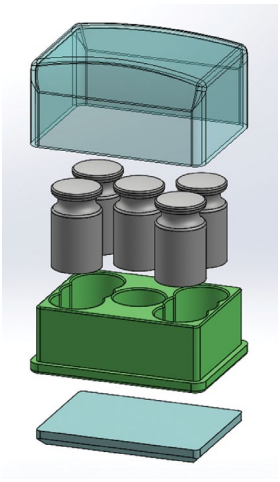


The standardised unitary weight specified in the EN 16615 method ranges from 2.3 to 2.5 kg, **but does this range truly reflect the force applied in practice?**

Tristel developed a bespoke test method that modified the standard 4-field methodology by incorporating multiple weights to address this.

Tristel DUO OPH was evaluated using weights above and below the standard range to simulate the varying forces applied during wiping. The results confirm that **Tristel DUO OPH maintains effectiveness, even when subjected to variable wiping forces.**

Click here for full article [1]



TEST METHOD	FORCE APPLIED TO SURFACE (KG)	ORGANISM	CONTACT TIME	RESULT	
				1ST RUN	2ND RUN
BESPOKE EN 16615 (P2, S2)	1.0	*Staphylococcus aureus*	30s	Pass	Pass
	1.5		30s	Pass	Pass
	2.0		30s	Pass	Pass
	2.5		30s	4.05*	Pass
	3.0		30s	Pass	Pass
	3.5		30s	Pass	Pass

According to the acceptance criteria of the European standard: Bacteria: ≥5 log_{10} reduction.
**Did not achieve a ≥5 log_{10} reduction, however, this result is considered to be an outlier due to the 2nd run showing a complete kill of microorganisms at the same weight category, as well as all tested weights above and below. No organisms were spread to the other test fields meeting the acceptance criteria of ≤50 cfu/cm².*

In another study, Tristel DUO OPH was applied to a contaminated PVC surface using a dry wipe. The wipe only had contact with the surface for 1 second, and no wiping action was performed. The results demonstrate that even when the wipe has minimum contact with a surface, an efficacious volume of solution is transferred.

TEST METHOD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS	CONTACT TIME	RESULT
BESPOKE EN 16615 (P2, S2)	Bacteria	*Enterococcus hirae*	Clean	30s	Pass

Phase 2, Step 2: P2, S2
According to the acceptance criteria of the European standard: Bacteria: ≥5 log_{10} reduction and F2-F4: ≤50 cfu/cm²

THE SOAKING DATA

Proven chemistry performance without wiping

Tristel DUO OPH is applied by wiping, but its disinfectant efficacy has also been tested by immersing contaminated surfaces into the solution.

Soaking tests highlight the activity of the chemistry alone.

TEST METHOD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS	CONTACT TIME	RESULT
EN 14563 (P2, S2)	Mycobacteria	*Mycobacterium terrae*	Clean	30s	Pass
			Dirty*	30s	Pass
		Mycobacterium avium	Clean	30s	Pass
			Dirty*	30s	Pass
EN 17111 (P2, S2)	Viruses	Adenovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Murine Norovirus	Clean	30s	Pass
			Dirty	30s	Pass
		Polyomavirus SV40	Clean	30s	Pass
			Dirty	30s	Pass
EN 14562 (P2, S2)	Fungi	*Aspergillus brasiliensis*	Clean	30s	Pass
EN 14562 (P2, S2)	Yeast	*Candida albicans*	Clean	30s	Pass
		Candidozyma auris (formerly *Candida auris*)	Dirty*	30s	Pass
EN 14561 (P2, S2)	Bacteria	*Staphylococcus aureus*	Clean	30s	Pass
		Enterococcus hirae	Clean	30s	Pass
		Pseudomonas aeruginosa	Clean	30s	Pass

**Testing performed with 5% FBS to meet specifc regulatory requirements*
Phase 2, Step 2: P2, S2
According to the acceptance criteria of the European standard: Mycobacteria, fungi, yeast and viruses: ≥4 log_{10} reduction.
Bacteria: ≥5 log_{10} reduction.

THE SOAKING DATA, CONTINUED

Tristel DUO OPH has been tested in a scenario without the action of wiping. These methods involve applying the disinfectant to a surface and leaving it for the contact time.

The effectiveness of the chemistry without the added effect of wiping has been proven.

TEST METHOD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS	CONTACT TIME	RESULT
ASTM E-1053	Viruses	Poliovirus	Dirty*	30s	Pass
		Adenovirus	Dirty*	30s	Pass
		Feline Calicivirus	Dirty*	30s	Pass
		Hepatitis B Virus (HBV)	Dirty*	30s	Pass
		Herpes Simplex Virus (HSV)	Dirty*	30s	Pass
		Human Immunodeficiency Virus (HIV)	Dirty*	30s	Pass
		Influenza A Virus (H1N1)	Dirty*	30s	Pass
EN 13697 (P2, S2)	Yeast	*Candida albicans*	Clean	30s	Pass
EN 13697 (P2, S2)	Bacteria	*Staphylococcus aureus*	Clean	30s	Pass
		Enterococcus hirae	Clean	30s	Pass
		Pseudomonas aeruginosa	Clean	30s	Pass
		Escherichia coli	Clean	30s	Pass

**Testing performed with 5% FBS*
Phase 2, Step 2: P2, S2
According to the acceptance criteria of the European standard:
Viruses and bacteria: ≥4 log_{10} reduction.
Yeast: ≥3 log_{10} reduction.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THE PRACTICAL DATA

Confirmed efficacy on medical devices

To simulate real-world conditions, Tristel DUO OPH has been tested on **actual ophthalmic devices** contaminated with **clinically relevant microorganisms commonly found in eye care settings**.

Simulated-use testing involves contaminating devices with microorganisms and an interfering substance, applying the disinfectant according to the instructions for use, and then evaluating the microbial reduction.

This process ensures that disinfectants perform effectively under real-world conditions.

OPHTHALMIC DEVICE	ORGANISM	CONTACT TIME	RESULT
Tonometer prism	*Mycobacterium terrae*	30s	Pass
Pachymeter*	*Mycobacterium terrae*	30s	Pass

**Testing included a residue reduction step using the Tristel DRY WIPE.*
According to the acceptance criteria of the European standard: Mycobactericidal (EN 14563) ≥4 log_{10} reduction.

This list is not exhaustive, Tristel DUO OPH has been tested and proven effective with the devices of major manufacturers. Contact mail@tristel.com for more information.

THE CLEANING DATA

Established cleaning ability

Cleaning is defined as the removal of organic matter from a surface. It is considered the most critical step in the decontamination process because many high-level disinfectants are ineffective in the presence of soiling. Choosing a high-level disinfectant that also offers combined cleaning performance is the optimal choice for ensuring patient safety.

Tristel DUO OPH has been proven to be an effective cleaning agent in removing soiling found in healthcare containing proteins and haemoglobin. Its cleaning ability has been assessed through testing on various healthcare surfaces, demonstrating its versatility as a cleaning agent. The soiling marker acceptance criteria are cleanliness thresholds based on established standards and scientific literature.

TEST METHOD	MATERIAL	SOILING MARKER	ACCEPTANCE CRITERIA	RESULT
AAMI ST98 AND ISO 15883-5	PVC	Protein	≤6.4µg/cm²	Pass
		Haemoglobin	≤2.2µg/cm²	Pass
	Stainless Steel (304)	Protein	≤6.4µg/cm²	Pass
		Haemoglobin	≤2.2µg/cm²	Pass
	High-Pressure Laminate (HPL)	Protein	≤6.4µg/cm²	Pass
		Haemoglobin	≤2.2µg/cm²	Pass

THE ORGANISMS OF CONCERN DATA

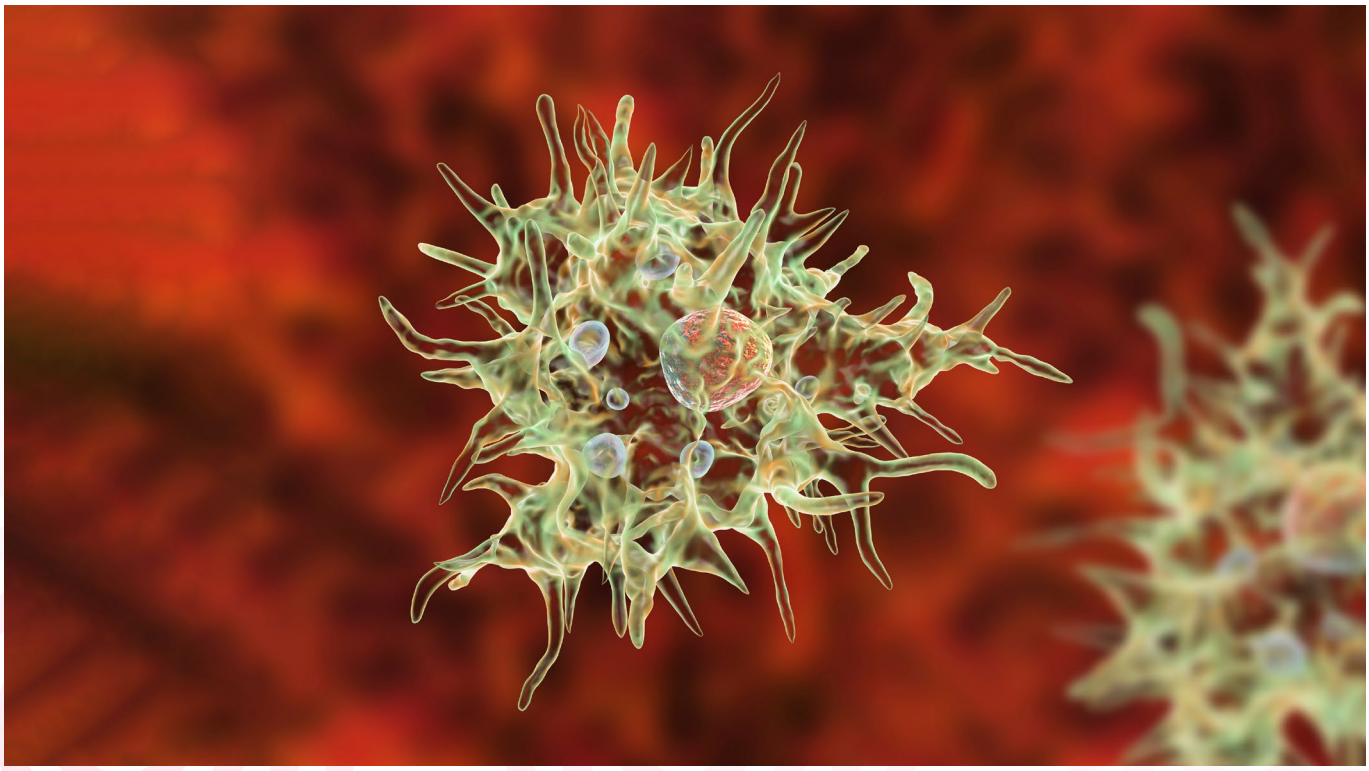
Efficacy against pathogens in ophthalmology

Ophthalmic medical devices are frequently exposed to microorganisms of concern due to their use in close proximity and contact with the surface of the eye. This exposure increases the risk of transmitting harmful pathogens that can cause serious infections, including conjunctivitis, keratitis, and endophthalmitis. Common pathogens include Adenovirus, Herpes simplex virus, and *Staphylococcus aureus*. To mitigate these risks, it is essential to use a high-level disinfectant with proven efficacy against such pathogens, ensuring adequate decontamination and preventing cross-contamination between patients.

In addition to the mandatory organisms stipulated in EN 14885, **Tristel DUO OPH has been challenged against specific organisms of concern within ophthalmology.**

Acanthamoeba castellanii cysts

Acanthamoeba is a free-living amoeba commonly found in soil, water, and sometimes contact lens solutions, and its cyst form is highly resistant to environmental stressors. The main concern related to this organism is its association with **Acanthamoeba keratitis**, a serious infection of the cornea. If left untreated, this condition can cause severe eye damage and permanent vision loss. Tristel DUO OPH has been assessed for its effectiveness to eliminate *Acanthamoeba castellanii* cysts in a suspension test at an ISO 17025 accredited laboratory. Triplicate test runs of an 80% dilution of the product were performed where the test sample was added to interfering substance (0.3g/l bovine albumin) and a test suspension containing *Acanthamoeba castellanii* cysts. The contact time of 30 seconds was observed within the test. **The product demonstrated a >3 $\log_{10}$ reduction, and a complete inactivation of *Acanthamoeba castellanii* cysts was observed.**

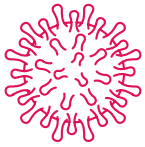


Tristel DUO OPH has achieved the acceptance criteria against the following organisms of concern: Yeast and viruses: ≥4 log_{10} reduction. Bacteria: ≥5 log_{10} reduction.

Adenovirus

Adenovirus, a non-enveloped virus, is the primary cause of viral conjunctivitis, an inflammation or irritation of the conjunctiva, accounting for approximately 65-95% of all cases.[2]
Highly contagious, it can be transmitted through direct contact, contaminated surfaces and ophthalmic instruments used during eye examinations.[3]

Herpes Simplex Virus (HSV)



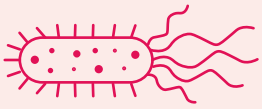
HSV is an enveloped DNA virus that can cause a range of diseases, including Herpes Simplex Keratitis (HSK), or ocular herpes, an infection that can lead to serious eye complications. HSV is highly contagious and spreads through direct contact with infected bodily fluids or lesions. HSV is estimated to cause 1.5 million cases annually, with 40,000 new cases of severe monocular visual impairment or blindness each year.[3]

Neisseria gonorrhoeae

N. gonorrhoeae that causes the sexually transmitted disease Gonorrhoea, can cause Gonococcal conjunctivitis (GC), a serious condition that can lead to complications like blindness or systemic infection. Approximately 10% of neonates exposed to fluids contaminated with *N. gonorrhoeae* during delivery may go on to develop GC.[4]

Pseudomonas aeruginosa

P. aeruginosa is an opportunistic pathogen that is ubiquitously found in the environment, posing a significant threat to public health. Globally, an estimated 10–15% of nosocomial infections are due to *P. aeruginosa*. In addition, it is the most identified causative organism in contact lens-related keratitis.[5]



Candida albicans

Candida species are among the most frequent microorganisms associated with fungal infections (candidiasis) such as keratitis and endophthalmitis, and candidemia. One study found that the incidence of ocular candidiasis in patients with candidemia ranged from 2-26%.[7]

Fusarium solani

Fusarium keratitis is a severe ocular infection, caused by the organism *Fusarium solani*, it is a common cause of monocular blindness. The annual prevalence of fungal keratitis is estimated to be over 1 million cases globally. Among these cases, *Fusarium* species is the most frequently isolated cause.[7, 8]

Staphylococcus aureus

In addition to causing skin and soft tissue infections, *S. aureus* is a common cause of ocular infections such as conjunctivitis, keratitis, and endophthalmitis. Approximately 35% of the general public and 50–66% of hospital workers become colonised with *S. aureus*.[6]

THE AMR DATA

Antimicrobial resistance (AMR) is a critical global healthcare challenge, as microorganisms continue to evolve, rendering treatments for common infections less effective. This leads to increased healthcare costs, prolonged patient recovery times, and higher mortality rates. It is crucial that disinfectants not only eliminate multi-drug-resistant microorganisms but also avoid contributing to their resistance build-up in the first place.[9]

According to the World Health Organisation (WHO), in 2019, an estimated **1.27 million deaths** were attributable to antibiotic-resistant bacteria, with an additional estimated **5 million associated deaths**.[10]

Tristel DUO OPH has successfully passed tests against pathogens with known resistance mechanisms, helping to prevent the spread of antimicrobial resistant organisms.

ORGANISM TYPE	ORGANISM	COMMON ANTIBIOTIC RESISTANCE	CONTACT TIME	RESULT
Bacterial spores	*Clostridioides difficile*	Aminoglycosides, lincomycin, tetracyclines, erythromycin, clindamycin, penicillins, cephalosporins, and fluoroquinolones[11]	30s	Pass
Yeast	*Candidozyma auris* (formerly *Candida auris*)	Azoles, polyenes, and echinocandins[12]	30s	Pass
Bacteria	Methicillin-resistant *Staphylococcus areus* (MRSA)	Beta-lactams[13]	30s	Pass
	Extended Spectrum Beta-Lactamase *Klebsiella pneumoniae* (ESBL)	ESBL - Cephalosporins and monobactams[14]	30s	Pass
	Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae*	CRE - Beta-lactams[14]	30s	Pass
	MOPHidrug-resistant Acinetobacter *baumannii* (MDRAB)	Penicillins and cephalosporins, fluoroquinolones, and aminoglycosides[15]	30s	Pass
	Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*	Beta-lactams and aminoglycosides[16]	30s	Pass

According to the acceptance criteria of the European standard: Bacterial spores and yeast: ≥4 log_{10} reduction. Bacteria: ≥5 log_{10} reduction.

Forecast 2050

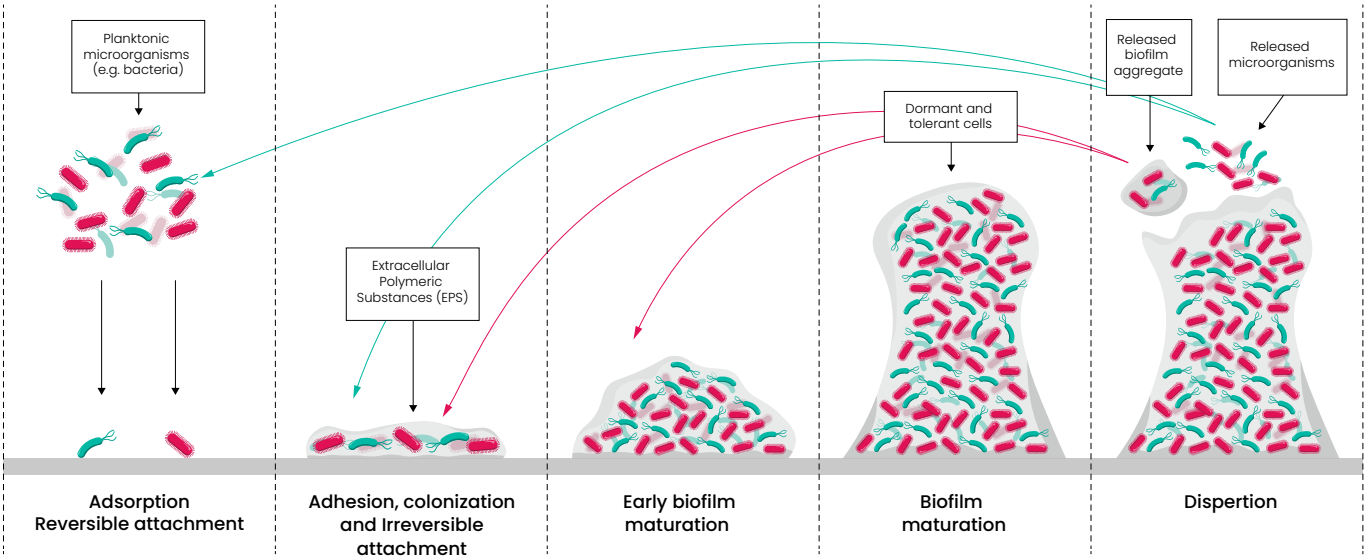
According to the World Health Organization, it could lead up to **10 million** deaths per year.[17]

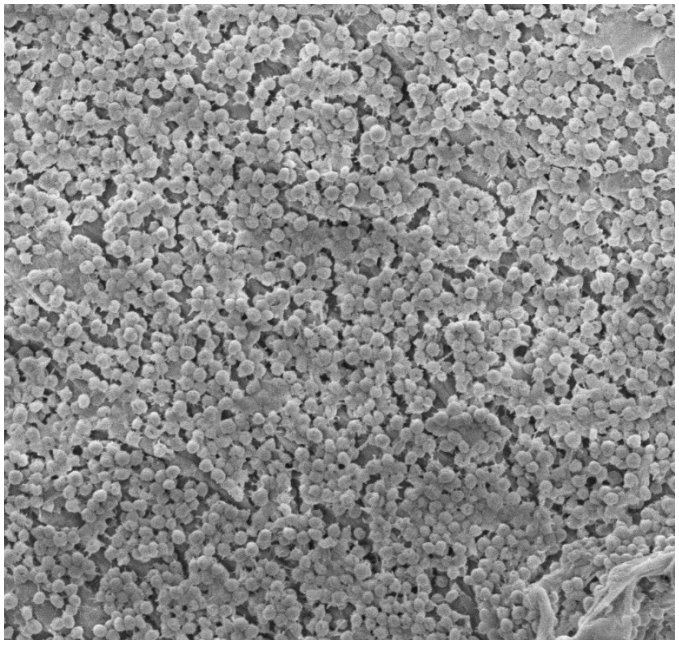
According to the World Bank Group, it could result in an additional cost of **$1 trillion** for healthcare systems.[17]

THE BIOFILM DATA

Biofilms are a significant issue in hospitals, they can provide a protective environment for microorganisms, allowing them to survive in harsh conditions, including exposure to disinfectants and antibiotics. These complex communities of microorganisms adhere to surfaces such as medical devices and general surfaces, making the microorganisms particularly difficult to eliminate.

Bacteria living in a biofilm exhibit a 10 to 1,000-fold increase in resistance to antibiotics compared to their planktonic counterparts.[18]





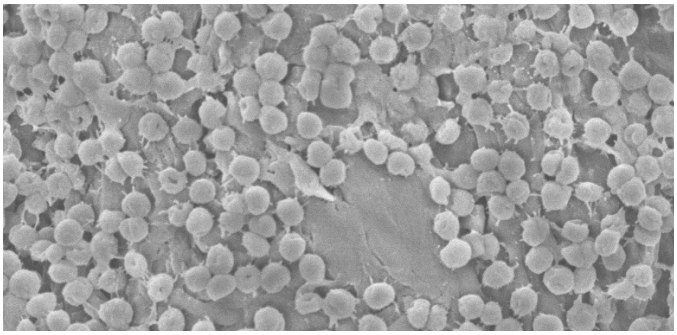
In healthcare settings, biofilms can lead to persistent infections, increased resistance to treatments, and a heightened risk of cross-contamination. Their presence on medical equipment, environmental surfaces, and within environments such as water systems can also contribute to hospital-acquired infections (HAIs), posing a serious risk to patient safety.

It is estimated that around **65-80% of Hospital Acquired Infections (HAI's) are linked to biofilms.** These infections are often associated with the presence or persistence of biofilms in the environment or associated devices.[18, 19]

THE BIOFILM DATA, CONTINUED

> Tristel DUO OPH has been specifically tested for its removal and efficacy against both wet and dry biofilms, ensuring your product is effective in these environments.

A **wet biofilm** is a type of biofilm that forms in moist environments, where microorganisms thrive due to the presence of water and available nutrients. These microorganisms secrete a slimy layer of extracellular polymeric substance (EPS) containing polysaccharides, proteins, and lipids, embedding themselves in a protective matrix. In healthcare, wet biofilms can develop on and within the channels of reusable medical devices, in water lines, and around sinks.[18]



TEST METHOD	BIOFILM TYPE	SURFACE TYPE	ORGANISM	CONTACT TIME	RESULT
MBEC ASSAY (ASTM E2799-22)	Grown in moist conditions- aged for 72 hours	Polystyrene pegs	Gram-negative: *Pseudomonas aeruginosa*	30s	Pass
CDC BIOFILM REACTOR (ASTM E2871-22)		Steel & PVC	Gram-positive: *Staphylococcus aureus*	30s	Pass

Tristel DUO OPH achieved a ≥5 log_{10} reduction.

A **dry biofilm** comprises microorganisms that form in dry or low-moisture and nutrient-deficient environments. Due to these harsh conditions, microorganisms within a developed dry biofilm tend to be more resilient. **Unlike wet biofilms, dry biofilms are found on surfaces with minimal moisture, such as on medical equipment or dry environmental surfaces.** These biofilms can be challenging to detect and remove, as they are often more resistant to cleaning and disinfection efforts due to their dry state.[20]

TEST METHOD	BIOFILM TYPE	SURFACE TYPE	ORGANISM	CONTACT TIME	RESULT
CDC BIOFILM REACTOR	Dry (semi-hydrated) – aged for 12 days	Steel & PVC	Gram-positive: *Staphylococcus aureus*	30s	Pass

Tristel DUO OPH achieved a ≥5 log_{10} reduction.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