Tristel™

TRISTEL DUO ULT
The Data

High-level Disinfectant Foam for Ultrasound

A complete set of evidence

CONTENTS

Document controls

Use the document controls located at the top of the pages to help you navigate through this brochure.

ABOUT TRISTEL DUO ULT

The Chemistry

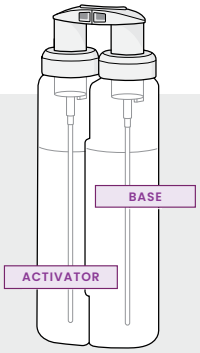
Chlorine dioxide has been Tristel's trusted chemistry **for over 30 years.**

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 ULT is intended for the **high-level disinfection** of endocavity ultrasound probes such as transrectal and transvaginal probes, and skin surface ultrasound transducers.

Tristel DUO ULT is sporicidal, mycobactericidal, virucidal, fungicidal, yeasticidal and bactericidal 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 ULT 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.

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


Tristel
DUO
ULT™

THE WIPING DATA

Demonstrated effectiveness through surface application

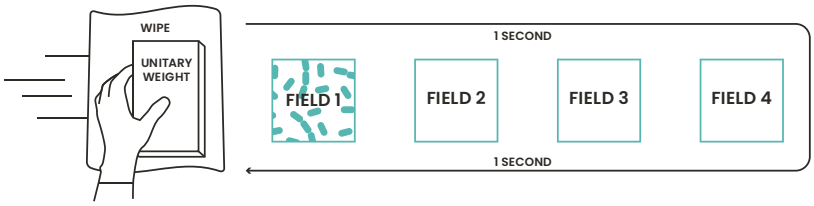
Tristel DUO ULT is a foam designed to be applied onto a device with a dry wipe (DUO WIPES are recommended). It has been rigorously tested using the **EN 16615 4-field test method**. This test was specifically developed to evaluate products that are wiped onto a surface. **The testing covers a range of microorganisms commonly found in healthcare environments, including ultrasound devices and clinical settings where ultrasound is frequently used.**

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.

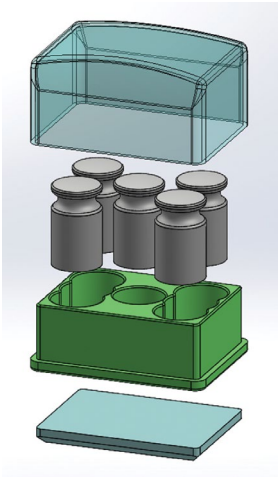


The standardised unitary weight specified in the EN 16615 method ranges from 2.3 to 2.5 kg, **but does this range truly reflect the force applied in practice?**

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

Tristel DUO ULT was evaluated using weights above and below the standard range to simulate the varying forces applied during wiping. The results confirm that **Tristel DUO ULT 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 ULT 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/cm ^2

THE SOAKING DATA

Proven chemistry performance without wiping

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

Soaking tests highlights 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***	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*
***Formerly known as Candida auris*
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 ULT 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, without wiping.

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.


Fisherbrand
FB50151
Boro 3.3

THE PRACTICAL DATA

Confirmed efficacy on devices

To simulate real-world conditions, Tristel DUO ULT has been tested on **actual ultrasound devices** contaminated with **clinically relevant microorganisms commonly found in settings where ultrasound is frequently used.**

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.

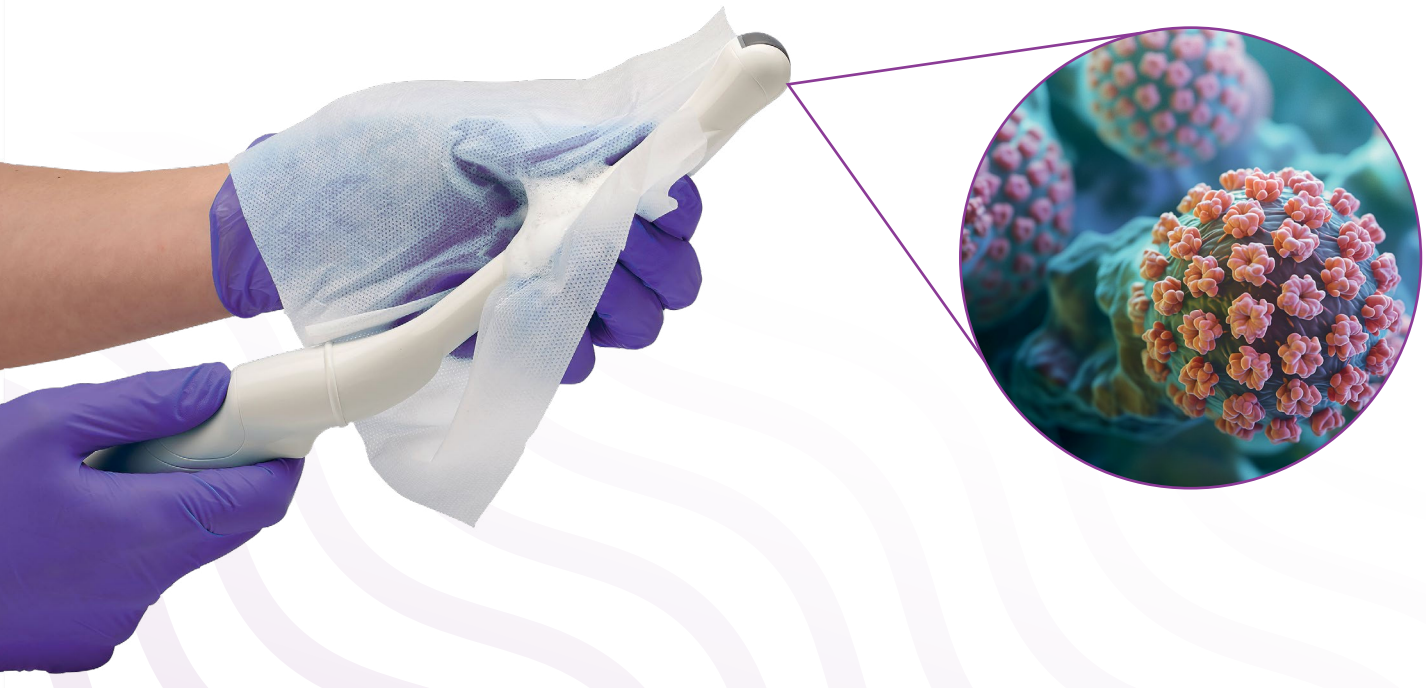
This process ensures that disinfectants perform effectively under real-world conditions.

ULTRASOUND DEVICE	ORGANISM	CONTACT TIME	RESULT
Transvaginal Probe	Human Papillomavirus (HPV) Type 16	30s	Pass
	Human Papillomavirus (HPV) Type 18	30s	Pass
Transvaginal Probe	*Staphylococcus aureus*	30s	Pass

According to the acceptance criteria of the European standard:
Viruses (EN 14476): ≥4 log_{10} reduction.
Bacteria (EN 14561): ≥5 log_{10} reduction.

Click here for full article

The ability of two chlorine dioxide chemistries to inactivate human papillomavirus-contaminated endocavitary ultrasound probes and nasendoscope.[2]



THE CLEANING DATA

Established cleaning ability

Cleaning is defined as the removal of organic matter from a surface. It is often 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 ULT has been proven to be an effective cleaning agent in removing soiling found in healthcare containing proteins, haemoglobin, and carbohydrates. Its cleaning ability has been assessed through testing on medical devices and various healthcare surfaces, demonstrating its versatility as a cleaning agent. The soiling marker acceptance criteria are cleanliness thresholds based on standards and scientific literature.

TEST METHOD	DEVICE	SOILING MARKER	ACCEPTANCE CRITERIA	RESULT
AAMI TIR 30 AND ISO 15883-5	GE Healthcare Ultrasound Transducer (RIC-5-9D)	Protein	≤6.4 µg/cm²	Pass
		Carbohydrate	≤1.8 µg/cm²	Pass
AAMI TIR 30	Mobile ODT EVA System 3.0	Protein	≤6.4 µg/cm²	Pass
		Bioburden (*Escherichia coli, Staphylococcus aureus & Candida albicans*)	>3 $\log_{10}$ reduction	Pass

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

THE ORGANISMS OF CONCERN DATA

Efficacy against pathogens in ultrasound

Ultrasound devices, particularly those used in invasive procedures, are frequently exposed to pathogens due to their contact with sensitive areas such as skin, mucous membranes, and internal orifices. Invasive probes can introduce harmful pathogens such as *Escherichia coli*, *Candida albicans*, and Human Papillomavirus (HPV), which cause infections and further health complications. These risks call for 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 ULT has been challenged against specific organisms of concern relevant to both invasive and non-invasive ultrasound use, and to the clinical areas where ultrasound devices are used the most.**

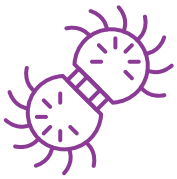
Tristel DUO ULT has achieved the acceptance criteria against the following organisms of concern:
Yeast and viruses: ≥4 log_{10} reduction.
Bacteria: ≥5 log_{10} reduction.

Gardnerella vaginalis

Gardnerella vaginalis is commonly associated with bacterial vaginosis (BV), an infection that affects the vaginal flora and is the most common cause of vaginal discharge among women of reproductive age. BV prevalence among women of reproductive age ranges from 23–29%.[4]

Pseudomonas aeruginosa

Pseudomonas aeruginosa is a gram-negative opportunistic pathogen that thrives in moist environments, including ultrasound gels and improperly decontaminated ultrasound equipment.[27] *Pseudomonas aeruginosa* is a concern in ultrasound procedures due to it's potential to cause bloodstream infections, urinary tract infections, and sepsis.[28]



Neisseria gonorrhoeae

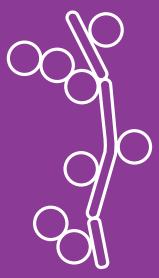
Neisseria gonorrhoeae is the bacterium responsible for the sexually transmitted infection (STI) gonorrhoea. An estimated 82 million new cases of gonorrhoea occur yearly.[3]

Human Papillomavirus (HPV) Type 16 and 18

There are over 200 types of HPV, of which HPV Types 16 and 18 are the two most common strains known to cause about 70% of all cervical cancer.[7, 8, 9] HPV is a significant concern in ultrasound procedures due to its potential for transmission through contaminated equipment, especially transvaginal and transrectal probes.

Candida albicans

Candida albicans is a common cause of fungal infections in the genital and rectal areas. It is responsible for about 70% of global fungal infections and despite there being treatments, available infections have a mortality rate of approximately 40%.[6] Transvaginal probes are particularly prone to contamination with this yeast as it is a common inhabitant of the vaginal flora.

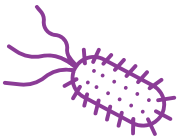


Human Immunodeficiency Virus (HIV)

HIV remains a major global public health issue. In 2023, an estimated 630,000 people died from HIV-related causes and an estimated 1.3 million people acquired HIV.[11] Although HIV is not typically transmitted through ultrasound procedures, maintaining strict hygiene and decontamination practices is essential to safeguard against any potential risk of cross-contamination, especially in settings involving invasive procedures or contact with bodily fluids.

Herpes Simplex Virus (HSV)

HSV-1 is primarily known for causing oral herpes but is also relevant in ultrasound procedures if there are open sores or lesions on the skin, as the virus can be transmitted through contact with infected surfaces. An estimated 500 million people have an HSV genital infection worldwide.[3]



Proteus vulgaris

Proteus vulgaris is an opportunistic human pathogen known for causing urinary tract infections (UTIs) and can be present in the gastrointestinal tract. Women are at a higher risk for developing *P. vulgaris* infections.[5]

Escherichia coli

E. coli can be transmitted during ultrasound procedures if proper hygiene and disinfection protocols are not followed. *E. coli* is commonly found in the gastrointestinal tract, meaning it can be present in the rectal area. Severe infection caused by certain *E. coli* strains, have reported mortality rates ranging from 3% to 20%.[10]

Influenza A Virus (H1N1)

Influenza virus causes 290 000 to 650 000 respiratory mortalities annually.[12] Influenza virus survives on medical surfaces for up to 48 hours, this can include ultrasound equipment.[13]

Hepatitis B Virus (HBV)

The WHO estimates that 254 million people were living with chronic hepatitis B infection in 2022, with 1.2 million new infections each year. HBV has several routes of transmission including infected bodily fluids such as saliva, menstrual, vaginal, and seminal fluid.[14] Cross-contamination of HBV from probes that come into contact with mucous membranes or non-intact skin is a risk.

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.[15]

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**.[16]

Tristel DUO ULT 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[17]	30s	Pass
Yeast	*Candidozyma auris**	Azoles, polyenes, and echinocandins[18]	30s	Pass
Bacteria	Methicillin-resistant *Staphylococcus areus* (MRSA)	Beta-lactams[19]	30s	Pass
	Extended Spectrum Beta-Lactamase *Klebsiella pneumoniae* (ESBL)	ESBL - Cephalosporins and monobactams[20]	30s	Pass
	Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae*	CRE - Beta-lactams[20]	30s	Pass
	Multidrug-resistant Acinetobacter *baumannii* (MDRAB)	Penicillins and cephalosporins, fluoroquinolones, and aminoglycosides[21]	30s	Pass
	Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*	Beta-lactams and aminoglycosides[22]	30s	Pass

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

**Formerly Candida auris*

Forecast 2050

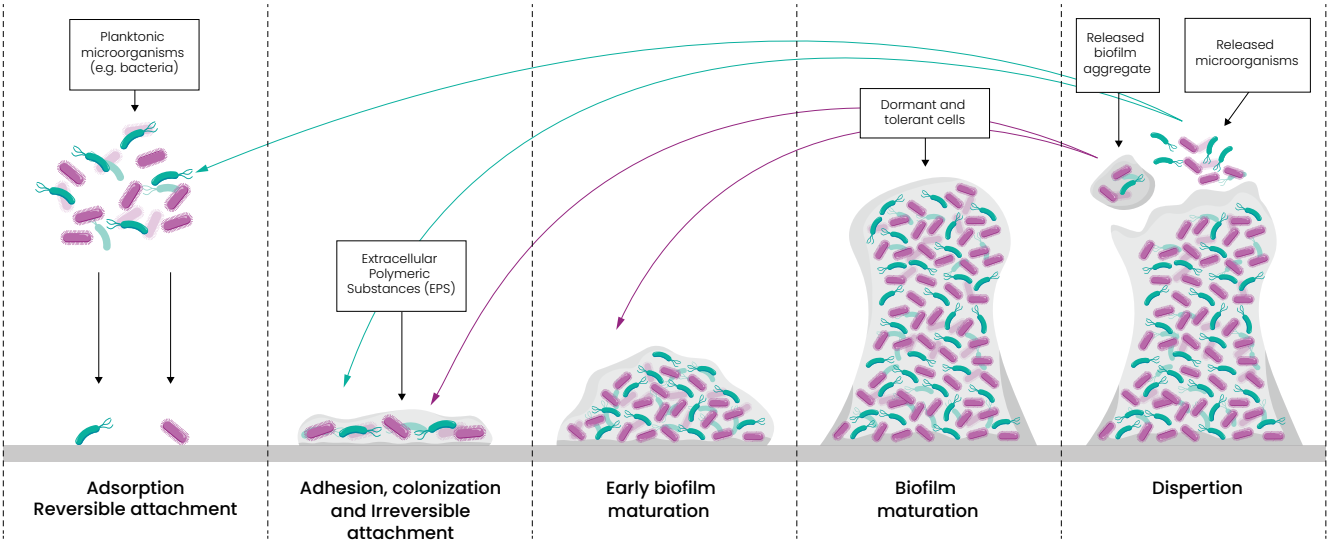
According to the World Health Organization, it could lead up to **10 million** deaths per year.[23]

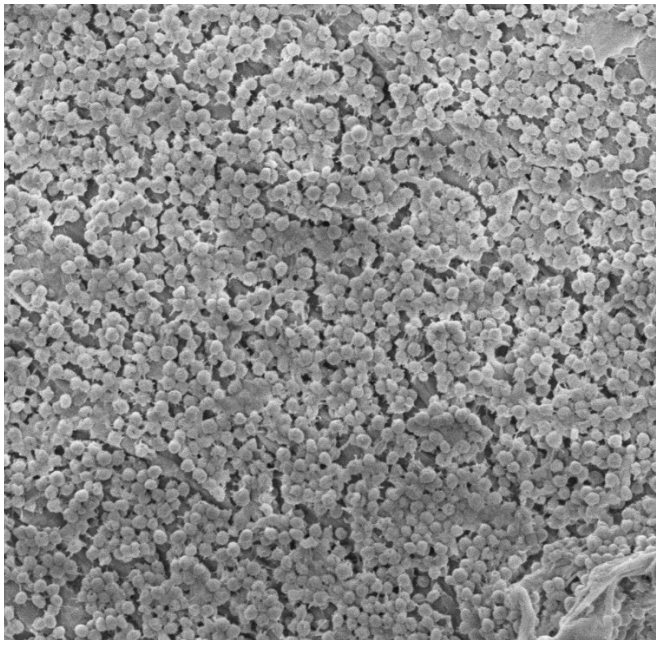
According to the World Bank Group, it could result in an additional cost of **$1 trillion** for healthcare systems.[23]

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.[24]





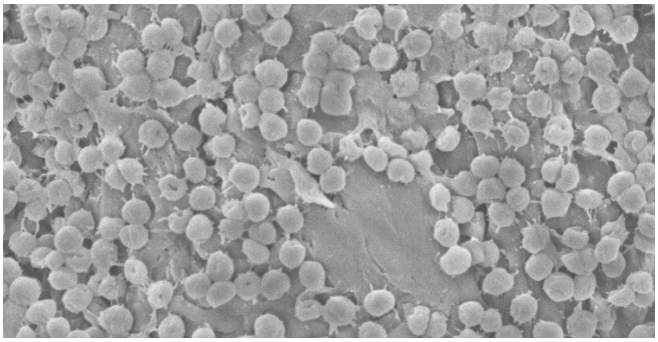
In healthcare settings, biofilms can lead to persistent infections, increased resistance to treatments, and a heightened risk of cross-contamination. Their presence on medical equipment, environmental surfaces, and within environments such as water systems can also contribute to hospital-acquired infections (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.[24, 25]

THE BIOFILM DATA, CONTINUED

> Tristel DUO ULT 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.[24]



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

Tristel DUO ULT achieved ≥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 have a thicker and more established matrix of extracellular polymeric substances (EPS), making them 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.[26]

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

Tristel DUO ULT achieved ≥5 log_{10} reduction.

THE *IN-VITRO* FERTILISATION DATA

High-level disinfection for IVF settings

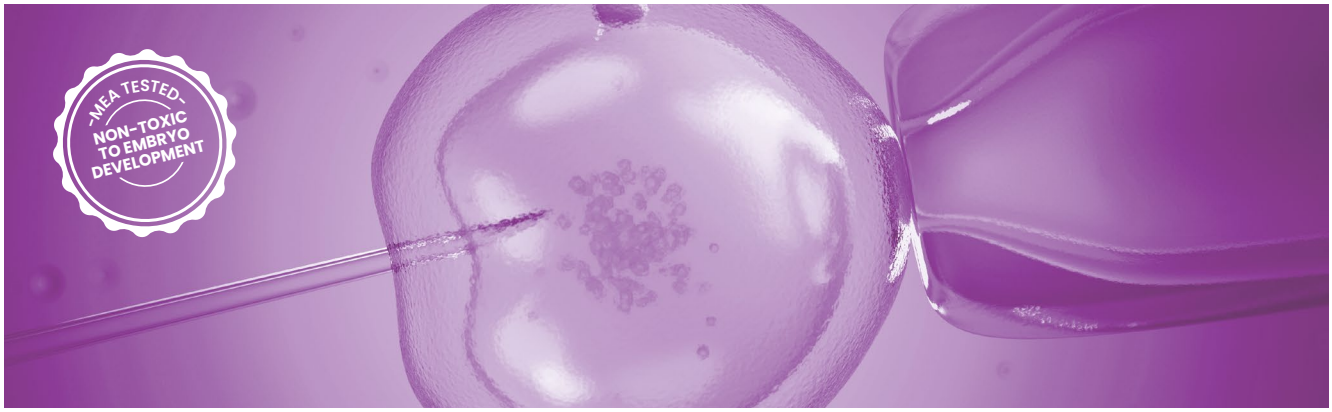
The Mouse Embryo Assay (MEA) evaluates the potential toxicity of the disinfectant by assessing its impact on embryo development.

The Sperm Motility Assay (SMA) determines the effect of the disinfectant on sperm motility and viability over time.

These tests ensure that exposure does not negatively impact sperm function, compromise viability, or hinder normal embryo growth.

The use of Tristel DUO ULT has been tested to confirm that it is non-toxic to embryos and sperm in assisted reproduction setting.

TEST METHOD	REPRODUCTIVE CELLS	ACCEPTANCE CRITERIA	CONTACT TIME	RESULT
MEA	Embryo	No toxicity to embryo development	30s	Pass
SMA	Sperm	No negative impact on sperm viability/motility	30s	Pass



REFERENCES

1. Die Bedeutung von unterschiedlichem Kraftaufwand zwischen Nutzern bei der Desinfektion mit Tristel Duo, einem manuellen Wischprozess. (2023). *Hygiene & Medizin*.

2. Meyers, C., Milici, J. and Robison, R. (2020). The ability of two chlorine dioxide chemistries to inactivate human papillomavirus-contaminated endocavitary ultrasound probes and nasendoscopes. *Journal of Medical Virology*. doi:https://doi.org/10.1002/jmv.25666.

3. World Health Organization (2024). Sexually Transmitted Infections (STIs). [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis).

4. World Health Organization (2023). Bacterial vaginosis. [online] www.who.int. Available at: https://www.who.int/news-room/fact-sheets/detail/bacterial-vaginosis.

5. Laupland, K.B., Parkins, M.D., Ross, T. and Pitout, J.D.D. (2007). Population-based laboratory surveillance for tribe Proteeae isolates in a large Canadian health region. *Clinical Microbiology and Infection*, 13(7), pp.683–688. doi:https://doi.org/10.1111/j.1469-0691.2007.01715.x.

6. Talapko, J., Juzbašić, M., Matijević, T., Pustijanac, E., Bekić, S., Kotris, I. and Škrlec, I. (2021). Candida albicans—The Virulence Factors and Clinical Manifestations of Infection. *Journal of Fungi*, 7(2), p.79. doi:https://doi.org/10.3390/jof7020079.

7. Burd, E.M. (2003). Human Papillomavirus and Cervical Cancer. *Clinical Microbiology Reviews*, [online] 16(1), pp.1–17. doi:https://doi.org/10.1128/cmr.16.1.1-17.2003.

8. World Health Organization (2024). *Cervical Cancer*. [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/cervical-cancer.

9. NHS Inform (2023). *Cervical cancer symptoms and treatments*. [online] www.nhsinform.scot. Available at: https://www.nhsinform.scot/illnesses-and-conditions/cancer/cancer-types-in-adults/cervical-cancer/.

10. European Centre for Disease Prevention and Control (2017). *Facts about Escherichia coli*. [online] European Centre for Disease Prevention and Control. Available at: https://www.ecdc.europa.eu/en/escherichia-coli-ecoli/facts.

11. World Health Organization (2024). *HIV and AIDS*. [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/hiv-aids.

12. WHO (2023). *Influenza (Seasonal)*. [online] Who.int. Available at: https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal).

13. Bean, B., Moore, B.M., Sterner, B., Peterson, L.R., Gerding, D.N. and Balfour, H.H. (1982). Survival of Influenza Viruses on Environmental Surfaces. *Journal of Infectious Diseases*, 146(1), pp.47–51. doi:https://doi.org/10.1093/infdis/146.1.47.

14. World Health Organization (2024). *Hepatitis B*. [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/hepatitis-b.

15. Noel, D.J., Keevil, C.W. and Wilks, S.A. (2025). Development of disinfectant tolerance in Klebsiella pneumoniae. *Journal of Hospital Infection*, 155, pp.248–253. doi:https://doi.org/10.1016/j.jhin.2024.11.006.

16. World Health Organization (2024). *WHO bacterial priority pathogens list, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance*. [online] www.who.int. Available at: https://www.who.int/publications/i/item/9789240093461.

17. Peng Z, Jin D, Kim HB, Stratton CW, Wu B, Tang YW, Sun X. Update on Antimicrobial Resistance in Clostridium difficile: Resistance Mechanisms and Antimicrobial Susceptibility Testing. *J Clin Microbiol.* 2017 Jul;55(7):1998-2008. doi: 10.1128/JCM.02250-16. Epub 2017 Apr 12. PMID: 28404671; PMCID: PMC5483901

18. Ademe M, Girma F. Candida auris: From Multidrug Resistance to Pan-Resistant Strains. *Infect Drug Resist*. 2020 May 5;13:1287-1294. doi: 10.2147/IDR.S249864. PMID: 32440165; PMCID: PMC7211321.

19. Ali Alghamdi, B., Al-Johani, I., Al-Shamrani, J.M., Musamed Alshamrani, H., Al-Otaibi, B.G., Almazmomi, K. and Yusnoraini Yusof, N. (2023). Antimicrobial Resistance in methicillin-resistant Staphylococcus Aureus. *Saudi Journal of Biological Sciences*, [online] 30(4), p.103604. doi:https://doi.org/10.1016/j.sjbs.2023.103604.

20. Huy, T.X.N. Overcoming Klebsiella pneumoniae antibiotic resistance: new insights into mechanisms and drug discovery. *Beni-Suef Univ J Basic Appl Sci* 13, 13 (2024). https://doi.org/10.1186/s43088-024-00470-4

21. Manchanda V, Sanchaita S, Singh N. Multidrug resistant acinetobacter. *J Glob Infect Dis*. 2010 Sep;2(3):291-304. doi: 10.4103/0974-777X.68538. PMID: 20927292; PMCID: PMC2946687.

22. Levitus M, Rewane A, Perera TB. *Vancomycin-Resistant Enterococci*. [Updated 2023 Jul 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK513233/

23. *WHO (2023). Antimicrobial Resistance. [online] World Health Organization. Available at*: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance.

24. Ledwoch, K., Dancer, S.J., Otter, J.A., Kerr, K., Roposte, D., Rushton, L., Weiser, R., Mahenthiralingam, E., Muir, D.D. and Maillard, J.-Y. . (2018). Beware biofilm! Dry biofilms containing bacterial pathogens on multiple healthcare surfaces; a multi-centre study. *Journal of Hospital Infection*, 100(3), pp.e47–e56. doi:https://doi.org/10.1016/j.jhin.2018.06.028.

25. Maillard, J.-Y. and Centeleghe, I. (2023). How biofilm changes our understanding of cleaning and disinfection. *Antimicrobial Resistance and Infection Control*, [online] 12(1), p.95. doi:https://doi.org/10.1186/s13756-023-01290-4.

26. K Ledwoch, Vickery, K. and Maillard, J-Y. (2022). Dry surface biofilms: what you need to know. *British journal of hospital medicine*, 83(8), pp.1–3. doi:https://doi.org/10.12968/hmed.2022.0274.

27. Chittick, P., Russo, V., Sims, M., Robinson-Dunn, B., Oleszkowicz, S., Sawarynski, K., Powell, K., Makin, J., Darnell, E., Boura, J.A., Boyanton, B. and Band, J. (2013). An Outbreak of Pseudomonas aeruginosa Respiratory Tract Infections Associated with Intrinsically Contaminated Ultrasound Transmission Gel. Infection Control & Hospital Epidemiology, 34(8), pp.850–853. doi:https://doi.org/10.1086/671268.

28. Wilson, M.G. and Pandey, S. (2023). Pseudomonas Aeruginosa. [online] www.ncbi.nlm.nih.gov. StatPearls Publishing. Available at: https://www.ncbi.nlm.nih.gov/books/NBK557831/.

For more information on Tristel DUO ULT and the Tristel ULT Combination Packs, please contact us:

mail@tristel.com