

## Microbiological Information

### Microbiological data

The Tristel chemistry has been extensively tested to international standards at independent and accredited laboratories or university laboratories.

Tristel has been proven to be sporicidal, mycobactericidal, virucidal, yeasticidal and bactericidal at concentrations below those achieved when the products are activated.

Selected key tests demonstrating **Tristel's micro-biological efficacy** include

Test authority	Standard	Organisms
Hospital Infection Research Laboratory, UK	As published in JoHI (1998, 38)	<i>Bacillus subtilis</i> spores
Conclusion	<i>'A &gt;6 log<sub>10</sub> reduction is used as an indication of acceptable sporicidal activity. Tristel Single Shot when tested for use in the Labcaire Endoscope Washer Disinfector gave a &gt;6 log<sub>10</sub> reduction in 10mins under clean and dirty conditions when tested at 10°C and 5mins at 20°C. The formulation for use in the Wassenburg Washer Disinfector gave a 6 log<sub>10</sub> reduction in 5 mins under clean and dirty conditions.'</i>	
Institute de Recherche Microbiologique, France	AFNOR T72-300	<i>Bacillus subtilis</i> spores, <i>Bacillus cereus</i> spores
Conclusion	<i>'Le dioxyde de chlore fabriqué par l'appareil Tristel Generator à partir des produits Tristel One Shot Base et Tristel One Shot Activator est efficace sur les spores des souches bactériennes testées en 5 minutes de contact à 20°C, selon la norme AFNOR T72-300, à la concentration de 15 ppm pour Bacillus subtilis et à 45 ppm pour Bacillus cereus en présence d'eau dure à 30°C.'</i>	
Institute de Recherche Microbiologique, France	EN 13704	<i>Bacillus subtilis</i> spores
Conclusion	<i>'Le dioxyde de chlore présente une activité sporicide dès 48 ppm (dioxyde de chlore à 60 ppm dilué à 80% (v/v)) en 1 minute à 20°C, en présence d'albumine bovine selon à 0,3 g/L.'</i>	

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Test authority	Standard	Organisms
Hospital Infection Research Laboratory, UK	As published in JoHI (1998, 38)	<i>Mycobacterium terrae</i>
Conclusion	<p>'A <math>&gt;5 \log_{10}</math> reduction in <i>Mycobacterium terrae</i> is used as an indication of high/intermediate level disinfection and tuberculocidal activity. Tristel Single Shot when tested for use in the Labcaire Endoscope Washer Disinfector gave a <math>&gt;5 \log_{10}</math> reduction in 5mins under clean and dirty conditions when tested at 10°C and 20°C. The formulation for use in the Wassenburg Washer Disinfector gave a <math>&gt;5 \log_{10}</math> reduction in 1 min under clean and dirty conditions at 40°C.'</p>	
Institute de Recherche Microbiologique, France	AFNOR T 72-301 & T 72-171	<i>Mycobacterium tuberculosis</i> , <i>Mycobacterium avium</i> , <i>mycobacterium terrae</i> ,
Conclusion	<p>'Le produit dioxyde de chlore est efficace à 20°C, selon la norme AFNOR T72-301 en eau dure à 30°C, sur les souches <i>Mycobacterium tuberculosis</i>, <i>Mycobacterium avium</i>, et <i>Mycobacterium terrae</i>:</p> <ul style="list-style-type: none"> <li>- à la concentration de 100 ppm en 5 minutes de contact</li> <li>- à la concentration de 50 ppm en 15 et 30 minutes de contact.'</li> </ul>	
Biotech-Germade, France	EN 14348	<i>Mycobacterium avium</i> , <i>Mycobacterium terrae</i>
Conclusion	<p>'According to EN 14348, the disinfectant solution "One Shot" (Tristel) when diluted in hard water at 0.66% (v/v) presents a mycobactericidal activity under clean conditions (0.3 g/l bovine albumin) against the reference strains of <i>Mycobacterium avium</i> and <i>Mycobacterium terrae</i> within:</p> <ul style="list-style-type: none"> <li>- 60 minutes at 20°C (obligatory test conditions)</li> <li>- 5 minutes at 20°C (use conditions).</li> </ul> <p>In those test conditions, the mean reduction of the two assays performed with each of the two test strains is above <math>10^6</math>'</p>	
Institute de Recherche Microbiologique, France	AFNOR T 72-180	<i>Picornaviridae</i> (Poliovirus type 1), <i>Adenovirus</i> , <i>Poxviridae</i> (Orthopoxvirus)
Conclusion	<p>'Le produit dioxyde de chlore à 120 ppm est virucide selon la norme AFNOR NF T72-180 en 5 minutes de contact à 20°C à la concentration de 90% (v/v).'</p>	

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Test authority	Standard	Organisms
PHLS, UK		<i>Poliovirus type 2,</i> <i>Herpes simplex virus type 1</i>
Conclusion	<i>'Virus infectivity as measured by the TCID<sub>50</sub> of the virus controls was 10<sup>7</sup> for poliovirus type 2 and 10<sup>3</sup> for herpes simplex virus type 1. No infectious virus was detected after treatment with Tristel 100 solution for 5, 15 or 30 minutes.'</i>	
Micropathology, UK		<i>Hepatitis C virus</i>
Conclusion	<i>'To be considered successful in this protocol a biocide must be able to reduce the amount of virus molecules to an undetectable level. Tristel One-Shot, with a 5 minute contact time, reduced the detectable virus specific molecule in the blood sample to below the limit of detection of the assay and it was therefore successful in this indirect estimation of its activity against HCV.'</i>	
Micropathology, UK		<i>HIV</i>
Conclusion	<i>'To be considered successful in this protocol a biocide must be able to reduce the amount of virus molecules to an undetectable level. Tristel One-Shot, with a 5 minute contact time, reduced the detectable virus specific molecule in the blood sample to below the limit of detection of the assay and it was therefore successful in this indirect estimation of its activity against HIV.'</i>	
Biotech-Germande, France	EN 13624	<i>Candida albicans</i>
Conclusion	<i>'According to EN 13624, the disinfectant solution "One Shot" (Tristel) when diluted in hard water at 0.66% (v/v) presents under clean conditions (0.3 g/l bovine albumin) a yeasticidal activity against the reference strain of Candida albicans within:</i> <ul style="list-style-type: none"> <li>- 60 minutes at 20°C (obligatory test conditions)</li> <li>- 5 minutes at 20°C (use conditions).'</li></ul>	



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Test authority	Standard	Organisms
Institute de Recherche Microbiologique, France	EN 13727	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i>
Conclusion	<i>'Le produit dioxyde de chlore préparé avec l'appareil Tristel Generator à partir des produits Tristel One Shot Base et Tristel One Shot Activator est bactéricide selon la norme NF EN 13727, en 5 minutes de contact à 20°C en présence d'albumine bovine à 0,3 g/l en final lors de l'essai sur les souches de référence Pseudomonas aeruginosa, Staphylococcus aureus et Enterococcus hirae à la concentration de 60 ppm.'</i>	
Hospital Infection Research Laboratory, UK	EN 13727	<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> Problematic clinical isolates of <i>Candida albicans</i> Methicillin resistant <i>Staphylococcus aureus</i> Gentamicin resistant <i>Pseudomonas aeruginosa</i> , Vancomycin resistant <i>Enterococcus faecium</i>
Conclusion	<i>'Tristel 100, when prepared in accordance with the manufacturers instructions, was found to be effective in destroying type strain cultures of Ps. Aeruginosa, Staph. Aureus and problematic clinical isolates of Candida albicans, Staph. Aureus (MRSA type 15), Ps. Aeruginosa (gentamicin resistant) and Enterococcus faecium (vancomycin resistant) under conditions of minimal or low soiling i.e. 0.03% albumin. Tristel 100, therefore, meets the requirements of [nowadays EN13727] i.e. at least a 5 log<sub>10</sub> reduction within the shorter time interval of 1 min. However, when the disinfectant was tested under dirty conditions, Tristel 100 just failed to achieve a &gt;5 log<sub>10</sub> reduction with one of the test organisms i.e. Staph.aureus (MRSA) and Candida albicans was greatly reduced, although a &gt;5 log<sub>10</sub> reduction was achieved. Tristel 100 is not recommended for instruments and surfaces that have not been pre-cleaned.'</i>	

## Microbiological Information

Test authority	Standard	Organisms
Biotech-Germade, France	EN 14561	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Enterococcus hirae</i>

Conclusion

*'According to EN 14561, the disinfectant solution "One Shot" (Tristel) when diluted in hard water at 0.66% (v/v) presents under clean conditions (0.3 g/l bovine albumin) a bactericidal activity against the referenced strains of Pseudomonas aeruginosa, Staphylococcus aureus, and Enterococcus hirae within:*

- 60 minutes at 20°C (obligatory test conditions)
- 5 minutes at 20°C (use conditions).

*In those test conditions, the mean reduction of the two assays performed with each of the three tested strains is above 10<sup>5</sup>'.*

The Tristel chemistry's efficacy is tested using off-the-shelf products that are offered in **liquid formats**, for instance Tristel One Shot products, Tristel Generator solutions and Tristel Fuse sachet formats. Not only do we test the Tristel's liquid chemistry, we also conduct addition tests on our specific product formats to confirm the validity of the data.

Additional tests demonstrating the micro-biological efficacy of the **Sporicidal Wipe** format include:

Test authority	Standard	Organisms
Institute de Recherche Microbiologique, France		<i>Bacillus subtilis</i> spores

Conclusion

*'L'utilisation de lingette STERILISING WIPES sur les surfaces d'essai a permis de réduire de 5,1 logarithmes décimaux la contamination de Bacillus subtilis. Il n'a pas été retrouvé de spores viables sur la lingette utilisée avec la méthode employée.'*

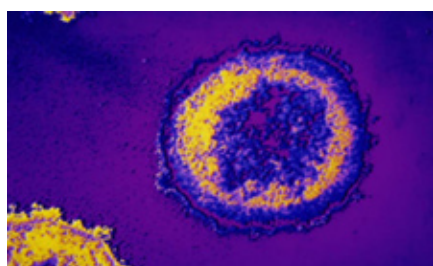
Hospital Infection Research Laboratory, UK	As published in JoHI (1998, 38)	<i>Mycobacterium terrae</i>
Conclusion	<i>'A &gt;5 log<sub>10</sub> reduction in Mycobacterium terrae is used as an indication of high/intermediate level disinfection and tuberculocidal activity. Tristel wipes solution tested freshly prepared gave a &gt;5 log<sub>10</sub> reduction in 15 seconds under clean conditions. 70% alcohol required 30 seconds and periods longer than 1 min are required for 100ppm chlorine releasing solutions.'</i>	

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Test authority	Standard	Organisms
Institute de Recherche Microbiologique, France	EN 14348	<i>Mycobacterium tuberculosis</i> , <i>Mycobacterium avium</i> , <i>mycobacterium terrae</i> ,
Conclusion	<i>'L'utilisation de lingettes STERILISING WIPES permet d'éliminer complètement les contaminations de Mycobacterium avium et Mycobacterium tuberculosis sur les surfaces d'essai (taux de réduction obtenus respectivement de 7,3 et 6,6 log) et de réduire de 5,1 log une contamination de Mycobacterium terrae. D'après la norme EN 14348, destinée au produit liquide, un produit est mycobactericide si le taux de réduction des souches Mycobacterium terrae et Mycobacterium avium est supérieur ou égale a 4 log.'</i>	
Hosp. Univ. Germans Trias i Pujol, Spain	EN 14348	<i>Mycobacterium avium</i>
Conclusion	<i>'According to prEN 14348, the batch 000132 of Tristel Sterilising Wipes possesses mycobactericidal activity in 30 seconds with mechanical action at 20°C under clean conditions (0.3 g/l bovine albumin) for referenced strain Mycobacterium avium.'</i>	
Micropathology, UK		<i>Hepatitis B virus</i>
Conclusion	<i>'After 30 seconds contact time to Tristel Wipe solution prepared as described, an aliquot of a serum sample with a high concentration of HBsAg became negative for the detection of HBsAg. This indicates that exposure to Tristel Wipes solution has destroyed the immunological reactivity of this viral antigen and that Tristel Wipes solution can be considered efficacious against this virus.'</i>	
Micropathology, UK		<i>Hepatitis C virus</i>
Conclusions	<i>'To be considered successful in this protocol a disinfectant must be able to reduce the concentration of HCV RNA to an undetectable level. Tristel Wipe solution, with 30 seconds contact time, reduced the concentration of detectable HCV RNA in the serum sample to below the limit of detection of the assay (50 HCV RNA copies/ml) and it was therefore successful in this indirect estimation of its activity against HCV.'</i>	

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Test authority	Standard	Organisms
Micropathology, UK		HIV
Conclusions	<p><i>'To be considered successful in this protocol a disinfectant must be able to reduce the concentration of HIV RNA to an undetectable level. Tristel Wipe solution, with 30 seconds contact time, reduced the concentration of detectable HIV RNA in the serum sample to below the limit of detection of the assay (50 HIV-1 RNA copies/ml) and it was therefore successful in this indirect estimation of its activity against HIV.'</i></p>	
Eurofins Q Laboratories, UK		Candida albicans
Conclusion	<p><i>'Washing/wiping with a Tristel Sterilising Wipe for 30 seconds was extremely effective against Candida albicans. Wiping the test surface with a 70% IPA wipe for 30 seconds was ineffective (achieving a &lt;math&gt;\lt;1 \log_{10}&lt;/math&gt; reduction of test organisms. This could be due to:</i></p> <ul style="list-style-type: none"> <li>- <i>An exposure time of 30 seconds was not long enough to kill the Candida albicans.</i></li> <li>- <i>The IPA evaporated off the test surface before the minimum exposure time required to kill the Candida albicans.</i></li> <li>- <i>The volume of IPA on the wipe was insufficient to deal with the <math>&gt;10^8</math> Candida albicans inoculated onto the 12 inch test surface.</i></li> <li>- <i>A combination of the above.</i></li> </ul> <p><i>[...]</i></p>	
Dr. David Coates		Methicillin resistant <i>Staphylococcus aureus</i> <i>Escherichia coli</i> <i>Pseudomonas aeruginosa</i>
Conclusion	<p><i>'Wiping with a Tristel Wipe for 30 seconds was completely effective. No test organisms were recovered from either the test surface or the wipes in duplicate experiments.</i></p> <p><i>[...]</i></p>	



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Supplementary tests confirming the validity of data for the **DUO foamer** format include:

Test authority	Standard	Organisms
Hospital Infection Research Laboratory, UK	As published in JoHI (1998, 38)	<i>Bacillus subtilis</i> spores
Conclusion	<i>'A &gt;6 log<sub>10</sub> reduction is used as an indication of acceptable sporicidal activity. Tristel foam solution tested freshly prepared at a 1 in 10 dilution of the in-use concentration gave &gt;6 l log<sub>10</sub> reduction in 30 secs under clean and dirty conditions.'</i>	
Hospital Infection Research Laboratory, UK	As published in JoHI (1998, 38)	<i>Mycobacterium terrae</i>
Conclusion	<i>'A &gt;5 log<sub>10</sub> reduction in Mycobacterium terrae is used as an indication of high/intermediate level disinfection and tuberculocidal activity. Tristel foam solution tested freshly prepared at a 1 in 10 dilution of the use concentration gave a &gt;5 log<sub>10</sub> reduction in 30 seconds under clean and dirty conditions.'</i>	
Bluscientific, UK		<i>Human Norovirus (Feline calicivirus)</i>
Conclusion	<i>'These data indicate that feline calicivirus levels are reduced by a least 2.23 log<sub>10</sub> at 30 seconds and 60 seconds contact in low soil and by 1.69 log<sub>10</sub> at 30 seconds and 60 seconds at high soil. The limit to this reduction is probably due to loss of infectivity of the virus due to desiccation, approximately by 5.0 x 10<sup>6</sup> TCID<sub>50</sub> units. However, in all cases virus infectivity is completely removed to the level of sensitivity of the assay (&lt;3.2 x 10<sup>2</sup>) by application of Tristel DUO wipes.'</i>	
MGS Laboratories, UK	EN 13624	<i>Candida albicans</i>
Conclusion	<i>'According to EN 13624 (2003), the batch L8042 and L8043 of the product Tristel Duo Foam, when diluted at 50% v/v L8042 and 50% v/v L8043 in hard water, possesses yeasticidal activity in 30 seconds at 20°C under clean conditions (0.3g/l bovine albumin) for the referenced strain of Candida albicans'</i>	
Bluscientific, UK		Five representative epidemic strains of <i>Methicillin resistant staphylococcus aureus</i>

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Conclusion *'These data indicate that with the exception of EMRSA 15 and EMRSA Iberian at a high soil load of 3.0 g/l BSA with a contact time of 30 seconds, Tristel DUO wipes effectively reduce the infectivity of a desiccated film of each of the five global EMRSA strains from a stainless surface by at least 5 log<sub>10</sub>. Desiccation itself has lead up to approximately a 200-fold reduction in viability, as illustrated by the experimental conditions control. A comparison of the Filtration Test Control (mock disinfectant neutralisation) and the Filtration Control indicates that residual disinfectant does not have a biostatic effect on bacterial growth, thus the neutralisation protocol employed has been effective.'*

MGS Laboratories, UK

EN 13727

*Enterococcus hirae*  
*Staphylococcus aureus*  
*Pseudomonas aeruginosa*

Conclusion *'According to EN 13727 (2003), the batch L8042 and L8043 of the product Tristel Duo Foam, when diluted at 50% v/v L8042 and 50% v/v L8043, possesses bactericidal activity in 30 seconds at 20°C under clean conditions (0.3g/l bovine albumin) for the referenced strains of Pseudomonas aeruginosa, Staphylococcus aureus and Enterococcus hirae'*

Our biguanide-based products, for instance the **DUO wipe for surfaces** and the **SOLO for Ultrasound** show an excellent intermediate level efficacy, including viruses and bacteria. Validation tests performed include:

Test authority

Standard

Organisms

Bluscientific, UK

SARS virus (*Feline Coronavirus*)

Conclusion *'Feline coronavirus (FCoV) was exposed to bulk wipe solution at concentrations of 2%, 5% and 80% v/v for 30 seconds, 1 minute and 5 minutes at 20°C with a soil load of 0.6 g/l (as protein). The virus showed a mean virus recovery of 7.3 x 10<sup>5</sup> following treatment with sterile distilled water for 5 minutes. The best result was obtained at a 5% v/v concentration, where a > 3.0 log reduction in viral infectivity was determined for all contact times (viral infectivity was reduced to below the level of sensitivity of the assay). A 2% v/v concentration of agent was marginally effective achieving a 1.4 log reduction in viability after 5 minutes contact. The 80% v/v concentration of agent resulted in an insensitive assay result because of high residual cytotoxicity of the agent. The result at a 5% v/v concentration of agent indicates that the working concentration of this agent (neat) would be expected to effectively reduce the infectivity of SARS virus within 30 seconds of contact.'*

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Bluscientific, UK

1 Norovirus (*Feline calicivirus*)

Conclusion

*'Feline calicivirus (FCV) was exposed to bulk wipe solution at concentrations of 2%, 5% and 80% v/v for 30 seconds, 1 minute and 5 minutes at 20°C with a soil load of 0.6 g/l (as protein). The virus showed a mean virus recovery of  $4.9 \times 10^7$  following treatment with sterile distilled water for 5 minutes. Reduction in virus viability was only observed at a concentration of 80% v/v agent and this was observed to be between 3.6 and 3.8 logs for contact times between 30 seconds and 5 minutes. This indicates that the working concentration (neat) of this agent would effectively reduce human norovirus infectivity within 30 seconds of contact.'*

Abbott Analytical

EN 13624

*Candida Albicans*

*'According to EN 13624 this batch of Tristel Solo Foam when used neat as received possesses satisfactory yeasticidal activity in 30 seconds at 20°C for the reference organism detailed.'*

Abbott Analytical

EN 13727

*Pseudomonas aeruginosa,  
Staphylococcus aureus,  
Enterococcus hirae*

*'According to EN 13727 this batch of Tristel Solo Foam when used neat as received possesses satisfactory bactericidal activity in 30 seconds at 20°C for the reference organism detailed.'*

Dr. David Coates

EN 1276

*Acinetobacter baumannii*

Conclusions

*'A Tristel DUO wipe wetted with 8ml of bulk wipe solution apparently achieved a 100% kill of vegetative cells of Acinetobacter baumannii (approximately  $10^8$ ) dried out on the 12 inch square stainless steel test surface (wipe time used: 30 seconds). However, tests were not done on the neutralizer employed so firm conclusions cannot be drawn.'*

Dr. David Coates

EN 1276

*Escherichia coli*

Conclusions

*'A Tristel DUO wipe wetted with 8ml of bulk wipe solution apparently achieved a 100% kill of vegetative cells of Escherichia coli (approximately  $10^8$ ) dried out on the 12 inch square stainless steel test surface (wipe time used: 30 seconds). However, tests were not done on the neutralizer employed so firm conclusions cannot be drawn.'*

## Microbiological Information

Test authority

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Dr. David Coates

EN 1276

*Clostridium difficile*

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Conclusions

*'A Tristel DUO wipe wetted with 8ml of bulk wipe solution apparently achieved a 100% kill of vegetative cells of Clostridium difficile ( $1.1 \times 10^8$ ) dried out on the 12 inch square stainless steel test surface (wipe time used: 30 seconds). However, tests were not done on the neutralizer employed so firm conclusions cannot be drawn. The culture of Clostridium difficile may have contained spores as well as vegetative cells but this possibility was not investigated.'*

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We instruct the laboratories we work with to test the contact time recommended in the product's user instructions, even if the employed European Norm allows for a longer contact time (usually 60 minutes to pass). We always test real product; this way the users can be sure that the test reports reflect the dilutions and contact times that are applied in the hospital environment.