



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Antimicrobials Division (7510P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

**EPA Reg. Number:**

92987-1

**Date of Issuance:**

4/19/18

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

**Term of Issuance:**

Conditional

**Name of Pesticide Product:**

Tristel Duo for Surfaces

**Name and Address of Registrant (include ZIP Code):**

Abigail T. D. Wacek  
 Regulatory Consultant  
 Agent for Tristel Solutions Ltd.  
 Technology Sciences Group Inc.  
 1150 18th Street, NW, Suite 1000  
 Washington, D.C. 20036

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:**

Demson Fuller, Product Manager 32  
 Regulatory management Branch II  
 Antimicrobials Division (7510P)

**Date:**

4/19/18

2. You are required to comply with the data requirements described in the DCI identified below:

Sodium chlorite GDCI-020502-29789

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36):  
<http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 92987-1."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/08/2018
- Alternate CSF 1 dated 02/08/2018

If you have any questions, please contact Srinivas Gowda by phone at 703-308-6354, or via email at [gowda.srinivas@epa.gov](mailto:gowda.srinivas@epa.gov).

Sincerely,



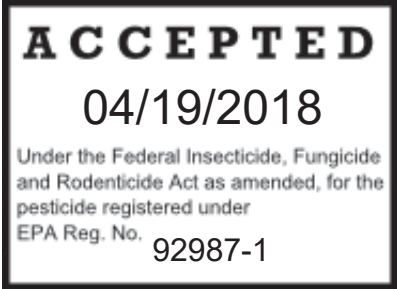
Demson Fuller, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped Label

# Tristel Duo for Surfaces

**[Alternate brand names:**

- Tristel Foam
- Tristel Foam ULT
- Tristel Foam Flex
- Tristel Foam Mobile
- Tristel Foam OPH
- Tristel Foam EVE
- Tristel Foam ORL
- Tristel Foam SUR
- Tristel Duo
- Tristel Duo ULT
- Tristel Duo OPH
- Tristel Duo ORL
- Tristel Duo EVE
- Tristel Duo SUR
- Tristel ClO<sub>2</sub> Foam
- Tristel Venus
- Tristel 911
- Tristel 911 for Disinfection in Emergency Care Facilities and Vehicles
- Tristel Venus for OB/GYN
- Tristel Endo
- Tristel Protect
- Tristel Pure
- Tristel Care
- Tristel Flex
- Tristel SOS
- Tristel Mobile ODT]



Bactericidal and virucidal\*, [cleaner and] disinfectant for hard non-porous surfaces, including surfaces of medical equipment [devices]

[For Professional Commercial, and Institutional Use]

**Tristel Duo Part A**

**Active Ingredient:**

Sodium chlorite .....0.5%  
**Other Ingredients**.....99.5%  
 Total..... 100.0%

**Tristel Duo Part B:**

**Active Ingredient:**

Citric acid.....5.26%  
**Other Ingredients**.....94.74%  
 Total..... 100.00%

Tristel Duo Part A and Part B are mixed when dispensed at ratio 1:1 to generate 320 ppm chlorine dioxide. Tristel Duo Part A and Part B are contained in a dual compartment dispenser (foam pump) and are ready for use.

## KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or when going for treatment.	

[See [attached] [pamphlet]/[reference sheet]] for [Directions for Use], [Applications], [Precautionary Statements], [First Aid], [Chemistry], [Optional Marketing Statements].]

{Note to reviewer: The pamphlet/reference sheet is provided because the product bottle size may not fit all information. The pamphlet/reference sheet content is based on the Master Label content and will not contain any additional information.}

**EPA Reg. No:** 92987-R

**EPA Est. No.:** XXXXX-XX-XXX

**Net Contents:**

[Container option 1 contains:] 1.69 fl oz [(50ml)] Tristel Part A solution and 1.69 fl oz [(50ml)] Tristel Part B solution

[Container option 2 contains:] 4.23 fl oz [(125ml)] Tristel Part A solution and 4.23 fl oz [(125ml)] Tristel Part B solution

**Manufactured By/For:**

Tristel Solutions Limited  
Lynx Business Park, Fordham Road  
Snailwell, CB8 7NY  
United Kingdom  
**Tel: +44 (0) 1638721500**  
**Email: mail@tristel.com**

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**CAUTION.** Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**STORAGE AND DISPOSAL**

Do not contaminate food or feed by storage or disposal or cleaning of equipment.

**STORAGE:** Store in a cool, well ventilated area. Keep container tightly closed. Store away from children. In case of spill, flood areas with large quantities of water.

**PESTICIDE DISPOSAL:** To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill container. Clean container promptly after emptying. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**TO CLEAN AND DISINFECT HARD, NON-POROUS SURFACES**

[How to use].

Tristel Duo Part B and Part A solution are dosed in equal measures and mix immediately when the Duo foam pump is depressed. A 320 ppm Chlorine dioxide solution is contained in the foam.

Tristel Duo is an effective chlorine dioxide foam which combines cleaning with disinfection.

## HOW TO USE

### [Step 1]

Wear gloves when handling disinfectants and medical equipment.

### [Step 2]

When using the Duo bottle for the first time remove and discard the transport locks that stop the pump being depressed in transit.

### [Step 3]

If [When] Tristel Duo is being used for the first time, depress the pump two to four times to prime the pump. Then, depress the pump once to dispense Tristel Duo onto the surface.

### [Step 4]

Leave on the surface for two (2) minutes. Reapply as necessary to ensure that the surface remains wet for the entire [two (2) minute] contact period.

### [Step 5]

Wipe with Tristel Dry Wipes or allow to air dry. Discard the used wipe to clinical waste, [do not macerate]. Do not re-use.

[Leave the surface for [two]/ [2] minutes to achieve efficacy against Drug Resistant bacteria and bacteria] Reapply as necessary to ensure that the surface remains wet for the entire contact period.

AND/OR

Bacteria (2 Minute Contact [Time])

*Pseudomonas aeruginosa* [ATCC 15442]

*Staphylococcus aureus* [ATCC 6538]

Drug Resistant Bacteria (2 Minute Contact [Time])

Methicillin Resistant *Staphylococcus aureus* [(MRSA)] [ATCC 33591]

Carbapenem-resistant *Klebsiella pneumoniae* [(CR-KP)] [(CRE)] [ATCC BAA-2146]

\* Viruses (30 second contact [Time]):

Norovirus [(using EPA approved Feline calicivirus)], [(Strain F-9, ATCC VR-782 surrogate)]

Herpes simplex virus Type 1 [ATCC VR-733]

Poliovirus Type 1 [ATCC VR-1562]

Adenovirus type 5 [ATCC VR-5]

[Optional directions:] Ultrasound transducers and probes:

For use on external surfaces of ultrasound transducers and probes only.

To disinfect: Clean [remove] gel from external surface of ultrasound transducer or probe to be disinfected by using a clean washcloth [wipe]. Then thoroughly wet the probe with Tristel Duo. Allow surface to remain wet for two (2) minutes. Reapply as necessary to ensure that the surface remains wet for the entire contact period. Let air dry.

OR

[Wear gloves when handling disinfectants and medical equipment.

When using the Duo bottle for the first time:

- remove and discard the transport locks that stop the pump being depressed in transit,
- depress the pump two to four times to prime the pump.

**[Step 1]**

Depress the pump once to dispense Tristel Duo onto the surface.  
Allow surface to remain wet for two (2) minute contact time.  
Reapply as necessary to ensure that the surface remains wet for the entire contact period. Allow to air dry.

*When using on ultrasound transducers and probes:*

Remove gel from external surface of ultrasound transducer or probe by using a clean washcloth or wipe. Then thoroughly treat the probe with Tristel Duo.

**[Step 2]**

Discard the used wipe to clinical waste. Do not re-use.

**DISINFECTION**

When used as directed, [Tristel Duo for Surfaces] [this product] is [a one step disinfectant] effective against bacteria and viruses\* on hard non-porous surfaces.

Tristel Duo for Surfaces is effective against:

- Norovirus [(using EPA approved Feline calicivirus)], [(Strain F-9, ATCC VR-782 surrogate)]
- Herpes simplex virus Type 1 [ATCC VR-733] [HSV]
- Poliovirus Type 1 [ATCC VR-1562] [Poliovirus]
- Adenovirus type 5 [ATCC VR-5] [Adenovirus]
- Methicillin-resistant *Staphylococcus aureus* [(MRSA)] [ATCC 33591]
- Carbapenem-resistant *Klebsiella pneumoniae* [(CR-KP)] [(CRE)] [ATCC BAA-2146]
- *Pseudomonas aeruginosa* [*P. aeruginosa*] [ATCC 15442]
- *Staphylococcus aureus* [*S. aureus*] [ATCC 6538]

**APPLICATIONS [AND USES]**

Tristel Duo is designed for the [cleaning and] disinfection of hard non-porous surfaces, [including those] of the following medical equipment [devices]:

- Ambulance equipment
- Anesthesia machines
- Apheresis machine
- Areas [surfaces] that come into contact with sterilized and high-level disinfected instruments
- A-scan and b-scan biometry probe equipment [station] [cable and screen]
- Aviscope
- Bath hoist
- Bed railings
- Bedpan washer & equipment
- Beds and mattress covers
- Beside TV's / entertainment system
- Birthing pools
- Blood pressure cuffs
- Cabinets
- Carts
- CAT -or- Computerized Axial Tomography equipment
- Chairs
- Coagulator
- Colposcope [head]
- Colposcope imaging equipment [colposcopes]
- Colposcope stand
- Commodes
- Counters
- Cryogas cylinder
- Cryogun and regulator
- Cryopen [handle] [casing]
- [LMIC adapted] Cryopen
- Dental equipment [stations]
- Diagnostic equipment
- Dialysis machines
- Dressing trolleys
- [Surface of] Drill without air / water channels
- ECG electrodes and cables
- Electro-caps [for EEG]
- Electronic charts
- Emergency rooms
- Endoscope storage and endoscope drying cabinets
- Endoscopy centers

*Tristel Duo for Surfaces (92987-TBD)*

Tristel Solutions Limited

- Exam rooms
- Exam tables
- Examination table
- Exterior surfaces of Dialysis Machines, Glucometers / Blood Glucose Meters
- Gurneys
- Halogen lamp
- Hand lens
- Hand-held monitors
- Handle [and/or] [video] screen of video laryngoscope
- Hospital facilities
- Infant incubators and care cribs
- Instrument storage [transport] trays
- Instrument tables
- Instrument trays
- Instrument trolley
- Intra-oral camera
- IV poles [/] [stands]
- Laboratory equipment
- Laboratory workstation / work bench
- LEEP equipment
- Mammography equipment
- Medical microscopes
- Mobile phones, tablets, or associated computing devices
- MRI [or] [Magnetic Resonance Imaging equipment]
- Nurse-call buttons
- Oxygen hoods
- Oxygen masks
- Pachymeter(s) [handle] [cable]
- Paddles
- Patient fans
- Patient monitoring equipment
- Patient monitors [displays]
- Phlebotomy trays
- Plastic mattress covers
- Polymerisation lights
- PVC tubing
- Respiratory equipment
- Scope reprocessing rooms
- Slit lamp
- Stretchers
- Stand(s)
- Surfaces of ophthalmic devices
- Tables
- Torch lights
- Trays
- Ultrasound probe holders, cables, keyboards
- Non-critical transducers [/] [probes]
- Non-invasive ultrasound probes
- Ultrasound stations/ units
- Visualization equipment
- Walking aids
- Weighing scales
- Wheelchairs
- Work surfaces
- X-ray rooms
- X-ray sensors

[Tristel Duo for Surfaces may be used to pre-clean transvaginal and transrectal ultrasound probes prior to high-level disinfection [HLD]]

{*Note to reviewer: This section is required when the label includes any medical device or medical equipment surface claims*} This product is not to be used as a terminal sterilant/high-level disinfectant on any surfaces or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi critical medical devices prior to sterilizations or high-level disinfection.

[For use in hospitals, laboratories, emergency centers, ambulances, dental and medical offices, and other healthcare facilities.]



**Areas of Use:**

**[Hospital and Healthcare Settings:** Ambulances, Ambulatory Surgical Centers (ASC), Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctors Offices, Donation Centers [blood][plasma][semen][milk][apheresis], Emergency Medical Settings, Emergency Rooms, E.R., Emergency Vehicles, Eye Surgical Centers, Healthcare Settings, Healthcare Facilities, Home Healthcare, Hospices, Hospitals, ICU, Isolation Areas, Laboratory, Laundry rooms, Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms (OR), Ophthalmic Offices, Orthopedics, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy, Physician's offices, Radiology, Recovery Rooms, Rehabilitation, Respiratory therapy, Surgery, Surgical Centers, Transport vehicles and X-Ray.]

*and/or*

**[Critical Care Areas:** CCU, Emergency Rooms, E.R., ICU, Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive Care Units (PICU) and Surgery.]

*And/or*

**[Hospital, Healthcare, and Critical Care Use Sites:** Intended for use on hard nonporous surfaces of: ambulance equipment surfaces; bed railings; cabinets; carts; chairs; counters; dental chairs; dental countertops; dental unit instrument trays; endodontic equipment such as apex locators; exam tables; gurneys; infant incubators [interior and exterior surfaces of]; infant warmers [interior and exterior surfaces of]; isolettes; IV poles; laboratory equipment and surfaces; loupes; operating room tables and lights; operatory light switches; oxygen hoods; physical therapy (PT) equipment surfaces; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telephones; toilet seats; and hard nonporous outside surfaces of: amalgamators and dental curing lights; anesthesia machines and respiratory therapy equipment; apheresis machines, diagnostic equipment, dialysis machines; patient monitoring equipment, patient support and delivery equipment, pulp testers and motors; toilets seats and external surfaces; and ultrasound transducers and probes.]

**[THE TRISTEL CHEMISTRY**

Tristel Duo for Surfaces utilises Tristel's patented chlorine dioxide chemistry. The chemical symbol for chlorine dioxide is ClO<sub>2</sub>.]

**Optional Marketing Statements**

**General Marketing Claims**

- Aids in reduction of cross-contamination on treated surfaces
- Alcohol free
- Antibacterial
- Antimicrobial
- Bleach free
- Broad spectrum [multi-purpose] cleaner/disinfectant
- Meets AOAC efficacy standards for hospital disinfectants
- Cleaner
- Cleans
- Compact
- Contains no perfumes
- Convenient
- [Convenient] [Portable] [way to disinfect hard nonporous surfaces]
- Do not use on copper, brass or bronze
- Does not contain bleach
- Does not produce mist or overspray
- Easy[-]to[-]use
- Fragrance free
- For use on instrument(s) and non-critical medical devices
- Healthcare
- For use on hard, non-porous [non-food contact] surfaces [when used as directed]

*Tristel Duo for Surfaces (92987-TBD)*

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A540 – June 28, 2017 Label Version (6) April 18, 2018

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- For use on hard, non-porous surfaces [when used as directed]
- Generates chlorine dioxide
- Inactivate micro-organisms on surfaces
- Independently tested
- Mobile
- No manual mixing [of solutions]
- [Requires] No measuring
- One step disinfectant that works in the presence of 5% organic soil
- Premeasured
- Ready[-]to[-]Use
- Saves valuable time
- Tristel Duo is a chlorine dioxide foam which combines cleaning with disinfection.
- To control mold and mildew on environmental surfaces for economic or aesthetic purposes.
- To control odor and slime forming bacteria
- Use by *[insert date]*

**Disinfectant Claims**

- Bactericidal Broad Spectrum Disinfectant
- Cleaning and disinfection of Ultrasound Transducers
- Disinfectant
- Disinfectant Cleaner
- Disinfecting Cleaner
- Disinfects hard, non-porous surfaces in 2 minutes when used as directed {use with appropriate contact time kill claims}
- Eliminates ([Bacteria,] [viruses\*] in 2] minutes when used as directed {use with appropriate contact time kill claims}
- Endoscope pre-cleaner
- Kills ([Bacteria,] [viruses\*] in 2 minutes when used as directed {use with appropriate contact time kill claims}
- [Kills] [Effective against] [MRSA] [(Methicillin Resistant Staphylococcus aureus)]
- [Medical] [/] [Surgical] [hospital] hard, non-porous surface and equipment disinfectant [cleaner]
- Kills [enveloped] [non-enveloped] viruses\*
- Virucidal\*

**Marketing Claims Against Emerging Viral Pathogens**

*{This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.}*

This product meets the criteria to make the claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses
- Small non-enveloped viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus type 5, ATCC VR-5, Strain Adenoid 75, Feline calicivirus, Strain F-9, ATCC VR-782, Poliovirus type 1, ATCC VR-1562, Strain Chat
Large, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782, Poliovirus type 1, ATCC VR-1562, Strain Chat

*Tristel Duo for Surfaces (92987-TBD)*

Tristel Solutions Limited

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Small, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782, Poliovirus type 1, ATCC VR-1562, Strain Chat
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Acceptable claim language:

*[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.*

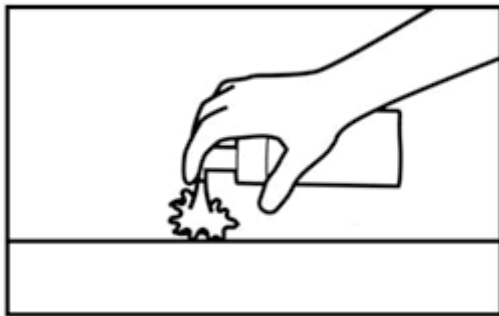
*[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.*

© [insert year] [insert company name]

[The following graphics and statements are optional. They may be placed anywhere on label/container.]



# Tristel





{Note to reviewer: Contact time below to be used in conjunction with the appropriate tested organism and directions for use.}



International Patent Numbers:

GB 2 422 545 B  
EP 1 843 795 B1  
ZL 200680002149.7  
CA 2,594,714  
AU 2006208899

International Patent Applications Pending:

US 2010-0036305-A1  
IN 4485/DELNP/2007