



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 3, 2021

Abigail T.D. Wacek
Senior Regulatory Consultant
Tristel Solutions Ltd.
Lynx Business Park
Fordham Rd., Snailwell, Newmarket
Cambridgeshire, UK CB8 7NY

Subject: PRIA Label Amendment – Application to Revise the Product Label’s
Precautionary Statements and Add Additional Organisms to the Product Label.
Product Name: “Tristel Duo for Surfaces”
EPA Registration Number: 92987-1
Received Date: September 11, 2020
Action Case Number: 00217756

Dear Ms. Wacek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Michael Varco by phone at 703-347-0403, or via email at Varco.Michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "DF", with a long horizontal flourish extending to the right.

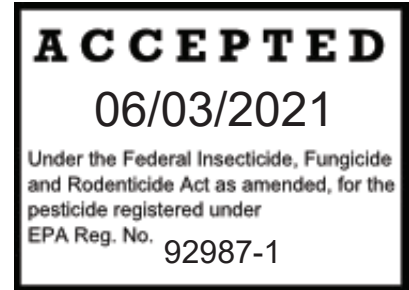
Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

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 ClO₂ 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
- Tristel Duo NCU
- Tristel Foam NCU
- Tristel Jet
- Tristel Jet SUR
- Tristel Jet Foam
- Tristel Jet Trigger
- JET (Jet)
- Jet Cache]



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

Or

Bactericidal, fungicidal, tuberculocidal, and virucidal* [cleaner and] disinfectant.

{Note to reviewer: The back panel of the label is necessary as per Chapter 3 of the Label Review Manual guidance on Small Containers because the product bottle size does not fit all information. The back panel label will be multiple layer label to ensure it contains all information.}

See Back Panel [of the label] for [list of ingredients], [Net contents], [Directions for Use], [Applications], [biocidal effect], [chemistry].

[See [page two] [next page] of the label for [Directions for use], [applications], [biocidal effect], [chemistry].]

[Open to read]

[For Professional Commercial, and Institutional Use]

Tristel Duo Part A	
Active Ingredient:	
Sodium chlorite	0.5%
Other Ingredients	<u>99.5%</u>
Total.....	100.0%

Tristel Duo Part B	
Active Ingredient:	
Citric acid.....	5.26%
Other Ingredients	<u>94.74%</u>
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/trigger) and are ready for use.

KEEP OUT OF REACH OF CHILDREN

[See [attached] [pamphlet]/[reference sheet]] for [Directions for Use], [Applications], [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: 92987-1

EPA Est. No.: 92987-GBR-1
82613-NJ-1

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

[Container option 3 contains:] 10.14 fl oz [(300ml)] Tristel Part A solution and 10.14 fl oz [(300ml)] Tristel Part B solution

[Container option 4 contains:] 13.53 fl oz [(400ml)] Tristel Part A solution and 13.53 fl oz [(400ml)] 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

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] [trigger] 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.] *[Note: Optional feature not applicable to all packaging variants]*.

[When using Duo pack with Trigger head, assemble the pack first. Align the Duo Trigger head with the bottle to match the color of the tube to the color of the caps. *[Blue]* with *[black]*, *[red]* with *[white]*. Remove bottle caps. Insert the *[Insert color]* tube into the *[Insert color]* capped bottle neck and the *[Insert color]* tube into the *[Insert color]* capped bottle neck. Fasten the levers on each side to secure the Duo Trigger head on the Duo pack.]

[Step 3]

[When using Tristel Duo for the first time, depress the pump two to four times to prime it. Then, depress the pump to dispense Tristel Duo onto the surface [or a cloth [wipe] [of your choice] then apply to the surface].]

[When Tristel Duo Trigger is used for the first time, depress the trigger a few times to prime the trigger. For all subsequent uses depress the trigger to dispense Tristel Duo onto the surface [or a cloth [wipe] [of your choice] then apply to the surface].]

[Step 4]

[Allow the surface to remain visibly wet for 2 [two] minutes.] OR [Leave the surface visibly wet for [two]/ [2] minutes to achieve efficacy against Multi-Drug and Drug Resistant bacteria, *Mycobacterium bovis* (TB), fungi, bacteria, and viruses*.]

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

[Step 5]

Wipe with [Tristel Dry Wipes]/[dry non-woven wipe]/[paper towel] or allow to air dry. Discard the used [wipe]/[towel] 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] [Leave the surface for [one]/ [1] minute to [achieve efficacy against *Mycobacterium bovis* (TB)]/[achieve tuberculocidal efficacy].]

Reapply as necessary to ensure that the surface remains visibly wet for the entire contact period.

AND/OR

[Effective against:]

Bacteria (2 Minute Contact [Time])

Pseudomonas aeruginosa [ATCC 15442]
Staphylococcus aureus [ATCC 6538]
Escherichia coli [(*E. coli*)] O157:H7 [ATCC 35150]
Extended Spectrum beta lactamase [(ESBL)] producing *Escherichia coli* [(*E.coli*)] [ATCC BAA196]
Neisseria gonorrhoeae [ATCC43069]
Streptococcus agalactiae [ATCC 13813]
Enterobacter cloacae [ATCC 13047]
Staphylococcus epidermis [ATCC 12228]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Burkholderia cepacia [ATCC 25416]

Drug Resistant Bacteria (2 Minute Contact [Time])

Methicillin-Resistant *Staphylococcus aureus* [(MRSA)] [ATCC 33591]
Carbapenem-resistant *Klebsiella pneumoniae* [(CR-KP)] [(CRE)] [ATCC BAA-2146]

Multi-Drug Resistant Bacteria (2 Minute Contact [Time])

Multi-Drug Resistant [(MDR)] *Streptococcus pneumoniae* [ATCC 700677]
Multi-Drug Resistant [(MDR)] *Acinetobacter baumannii* [(MDRAB)] [ATCC19606]

Mycobacteria (1 Minute Contact [Time])

Mycobacterium bovis BCG [(EPA approved surrogate of *Mycobacterium tuberculosis*)] [ATCC 35743]

Fungi (1 Minute Contact [Time])

Trichophyton interdigitale [ATCC 9533]
Candida albicans [ATCC 10231]

* 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]
2009-H1N1 Influenza A Virus [(Novel H1N1)] [(Strain A/Mexico/4108/2009, CDC #2009712192)]
+Hepatitis B virus [(HBV)] [(using EPA approved Duck Hepatitis B Virus surrogate)] [(11/4/12 strain)]
+Human Immunodeficiency Virus Type 1 [(HIV)] [Strain HTLV-IIIB]

[Denatures] [Destroys] [Breaks down] Deoxyribonucleic Acid [(DNA)] and Ribonucleic Acid [(RNA)]

{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 visibly wet for two (2) minutes. Reapply as necessary to ensure that the surface remains wet for the entire contact [period]/[time]. 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, [*Note: Optional feature not applicable to all packaging variants*].
- depress the pump two to four times to prime it [the pump].

[Step 1]

Depress the pump to dispense Tristel Duo onto the surface [or a cloth [wipe] [of your choice] then apply to the surface].

Allow surface to remain visibly wet for two (2) minute contact time.

Reapply as necessary to ensure that the surface remains visibly wet for the entire contact [time]/[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.]

{Administrative Note: If a virucidal claim for HIV-1, HBV is made the following paragraph and special instructions are required}

+KILLS HIV-1 ON HBV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HIV-1 (associated with AIDS), HBV, and HCV.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

- **PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gown, masks and/or eye coverings.
- **CLEANING PROCEDURE:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of [Product Name] [this product].
- **CONTACT TIME:** Allow surfaces to remain visibly wet for 30 seconds. This contact time will not control other common types of viruses and bacteria.
- **DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

DISINFECTION

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

Tristel Duo for Surfaces is effective against:

- *Mycobacterium bovis* BCG [ATCC 35743]
- *Trichophyton interdigitale* [ATCC 9533]
- *Candida albicans* [ATCC 10231]
- Norovirus [(using EPA approved Feline calicivirus)], [(Strain F-9, ATCC VR-782 surrogate)]
- Herpes simplex virus Type 1 [ATCC VR-733] [HSV-1]
- Poliovirus Type 1 [ATCC VR-1562] [Poliovirus]
- Adenovirus type 5 [ATCC VR-5] [Adenovirus]
- 2009-H1N1 Influenza A Virus [(Novel H1N1)]
- +Hepatitis B virus [(HBV)]

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- +Human Immunodeficiency Virus Type 1 [(HIV)]
- Methicillin-resistant *Staphylococcus aureus* [(MRSA)] [ATCC 33591]
- Carbapenem-resistant *Klebsiella pneumoniae* [(CR-KP)] [(CRE)] [ATCC BAA-2146]
- Multi-Drug Resistant [(MDR)] *Streptococcus pneumoniae* [ATCC 700677]
- Multi-Drug Resistant [(MDR)] *Acinetobacter baumannii* [(MDRAB)] [ATCC 19606]
- *Pseudomonas aeruginosa* [*P. aeruginosa*] [ATCC 15442]
- *Staphylococcus aureus* [*S. aureus*] [ATCC 6538]
- *Escherichia coli* [(*E. coli*)] O157:H7 [ATCC 35150]
- Extended-Spectrum beta-lactamase [(ESBL)] producing *Escherichia coli* [(*E. coli*)] [ATCC BAA-196]
- *Neisseria gonorrhoeae* [ATCC 43069]
- *Streptococcus agalactiae* [ATCC 13813]
- *Enterobacter cloacae* [ATCC 13047]
- *Staphylococcus epidermis* [ATCC 12228]
- *Salmonella enterica* [ATCC 10708]
- *Serratia marcescens* [ATCC 14756]
- *Burkholderia cepacia* [ATCC 25416]
- Denatures Deoxyribonucleic Acid [(DNA)] and Ribonucleic Acid [(RNA)]

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
- Bedpan
- Bed railings
- Bedpan washer & equipment
- Beds and [plastic] 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
- Curtain rails
- Dental equipment [stations]
- Diagnostic equipment
- Dialysis machines
- Door knobs/handles
- 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
- 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

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- 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
- Toilet seat / surfaces
- Torch lights
- Tourniquets
- 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 [semi-critical devices, such as] 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, SANE (Sexual Assault Nurse Examiners), 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 utilizes Tristel's patented chlorine dioxide chemistry. The chemical symbol for chlorine dioxide is ClO₂. Tristel Duo pack incorporates two separate reservoirs that contain Part A solution (sodium chlorite) and Part B solution (citric acid). When mixed upon pressing the foam pump or trigger, Tristel's proprietary chlorine dioxide chemistry is generated.]

Optional Marketing Statements

General Marketing Claims

- Aids in reduction of cross-contamination on treated surfaces
- Alcohol free
- Antibacterial
- Antimicrobial
- Based on proprietary chlorine dioxide technology
- Bleach free
- Broad spectrum [multi-purpose] cleaner/disinfectant when used according to disinfection directions for use
- Broad spectrum disinfectant
- Tested according to AOAC Use-Dilution Method
- Category IV [classification for safety]
- Cleaner
- Cleans
- Compact
- Compatible with many materials
- Contains no perfumes
- Convenient
- Cost effective [Convenient] [Portable] [way to disinfect hard nonporous surfaces]
- Do not use on aluminum, copper, brass or bronze
- Does not contain bleach
- Does not produce mist or overspray
- Easy[-]to[-]use
- Economic
- Fragrance free
- For use on instrument(s) and non-critical medical devices
- Helps to reduce cross-contamination on treated surfaces
- For use on hard, non-porous [non-food contact] surfaces [when used as directed]
- For use on hard, non-porous surfaces [when used as directed]
- Generates chlorine dioxide
- Inactivate micro-organisms on surfaces
- Independently tested

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- Intended for use on non-invasive medical devices such as colposcopes and non-porous surfaces of medical equipment used in [Women's Health], [by SANE (Sexual Assault Nurse Examiners)] [specialists].
- Mobile
- No manual mixing [of solutions]
- Non-irritating to eyes / [not an eye irritant]
- No rinsing is required
- No added fragrance
- No dilutions, no mistakes
- Not for sale in [insert name of state(s)]
- [Requires] No measuring
- One step disinfectant that works in the presence of 5% organic soil
- Premeasured
- Portable
- Question? Comments? Call [insert number]
- Ready[-]to[-]Use
- Saves valuable time
- Simple [to use]
- Supported by Tristel App
- Tristel Duo is a chlorine dioxide foam which combines cleaning with disinfection.
- Tristel Duo is an effective foam which combines the powers of chlorine dioxide with cleaning action.
- To control mold and mildew on environmental surfaces for economic or aesthetic purposes.
- To control odor and slime forming bacteria
- [Offers] Unique opportunity to record disinfection procedure by using Tristel App
- Use by [insert date]

Supported by Tristel App.

The Tristel App is designed to provide **compliance** with user instructions and **traceability** for every disinfection event. When used in tandem with Tristel Duo, the Tristel App records operator data, product data (LOT & Expiry) and application [device] data. At the end of every successfully completed disinfection event, the Tristel App produces a digital **traceability record** including a unique validation code. Each record is uploaded to both the mobile disinfection log and a Web Portal which operators can use to filter and extract disinfection event data.

Disinfectant Claims

- Bactericidal Broad Spectrum Disinfectant
- Cleaning and disinfection of Ultrasound Transducers
- Denatures DNA [(Deoxyribonucleic Acid)] and RNA [(Ribonucleic Acid)]
- Disinfectant
- Disinfectant Cleaner when used according to the disinfection directions for use.
- Disinfecting Cleaner when used according to the disinfection directions for use.
- Disinfects hard, non-porous surfaces in 2 minutes when used as directed {use with appropriate contact time kill claims} Effective against [bacteria,] [viruses*], [fungi], [*Mycobacterium bovis* (TB)] in [[2], [1] minutes], [30 seconds] when used as directed {use with appropriate contact time kill claims}
- Endoscope pre-cleaner
- Fungicidal
- Hospital Disinfectant
- Kills [bacteria,] [viruses*], [fungi], [*Mycobacterium bovis* (TB)] in 2 minutes when used as directed {use with appropriate contact time kill claims}
- [Kills] [Effective against] [MRSA] [Methicillin Resistant *Staphylococcus aureus*], [*Pseudomonas aeruginosa*] [*P. aeruginosa*], [*Staphylococcus aureus*] [*S. aureus*], [*Escherichia coli* O157:H7] [*E. coli* O157:H7] , [Extended-Spectrum beta-lactamase producing *Escherichia coli*] [ESBL producing *E. coli*]

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[*Neisseria gonorrhoeae*] [*N. gonorrhoeae*], [*Streptococcus agalactiae*], [*S. agalactiae*], [*Enterobacter cloacae*], [*E. cloacae*], [*Staphylococcus epidermis*], [*S. epidermis*], [*Salmonella enterica*], [*S. enterica*], [*Serratia marcescens*], [*S. marcescens*], [*Burkholderia cepacia*], [*B. cepacia*], [Multi-Drug Resistant *Streptococcus pneumoniae*], [MDR *S. pneumoniae*], [Multi-Drug Resistant *Acinetobacter baumannii*], [MDRAB], [*Mycobacterium bovis* BCG], [*M. bovis*], [*Trichophyton interdigitale*], [*T. interdigitale*], [*Candida albicans*], [*C. albicans*], [2009-H1N1 Influenza A Virus], [+Hepatitis B virus], [+HBV] [+Human Immunodeficiency Virus], [+HIV], [Norovirus], [Herpes Simplex Virus Type 1], [HSV-1], [Poliovirus Type 1], [Adenovirus Type 5]

- [Kills] [Effective against] [*Insert organism from the “Effective Against” list*].
- Kills [enveloped] [non-enveloped] viruses*
- [Medical] [/] [Surgical] [hospital] hard, non-porous surface and equipment disinfectant [cleaner]
- Tuberculocidal
- 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
Small, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782, Poliovirus type 1, ATCC VR-1562, Strain Chat

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, 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, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

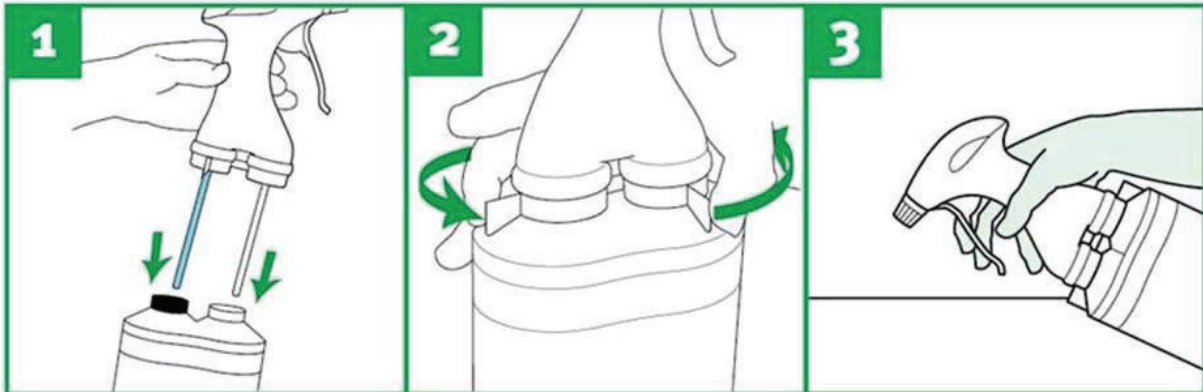
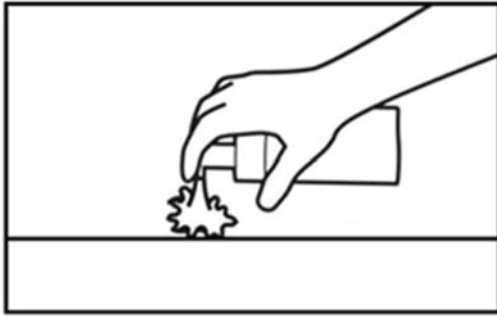
[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard non-porous surfaces. Refer to the [CDC or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

© [insert year] [insert company name]

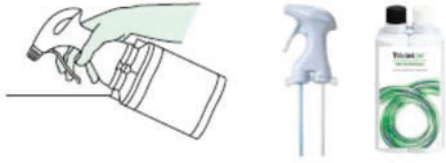
[The following graphics and statements are optional. They may be placed anywhere on label/container.]



Tristel



{Administrative Note: [Brackets throughout label indicate optional or instructional language]}



{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

US 8,840,847
IN 268,244