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Where can I order?

You can order Tristel OPH and Tristel Test strips from healthcare suppliers, including Advancing Eyecare.

For more information, contact Tristel Inc at:

Email: mail-us@tristel.com

Call: 857-557-8023

How supplied

PRODUCT CODE	DESCRIPTION	CASE CONTENTS
TSL025126	Tristel OPH: A dual compartment bottle and a tub of wipes. User Guide. Each set delivers 150 HLD cycles.	2

Additional products sold separately

PRODUCT CODE	DESCRIPTION	CASE CONTENTS
45-13	Tristel Test Strips starter pack: A vial/bottle of 50 test strips. Stopwatch. Polyethylene container. 10ml measure syringe. User Guide. 50 MRC check complete stickers.	1
45-10	Tristel Test Strips: A vial/bottle of 50 test strips. User Guide. 50 MRC check complete stickers.	1

Where is Tristel OPH manufactured?

Tristel OPH is designed by Tristel Solutions Limited in the United Kingdom and is manufactured in the USA under license by Parker Laboratories, Inc. in Fairfield, NJ.

Parker is an ISO and MDSAP-certified manufacturer. Parker is registered with the U.S. Food and Drug Administration as a manufacturer of medical devices, and all products are produced under Good Manufacturing Practices (GMP) directives.

Is Tristel OPH FDA-Cleared?

Yes, Tristel OPH is included on the list of FDA-Cleared Sterilants and High-Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices.

In May 2025, the FDA granted Tristel's 510(k) premarket notification request and cleared Tristel OPH as a Class II device in the category "Foam or gel chemical sterilant/high level disinfectant."

How was Tristel OPH evaluated & cleared by the FDA?

The FDA reviewed Tristel's dossier of evidence which proved the performance and safety of Tristel OPH. The regulatory pathway followed to achieve this approval was the 510(k) premarket notification.

Following a thorough review, Tristel OPH was cleared for the high-level disinfection of reusable ophthalmic devices.

Is Tristel OPH safe to use at the point-of-care (POC)?

Yes, Tristel OPH can be used at the point-of-care; it is one of the key benefits of Tristel OPH.

Tristel OPH is mobile and can be used at a site closest to the point-of-care. This eliminates the need for transportation of the ophthalmic device, reducing the risk of device damage during transportation. Point-of-care reprocessing increases device availability by reducing reprocessing time.

Tristel OPH is also delivered ready-to-use; it does not require equipment or installation. It can be used at room temperature.

Many other high-level disinfectants require electricity to power them and to increase the temperature of the disinfectant.

Does Tristel OPH have prescribed ventilation or air filtration requirements?

No. The Tristel OPH instructions for use (IFU) do not prescribe mandatory conditions for room ventilation during product use.

It is a general good practice for all chemical agents to be stored and used in a ventilated area.

Healthcare facilities in the USA are expected to comply with local regulations on air quality within facilities, including frequency of air changes.[1]

Is there a limit to how many times Tristel OPH can be used per day?

The answer depends on the conditions of the room in which Tristel OPH is being used. Tristel has conducted a work exposure limit study. The study was conducted in a room with limited ventilation.

It is generally expected that when used in a clinical setting Tristel OPH will be used in the facilities that follow CDC guidelines for room ventilation. For example, treatment and examination rooms, soiled or decontamination rooms require a minimum of 6 air changes per hour.[1]

Tristel conducted an inhalation study in a room with 5 changes per hour. The operator performed 51 high-level disinfection procedures with Tristel OPH over 8 hours. The 8-hour time-weighted average (TWA) readings did not exceed the OSHA permissible exposure limit of 0.1 ppm of chlorine dioxide. The results for the average 15-minute short-term exposure limit (STEL) did not exceed the California Division of Occupational Safety and Health permissible exposure limit of 0.3 ppm.

Is PPE required when using Tristel OPH?

Yes. Gloves should be worn when using Tristel OPH and handling medical devices.

Although it is not corrosive to the eye, Tristel OPH is an eye irritant in direct contact with the eye. It does not cause eye damage. Tristel recommends the users wear glasses to prevent accidental exposure to Tristel OPH foam during use. Hospitals can perform their own safety assessment of the likely exposure and define specific PPE requirements under their own standard operating procedures.

Do I need to test MRC every time I use Tristel OPH?

No. Tristel OPH is designed and used in a way that each dose of the high-level disinfectant foam is single-use and is dosed as ready-to-use at or above the minimum required concentration (MRC). Therefore, there is no need to test Tristel OPH MRC before each use.

Tristel OPH is released following a stringent quality control procedure that confirms the product meets performance specifications including the minimum required concentration of the active ingredient.

Use Tristel Test Strips to test MRC when opening a new bottle of Tristel OPH. Tristel Test Strips help to verify that the Tristel OPH Foam bottle is dosing accurately and the concentration of Tristel OPH is at or above MRC.

What options do I have for traceability with Tristel OPH?

Tristel has developed a digital traceability solution called 3T. 3T combines an intuitive mobile app with an interactive web portal, walking users through the Tristel OPH HLD process, tracking each event, and making the record available in real time. The 3T app is available on Apple and Android devices.

Aggregated device reprocessing event data is securely stored and can be viewed on interactive dashboards, enabling administrators to view and share customized reports.

3T helps you standardize your ophthalmic infection prevention practices, meet accreditation requirements and deliver best patient care practices throughout your organization. For more information on 3T, please visit our website.

Alternatively, Tristel can provide a free paper based, manual traceability resource.

Is an eye-washing station required in the room where Tristel OPH is used?

No. Wearing glasses when using Tristel OPH will prevent accidental exposure to Tristel OPH foam. If the Tristel OPH foam is in the eye it may cause irritation. Hold eye open and rinse slowly and gently with water.

Where can I obtain a Certificate of Conformance for Tristel OPH?

Certificate of conformance for specific batches/lots of Tristel OPH and Tristel Test Strip can be requested from Tristel Inc., by email or downloaded from our website.

What ophthalmic devices are Tristel OPH is compatible with?

Tristel OPH is compatible with many ophthalmic devices from leading manufacturers.

For a detailed list of all manufacturers and models, please refer to the Device Compatibility Summary.

What is a high-level disinfectant (HLD)?

A high-level disinfectant (HLD) is defined by the U.S. Food and Drug Administration (FDA) as a chemical germicide capable of inactivating all microbial pathogens, except large numbers of bacterial endospores, when used according to its labeling.[2,3]

When used under the same conditions but with a shorter contact time, an HLD may also function as a sterilant.

This classification is based on the Spaulding scheme (1970), which categorizes medical devices into three types—critical, semicritical, and noncritical—depending on the risk of infection associated with their use. The Centers for Disease Control and Prevention (CDC) further defines four levels of processing: sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection.[4]

Semicritical devices, such as tonometer prisms, pachymeters, diagnostic lenses, and ultrasound probes, come into contact with mucous membranes or non-intact skin. These devices must be free of all microorganisms, although small numbers of bacterial spores may be acceptable. Therefore, semicritical devices require at minimum high-level disinfection using appropriate chemical disinfectants.

Is Tristel OPH effective against Adenovirus?

Yes, Tristel OPH is effective against Adenovirus when used in accordance with its instructions for use.

As part of the potency testing required for FDA clearance as a high-level disinfectant, Tristel OPH has demonstrated efficacy against Adenovirus Type 5. It has also shown effectiveness against other highly resistant viruses, including Poliovirus Type 1 and the Human Norovirus Surrogate, Feline Calicivirus in accordance with ASTM E1053 surface test method.

Additionally, as a high-level disinfectant, Tristel OPH is considered virucidal, exhibiting efficacy against non-enveloped viruses.

Is Tristel OPH effective against *Aspergillus brasiliensis*?

Yes, Tristel OPH is effective against *Aspergillus brasiliensis* when used in accordance with its instructions for use. As a high-level disinfectant, Tristel OPH is considered fungicidal.

During potency testing conducted as part of Tristel's 510(k) premarket notification, Tristel OPH demonstrated efficacy against *Aspergillus brasiliensis*, as well as other resistant fungi such as *Trichophyton interdigitale* and *Candida albicans*. These results were achieved using the AOAC Use Dilution Method.

Is Tristel OPH effective against *Candida albicans*?

Yes, Tristel OPH is effective against *Candida albicans* when used in accordance with its instructions for use.

As a high-level disinfectant, Tristel OPH is considered fungicidal and yeasticidal.

During potency testing conducted as part of Tristel's 510(k) premarket notification, Tristel OPH demonstrated efficacy against *Candida albicans*, as well as other resistant fungi such as *Trichophyton interdigitale* and *Aspergillus brasiliensis*. These results were achieved using the AOAC Use Dilution Method.

Is Tristel OPH effective against *Staphylococcus aureus*?

Yes, Tristel OPH is effective against *Staphylococcus aureus* when used in accordance with its instructions for use. As a high-level disinfectant, Tristel OPH is considered bactericidal.

As part of the potency testing required for an FDA-cleared high-level disinfectant, Tristel OPH has demonstrated efficacy against *Staphylococcus aureus* and other resistant bacteria such as *Pseudomonas aeruginosa*, *Salmonella enterica* and another *Staphylococcus* species. These results were achieved using the AOAC Use Dilution Method.

Is Tristel OPH effective against Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*?

Yes, Tristel OPH is effective against Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium* when used in accordance with its instructions for use. As a high-level disinfectant, Tristel OPH is considered bactericidal, meaning it is effective against the full range of bacteria, including antimicrobial-resistant strains.

During potency testing conducted as part of Tristel's 510(k) premarket notification, Tristel OPH demonstrated efficacy specifically against VRE using the AOAC Use Dilution test method.

Is Tristel OPH effective against Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae*?

Yes, Tristel OPH is effective against Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae* when used in accordance with its instructions for use. As a high-level disinfectant, Tristel OPH is considered bactericidal, meaning it is effective against the full range of bacteria, including antimicrobial-resistant strains.

During potency testing conducted as part of Tristel's 510(k) premarket notification, Tristel OPH demonstrated efficacy against CRE using the Use Dilution test method.

References

1. CDC Appendix B Air

CDC online resources: CDC | Infection Control | Environmental Infection Control Guidelines | Part IV. Appendices | Appendix B. Air

2. FDA Definition of High-Level Disinfectant

U.S. Food and Drug Administration (FDA). *Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants – Guidance for Industry and FDA Reviewers*. January 2000. [Accessed via FDA.gov](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level) [1](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level).

3. Spaulding Classification Scheme

Spaulding, E.H. *The role of chemical disinfection in the prevention of nosocomial infections*. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago, IL: American Hospital Association; 1971. Summary available via CDC: [A Rational Approach to Disinfection and Sterilization](https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html)[2](https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html).

4. CDC Disinfection Levels (Favero & Bond, 1993)

Favero, M.S., & Bond, W.W. *Chemical disinfection of medical and surgical materials*. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*. Philadelphia: Lippincott Williams & Wilkins; 2001:881–917. Cited in CDC Guidelines: [References – Disinfection and Sterilization in Healthcare Facilities](https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/references.html) [3](https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/references.html).