TEE COMPLETE CARE®

TD8®

DISINFECTANT

SDS

CS Medical

Safety Data Sheet

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product name: TD 8® Disinfectant
Synonyms: None.
Composition: an aquous 0.59% (w/v) ortho-phthalaldehyde (OPA) solution.
Product code: CS-TD-8
1.2 Relavent identified uses: High level disinfectant for use in TD 100® / TD 100CE disinfector.
1.3 Supplier:

CS Medical, LLC
2179 East Lyon Station Road
Creedmoor, North Carolina 27522
United States of America

Company service telephone: +1-(919) 255-9472
CS Medical email contact: info@csmedicalllc.com

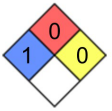
1.4 Emergency Telephone Number: CHEMTREC Emergency telephone number: in USA (800-424-9300), outside USA +1-(703) 527-3887

Section 2. Hazards identification

2.1 Classification:

GHS Classification
Skin Irritation 2
Eye Irritation 2
Signal Word: Warning

NFPA Rating
Health 1
Flammability 0
Reactivity 0



2.2 GHS Label Elements:

Code	Hazard Statements
H315:	Causes skin irritation
H319:	Causes serious eye irritation

Code	Precautionary Statements
P264:	Wash skin thoroughly after handling.
P302+P352:	IF ON SKIN, wash with plenty of soap and water.
P305+P351+P338:	IF IN EYES rinse continuously with water for several minutes. Remove contact lenses if present. Continue rinsing.

Code	Prevention
P280:	Wear protective gloves/ protective clothing/ eye protection/ face protection

Code	Response
P332+P313:	IF SKIN irritation occurs: get medical attention/advice.
P362:	Take off contaminated clothing and wash before reuse

Section 3. Composition/Information on ingredients

Component	Weight %	CAS Number	CS Medical	NTP:	IARC:	California Prop. 65 limit
Ortho-phthalaldehyde (OPA or 1,2-benzenedicarboxaldehyde)	0.59%	643-79-8	Not determined	Not determined	Not determined	Not determined

Section 4. First aid measures

4.1 Description of first aid measures:

4.1.1 General information: Remove contaminated, saturated clothing immediately. In the case of accident or illness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.1.3 Following skin contact: Wash immediately with soap and water. In case of skin irritation, consult a physician.

4.1.4 Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult and ophthalmologist immediately.

4.1.5 Following ingestion: Do not induce vomiting. Rinse mouth followed by drinking a large quantity of water. Seek medical attention.

4.1.6 Self-protection of the first aider: First aider: pay attention to self-protection.

4.2 Most important symptoms: Development of gray skin lesions upon spill contact with skin.

4.3 Indications of immediate medical attention: Provide first aid, decontaminate area. Seek medical attention if eye contact or ingestion occurs. See a physician if skin contact results in irritation. Notes to physician: Probable damage to the mucosa from oral exposure may contraindicate the use of gastric lavage.

Section 5. Firefighting measures

Flash point : Not applicable
Autoignition temperature: Not applicable
Flammable limits: Not applicable
Explosion: Not normally an exlosion hazard

5.1 Extinguishing media: Any means suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture: Hazardous combustion products: None

5.3 Advice for fire-fighters: Special protection equipment: Wear a self-contained breathing apparatus and chemical protective clothing.

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: User personal protective equiment, see Section 8.

6.1.2 For emergency responders: Remove persons to safety. Isolate hazard area and deny entry. Ventilate closed spaces before entering. Use personal protective equipment. see Section 8.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Avoid washing down sewers or waterways. Discharge into the environment must be limited.

6.3 Methods and materials for containment and cleanup:

6.3.1 For containment: Absorb with a suitable absorbent (such as paper towels) and store in a suitable container for disposal. Large spills may be neutralized with sodium bisulfite (~ 100 gr/liter), glycine (~10 gr/liter), or Glycinex™ Neutralizer (~10 gr/liter). Allow 5 minutes contact for neutralization, then transfer to a properly labeled container. Dispose of according to local regulations. Prevent further leakage or spillage if safe to do so.

6.3.2 For cleanup: Clean contaminated surfaces thoroughly.

6.4 Reference to other sections: Personal protection equipment: See Section 8.

Section 7 Handling and storage

7.1 Precautions for safe handling: Put on personal protective equipment. This includes nitrile gloves, chemically resistant gown or apron, and chemical goggles. Wear protective attire for the entire procedure. Handle containers with care. Remove the lid of the unopened bottle of TD-8 Disinfectant while leaving the foil seal intact. Make sure the foil is intact, then invert the bottle and place in the loading position of the TD 100/TD 100CE Disinfector. You will feel resistance as the piercer penetrates the foil seal. Push the bottle down to complete the piercing. The disinfectant will drain into the

disinfecting reservoir. Retain the cap for use after the run is complete. Remove the bottle after run is complete, re-cap and discard.

7.2 Conditions for safe storage, including incompatibilities: This product should be stored at controlled room temperature between 59°F (15°C) and 86°F (30°C). Keep containers tightly closed. This product can be stored with other chemicals, is not flammable, and no special fire protection measures are necessary.

7.3 Specific end uses: TD-8 disinfectant is for exclusive use in the TD 100/TD 100CE Disinfector in accordance with operating instructions. Do not use content for any other reason. Do not use with any other disinfector device, either manual or automated.

Section 8. Exposure control/personal protection

Control Parameters: TD-8 Disinfectant contains no chemical substances with occupational exposure limit values.
Skin protection: Chemical resistant gloves are recommended. Use nitrile, not latex, gloves.
Eye Protection: Laboratory safety goggles, safety glasses or face shield are required.
Ingestion: Do not ingest, drink, or use in the presence of food.
Environmental exposure controls: In the case of a spill decontaminate as described in Section 6 of this SDS. Prevent further leakage or spillage if safe to do so.

Section 9. Physical and chemical properties

Physical state:	Liquid	**Freezing point/range:**	0ºC (32 ºF)
Color/appearance:	Light blue/clear	**pH:**	7 - 8
Boiling temperature:	100ºC (212ºF)	**Specific gravity:**	1.00 g/cc
Odor:	Slight Odor	**Evaporation rate:**	Similar to water

Section 10. Stability and reactivity

Chemical stability: Stable under recommended storage conditions.
Hazardous polymerization: Hazardous polymerization not known to occur.
Hazardous decomposition products: Hazardous decomposition not known to occur.

Section 11. Toxicological information

Acute toxicity
LD50/oral/rat (mg/kg): >5000 mg/kg
LD50 Dermal Rabbit (mg/kg): >2000 mg/kg

Local effects		**Chronic toxicity**	
Oral:	Non-toxic	**Oral:**	Unknown for product
Eye irritation:	May cause eye irritation	**Reproductive:**	Unknown for product
Skin irritation:	May cause skin irritation	**Dermal:**	Unknown for product
Inhalation:	Unknown on product.	**Inhalation:**	Unknown for product

Subchronic toxicity: No observed effect limit of 5 mg/kg/day observed in rats administered pure OPA once per day for 90 days.
Developmental effects: Oral administration of OPA to pregnant rats indicated that at maternally non-toxic doses (less than 10 mg/kg/day) there was no developmental effect.
Allergic reactions: Anecdotal evidence in human case studies **Corrosive effects:** None
Target organ effects: None **Ames test:** Negative
Carcinogenicity: Ingredients in TD-8 Disinfectant are not known or suspected carcinogens.

Section 12. Ecological information

12.1 Toxicity:

Code Statement:
H412: Hazard Statement: May cause long-term adverse effects in the aquatic environment

P273: Precautionary statement prevention: Avoid release to the environment
P501: Precautionary statement disposal: Dispose of container and waste effluent according to local, state, federal, and Union regulations.

LC50 of OPA for freshwater fish: 0.07 mg/liter
EC50 of OPA for freshwater Crustaceans: 0.09 mg/liter

12.2 Persistence and degradability: Not established
12.3 Bioaccumulative potential: Not established
12.4 Mobility in soil: No information available

Section 13. Disposal considerations

13.1 Waste treatment methods: Waste disposal recommendations: Waste disposal according to Directive 2008/98/EC, covering waste and dangerous waste.

13.1.1 Waste-treatment-relevant information: Dispose of container and waste effluent according to local, state, federal, and Union regulations.

13.1.2 Sewage disposal-relevant information: Neutralize aldehyde in effluent with Glycine (~10 gr/liter).

Section 14. Transportation information- Not regulated

Section 15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU Regulations: No REACH Annex XVII restrictions. Contains no REACH candidate substance.

15.1.2 National regulations: No additional information available

15.2 Chemical safety assessment: No chemical safety assessment has been carried out.

Section 16. Other information

This Safety Data Sheet was formatted for compliance with (EC) 1907/2006. Classifications and procedures used to derive the hazards categories for mixtures is according to Regulation (EC) 1272/2008 (CLP).
This SDS information is believed to be correct but is not warranted as such, nor does it purport to be all-inclusive.
Prepared by Kendall Ashe Last revised on December 19, 2022.

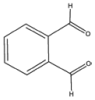
End of Safety Data Sheet

Package Insert

Trade Name and Synonyms: **TD 8®** high-level disinfectant, 0.59% (w/v) ortho-phthalaldehyde

Chemical Family: Di-aldehydes

Formula: $C_8H_6O_2$



Chemical Name, Synonyms: ortho-phthalaldehyde, OPA or 1,2-benzenedicarboxaldehyde
CAS No.: 643-79-8

GENERAL INFORMATION

TD-8 high-level disinfectant is a **SINGLE USE** high-level disinfectant to be used **EXCLUSIVELY** in the **TD 100/TD 100CE** disinfector for the high-level disinfection of TEE ultrasound probes. Review this information and the Operator and Installation Manual for the **TD 100/TD 100CE** disinfector prior to use. Contact CS Medical with any questions about the use of **TD-8** high-level disinfectant or the **TD 100/TD 100CE** disinfector.

WARNING!

⚠ DO NOT ATTEMPT TO MANUALLY OPEN A SEALED CONTAINER OF **TD-8** HIGH-LEVEL DISINFECTANT

⚠ DO NOT USE **TD-8** HIGH-LEVEL DISINFECTANT AFTER THE EXPIRY DATE PRINTED ON CONTAINER LABEL

⚠ DO NOT REUSE **TD-8** HIGH-LEVEL DISINFECTANT. DOING SO WILL RESULT IN A PROBE THAT IS NOT HIGH LEVEL DISINFECTED.

⚠ CAUSES SKIN IRRITATION. CAUSES SERIOUS EYE IRRITATION. WEAR PROTECTIVE GLOVES/PROTECTIVE CLOTHING/EYE PROTECTION/FACE PROTECTION.

⚠ DO NOT SUBSTITUTE OTHER PRODUCTS FOR **TD-8** HIGH-LEVEL DISINFECTANT.

⚠ DO NOT USE A LEAKING CONTAINER OF **TD-8** HIGH-LEVEL DISINFECTANT.

⚠ INSPECT THE **TD-8** HIGH-LEVEL DISINFECTANT SHIPPING BOX AND CONTAINER FOR DAMAGE AND/OR LEAKAGE.

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