Customer Service: Phone (919) 255-9472

FAX (919) 528-3400



Section I - Identification

Product Identification

Product Form: An aqueous, buffered, germicide, glutaraldehyde solution. Slightly acidic pH 6.3 (The pH is about the same as distilled water).

Product Name: TD-5

Synonyms: Glutaraldehyde Based Disinfectant

Intended Use of the Product

TD-5 has the intended use of High-Level Disinfection of TEE probes, for professional use only

Name, Address and Telephone of Responsible Party

CS Medical

2179 East Lyon Station Rd Creedmoor, NC 27522 USA

Emergency Telephone Number

CHEMTREC Emergency Response Telephone Number: (800) 424-9300, outside the US +1 (703) 527-3887.

Note: The CHEMTREC phone number is only for emergencies involving spills, leaks, fire, exposure or accident. Please direct all other inquiries to our customer service phone number.

Section II - Hazards Identification

Warning: Causes skin irritation. Wash thoroughly after handling. Wear protective clothing, eye and face protection and respirator. If swallowed, rinse mouth and immediately contact a poison control center. Remove contaminated clothing and wash before reuse. Rinse skin with water.

Safety Ratings

Health: Hazardous Flammability: None Reactivity: None Contact: Slight

Recommended safety equipment: safety goggles, lab coat and proper gloves

Storage: General storage

NFPA Ratings

Health = 2 Flammability = 0 Reactivity = 0



GHS-US Classification

Signal Word (GHS-US) : Warning

Hazards Statements (GHS-US) H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

H302 – May be harmful if swallowed

H315+H320 – Cause skin and eye irritation P264 – Wash thoroughly after handling

Precautionary Statements (GHS-US)

P264 – Wash thoroughly after handling
P261 – Avoid breathing dust/fume/gas/mist/vapors/spray

P270 - Do not eat, drink or smoke when using this product

P285 – In case of inadequate ventilation wear respiratory protection

P321 - Specific treatment (see Section II and IV on this label)

P330 – Rinse mouth P405 - Store locked up

P501 - Dispose of contents/container (see Section XIII of this label)

P301+310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor (see Section IV) P304+P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a

position comfortable for breathing

P342+P311 - IF experiencing respiratory symptoms: Call a POISON CENTER/doctor

Potential Health Effects

The toxicology of this compound has not been completely examined. It is presumed that the toxicity of this item is similar to other aldehydes. *Inhalation*: Irritating to respiratory tract. May cause asthma like symptoms in sensitive individuals.

Ingestion: Can cause irritation and chemical burns to the mouth, throat, esophagus and stomach. Can also cause nausea, vomiting, diarrhea, etc.

Skin contact. May cause skin irritation or aggravation of existing dermatitis. May cause temporary discoloration of the skin.

Eye contact. Vapors may cause stinging sensation and tearing. Solution contact can cause corneal injury that can cause visual impairment if not dealt with immediately.

Chronic Exposure: May be a sensitizer in some individuals.

Aggravation of preexisting conditions: May aggravate preexisting asthma and other lung diseases.

Unknown Acute Toxicity (GHS-US)

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No data available

Section III - Composition/Information on Components

Ingredients	CAS#	OSHA Pel	ACGIH TLV	Other Limits	% w/v
Glutaraldehyde	111-30-8	0.2 ppm	0.05 ppm	None	2.65%
Water (inactive)	7732-18-5	Not established	Not established	None	93.80%
proprietary buffers, proprietary surfactants, proprietary defoamers	n/a	n/a	n/a	None	3.55%

Section IV - First Aid Measures

First-aid Measures after Inhalation: Remove from source of exposure and get medical attention for any breathing difficulty.

Note to Physician: Probable mucosal damage from oral exposure may contraindicate gastric lavage.

First-aid Measures after Skin Contact: Remove contaminated clothing and wash affected area with soap and water. Get medical advice if irritation develops. Wash or discard contaminated clothing before reuse.

First-aid Measures after Eye Contact. Immediately flush thoroughly with running water for at least 15 minutes. Get immediate medical advice. First-aid Measures after Ingestion: Rinse mouth and immediately contact a poison control center.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

Section V - Fire Fighting Measures

Suitable Extinguishing Media: Any means suitable for surrounding fire. Unsuitable Extinguishing Media: N/A

Advice for Firefighters: Exercise caution when fighting any chemical fire. Use water spray of fog for cooling exposed containers. Remove containers from fire area if this can be done without risk. Do not breathe fumes from fires or vapors from decomposition. Do not enter fire area without proper protective equipment, including respiratory protection. Pyrolysis will release carbon monoxide

Special Hazards:

Flash point: Not applicable.
Flammable Limits: Not applicable.
Fire: Not normally a fire hazard.

Explosion: Not Normally an explosion hazards. **Fire Extinguishing Media**: Any means suitable for surrounding fire. **Special information**: Pyrolysis will release carbon monoxide.

Section VI - Accidental Release Measures

Wear appropriate protective gear such as gloves, apron, protective eyewear and respirator. 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 (about 230 g/gallon), glycine or ammonia.

Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel. Stop leak and clean up released material if safe to do so.

Emergency Personnel

Protective Equipment: Equip cleanup crew with protective equipment.

Emergency Procedures: Eliminate ignition sources. Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of hazardous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

Environmental Precautions

See Section XIII- Disposal

Methods and Materials for Containment and Cleaning Up

See Section VI (Accidental Release Measures) and Section XIII (Disposal)

Section VII - Handling and Storage

Store in a closed container at controlled room temperature, 59°F to 86°F (15°C to 30°C). Solution that is being reused should be stored in a tightly closed container and used in a room with adequate ventilation (i.e. at least ten changes of air per hour).

Precautions for Safe Handling: Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating or drinking. Do not get in eyes, on skin, or on clothing. Do not breathe mist, spray, or vapors. Handle empty containers with care because they may still present a hazard. Use appropriate personal protective equipment (PPE).

Section VIII - Exposure Control/Personal Protection

Airborne Exposure Limits: See section III

Ventilation System: Use appropriate ventilation. If the vapor is irritating to the eyes and nose the threshold limit value is probably exceeded and additional ventilation may be needed. When required, Refer to the ACGIH document, "Industrial Ventilation, a Manual of Recommended Practices" for details about ventilation.

Ingredients	CAS#	OSHA Pel	ACGIH TLV

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Glutaraldehyde	111-30-8	0.2 ppm	0.05 ppm

Personal Respirator. Not required unless the threshold limit value for glutaraldehyde is exceeded. In case of emergency, or when exposure levels are unknown, use a half face or full face respirator that is NIOSH approved with organic vapor cartridges.

Skin protection: Chemical resistant gloves are recommended. Latex gloves are not impervious to glutaraldehyde and are not as appropriate as nitrile gloves.

Eye Protection: Laboratory safety goggles, safety glasses or face shield are required.

Section IX - Physical and Chemical Properties

Boiling Point:100°CDensity:About 1.01 g/mlVapor pressure (mm Hg):18 @ 20°CEvaporation Rate (water = 1):1Vapor Density (air = 1):0.6Solubility:Infinitely miscible with water

Appearance and Odor: A clear, yellowish liquid with the characteristic odor of glutaraldehyde.

Flash Point: : Not Applicable

Auto-ignition Temperature: Not Applicable Decomposition Temperature: Not Applicable Flammability (solid, gas): Not Applicable

pH: 5.9 -6.3 Freezing Point: 0°C

Partition coefficient: n-octanol/water: Not Applicable

Viscosity: 1 cSt

Section X - Stability and Reactivity

Stability: Freezes at low temperature.

Hazardous Decomposition Products: Nothing unusual.

Hazardous polymerization: Will not occur.

Incompatibilities: Nothing unusual.

Conditions to avoid: Excessive cold/heat and light. High pH catalyses an aldol type polymerization that is exothermic but not expected to be violent

Section XI - Toxicological Information

Toxicity: The chronic toxicity of this product is unknown but may include sensitization in sensitive individuals. The toxic effects of glutaraldehyde are believed to be the result of its ability to cross link proteins, which is the same property responsible for its antimicrobial effect. The manufacturer is unaware of any target organ toxicity.

Mutagenicity: CS Medical is unaware of any evidence that the product is mutagenic or teratogenic. However the effects of these products, glutaraldehyde based disinfectants, are not well investigated and we recommend that pregnant customers use an abundance of caution with these products.

Oral LD50 for rats = 134 mg/kg for pure glutaraldehyde Oral LD50 for mouse = 100 mg/kg for pure glutaraldehyde

Cancer lists:

TD-5 is not a carcinogen or suspected carcinogen.

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Ingredient	Known Carcinogenicity?	NTP?	Anticipated?	IARC Category
Glutaraldehyde	No	No	No	None

Section XII - Ecological Information

Environmental Fate: Biodegradable, TD-5 is biodegradable when diluted to a level such that it is not microbiocidal.

Environmental Toxicity: Hazardous to fish.

Section XIII - Disposal

Normally not restricted but local governments may restrict the amounts of aldehydes that can be flushed down the drain. In localities where drain disposal is restricted the product may often be neutralized with glycine or sodium bisulfite and then flushed down drain. Ensure compliance with all government regulation.

Section XIV - Transportation information

Not Regulated.

Section XV - Regulatory Information

Chemical Inventory Status

Ingredient	TSCA	EC
Glutaraldehyde	Yes	Yes
E 1 1011 111 11 15 15		

Federal, State and International Regulations

	SARA 3	302	SARA 3	13	RCRA	TSCA
Ingredient	RQ	TPQ	List	Category	261.33	8(D)
Glutaraldehyde	No	No	No	No	No	No

Chemical Weapons Conventions: No TSCA 12(b): No

SARA 311/312: Acute: None, Chronic: None

CDTA: No

Section XVI - Other Information

This information is believed to be correct but is not warranted as such, nor does it purport to be all-inclusive. Prepared by: K.A. Last Reviewed: January 10, 2019.

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Trade Name and Synonyms: TD-5® high-level disinfectant 2.65% Solution

Chemical Family: Di-aldehydes

Chemical Name and Synonyms: Glutaraldehyde or 1,5 Pentanedial

CAS No.: 111-30-8

GENERAL INFORMATION

TD-5® high-level disinfectant is a **SINGLE USE** high-level disinfectant to be used **EXCLUSIVELY** in the **TD 100**® disinfector or **TEEClean**® cleaner disinfector for the high-level disinfection of TEE ultrasound probes. Review this information and the Operator and Installation Manual for the **TD 100**® disinfector or **TEEClean**® cleaner disinfector prior to use. Contact CS Medical with any questions about the use of **TD-5**® high-level disinfectant or the **TD 100**® disinfector or **TEEClean**® cleaner disinfector

WARNING!



DO NOT ATTEMPT TO MANUALLY OPEN A SEALED CONTAINER OF **TD-5**® HIGH-LEVEL DISINFECTANT



DO NOT USE **TD-5**® HIGH-LEVEL DISINFECTANT AFTER THE EXPIRY DATE PRINTED ON CONTAINER LABEL



△ DO NOT SUBSTITUTE OTHER PRODUCTS FOR **TD-5**® HIGH-LEVEL DISINFECTANT.

△ DO NOT USE A LEAKING CONTAINER OF **TD-5**® HIGH-LEVEL DISINFECTANT.

 $oldsymbol{\Lambda}$ INSPECT THE **TD-5** $^{\circ}$ HIGH-LEVEL DISINFECTANT SHIPPING BOX AND CONTAINER.



DISPOSAL OF LEAKING TD-5® CONTAINER

One Bottle:

- 1. Put on personal protective equipment. This includes nitrile gloves, chemically resistant gown or apron, and chemical goggles.
- 2. Remove leaking bottle from box, sprinkle area with neutralizer (glycine (~10 g/l), or Glycinex[™] Neutralizer (~10 gr/liter), allowing 5 minutes contact for neutralization) and solidifier. Rinse under running cold water.
- 3. Fill sink with cold water, submerge bottle and pierce aluminum foil. By gently squeezing bottle under water, flush out all the disinfectant.
- 4. Drain sink, and thoroughly rinse sink and bottle.
- 5. Discard bottle following procedures for clean plastic/paper waste.

More Than One Bottle:

- 1. Increase ventilation use fans, open doors etc.
- 2. Put on personal protective equipment. This includes nitrile gloves, chemically resistant gown or apron, and a full-face respirator with organic vapor cartridges.
- 3. Remove boxes to large rinse area (floor drain or large sink). Liberally sprinkle neutralizer (glycine (~10 g/l), or Glycinex[™] Neutralizer (~10 gr/liter) and solidifier on any spilled disinfectant.
- 4. Rinse with at least 20 gallons of cold water (2-3 minutes of open faucet).
- 5. Fill sink with cold water.
- 6. Remove individual bottle, submerge bottle in water and pierce aluminum foil. By gently squeezing bottle under water, flush out all the disinfectant.
- 7. Drain sink and thoroughly rinse sink and bottle.
- 8. Place cap on empty bottle and discard bottle following procedures for clean plastic/paper waste.

In "No Water Available" Area:

- 1. Increase ventilation to area open truck doors or warehouse doors, use fans. Liberally sprinkle neutralizer (glycine (~10 g/l), or Glycinex[™] Neutralizer (~10 gr/liter) and solidifier over spill.
- 2. Put on personal protective equipment. This includes nitrile gloves, chemically resistant gown or apron, and a full-face respirator with organic vapor cartridges.
- Seal boxes with containers into plastic bag(s) and take to a water source. Then follow steps 4-8 above.

KEY FACTS/MODE OF ACTION

TD-5® high-level disinfectant solution is a slightly acid (pH 6.3) aqueous solution of glutaraldehyde which also contains a non-ionic surfactant, a silicone antifoam, and a corrosion inhibitor. Glutaraldehyde is the sole active ingredient (26.5g/l). Biocidal properties of glutaraldehyde solutions derive from the ability of the aldehyde groups to react with the amino groups of proteins. Like most aldehydes, glutaraldehyde monomers in aqueous solution are in equilibrium with various types of polymers, aldo-condensates and oxidized molecules. However, it is the monomer in glutaraldehyde, which is mainly responsible for any cidal action. Contrary to acid glutaraldehyde, alkaline solutions have a strong tendency to polymerize under the influence of heat or time. At equal concentration, the initial rate of kill is quicker for the alkaline glutaraldehyde. However, the drop in concentration is also faster.



INDICATIONS FOR USE

The **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector is designed to provide high-level disinfection of Transesophageal (TEE) probes. The system can use the **TD-5**[®] disinfectants, which are designed to be used only with the **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector. The disinfectant bottles cannot be reused in the system.

TD-5[®] disinfectant is intended for use as single use high-level disinfectants to be used exclusively in the **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector for the high-level disinfection of TEE ultrasound probes.

TD-5[®] high-level disinfectant and **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector is intended for use by qualified individuals trained in its use.

TD-5® disinfectant should be used with the following contact conditions in the **TD-100**® disinfector or TE**EClean**® cleaner disinfector:

High-level disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-5®	5 minutes	38° – 40°C	1.7% glutaraldehyde

Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of **TD-5**® high-level disinfectant.

Bacteria		Fungi	Viruses	
Spores	Vegetative Organisms		Non-enveloped	Enveloped
Bacillus subtilis	Staphylococcus	Trichophyton	Poliovirus Type 3	Respiratory
	aureus	mentagrophytes		Syncytial virus
Clostridium	Salmonella		Rhinovirus Type	Cytomegalovirus
sporogenes	choleraesuis		1A	
	Pseudomonas		Rotavirus Type	Influenza virus Type
	aeruginosa		WA	A (PR)
	Mycobacterium		Coxsackievirus B-	Herpes simplex,
	bovis		6	Types 1 and 2

Directions for Use

- 1. TEE probe preparation- Probes should be bedside cleaned and manually cleaned and dried using the recommendations of the TEE probe manufacturer prior to processing in the **TD 100**[®] disinfector or **TEEClean**[®] cleaner disinfector. Blood and other body fluids must be thoroughly cleaned from surfaces before introducing TEE Probe into the **TD 100**[®] disinfector or **TEEClean**[®] cleaner disinfector. Always follow the probe manufacturer's instructions.
- 2. Initiate **TD 100**[®] disinfector or **TEEClean**[®] cleaner disinfector sequence as described in the Operator and Installation Manual.
- 3. When the **TD 100**® disinfector or **TEEClean**® cleaner disinfector display indicates, load **TD-5**® bottle as follows: open the disinfectant door on the top of the disinfector. Remove the cap from the **TD-5**®



bottle exposing the inner aluminum foil seal. Check for any leakage from the bottle. Invert the TD-**5**[®] bottle and insert into the loading position. You will feel resistance as the piercer penetrates the foil seal. Push the bottle down and under the rear-positioning shelf. The disinfectant in the bottle will now drain into the reservoir. Retain the cap for use after the run is complete.

4. When run is complete, re-attached the cap and dispose of the capped bottle following procedures for clean plastic/paper waste.

Precautions

- 1. Wear appropriate person protective attire: This includes nitrile gloves, chemically resistant gown or apron, and chemical goggles. Wear protective attire for the entire procedure.
- 2. TEE Probes MUST BE THOROUGHLY CLEANED and dried prior to disinfection, since residual contamination will decrease effectiveness of the germicide.
- 3. The user MUST adhere to the Operator and Installation Manual procedures since any modification will affect the safety and effectiveness of the germicide.
- 4. Observe standard precautions for medical instruments or equipment that are soiled with blood and/or body fluids. Blood and other bodily fluids should be disposed of according to approved hospital procedures.
- 5. Observe universal precautions for medical instruments or equipment soiled with blood and/or body fluids.

WARNING!



riangle TD-5 $^{\circ}$ HIGH LEVEL DISINFECTANT IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS. HARMFUL IF SWALLOWED, SPLASHED ON SKIN OR IN EYES.



riangle KEEP OUT OF REACH OF CHILDREN

First aid measures

- 1. General information: Remove contaminated, saturated clothing immediately. In the case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
- 2. Following skin contact: Wash immediately with soap and water. In case of skin irritation, consult a physician.
- 3. Following eye contact: After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.
- 4. Following injestion: Do not induce vomiting. Rinse mouth followed by drinking a large quantity of water... Seek medical attention.
- 5. Self-protection of the first aider: First aider: pay attention to self-protection.
- 6. Most important symptoms: Development of grey skin lesions upon spill contact with skin.
- 7. Indictions of immediate medical attention: Provide first aid, decontaminate area. Seek medical attention if eye contact or injestion occurs. See a physician if skin or eye contact results in irritation.
- 8. Notes to physician: Probable damage to the mucosa from oral exposure may contraindicate the use of gastric lavage.

Classification

Health: Hazardous Flammability: None Reactivity: None Contact: Slight

Recommended safety equipment: safety goggles, lab coat and proper gloves

Storage: General storage



NFPA Ratings

Health = 2 Flammability = 0 Reactivity = 0



DANGER: Keep Out of Reach of Children, contains glutaraldehyde.

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately. Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Material Compatibility

<u>Metals</u>	Plastic & Elastomeric	
Stainless Steel 303	Buna	
Stainless Steel 304	Acetal	
Stainless Steel 316	PVC	
Brass	PVC Tubing	
	Viton – HK	
	Nylon	
	Santoprene	
	EPDM	
	CPVC	
	HDPE	
	Polycarbonate	
	Polysulfone	
	ABS	
	Polypropylene	
	LLDPE Tubing	
	PPS Composite	
	Kydex	

Materials were tested at 41±1°C for 420 hours (equivalent to approximately 5000 cycles).

GE, Philips and Siemens TEE probes are compatible with TD-5.

Material sample testing may not reflect compatibility of the germicide with finished medical devices. If questions arise regarding the compatibility of a device with TD-5, contact the device manufacturer.

Cleaning Agent Compatibility

TD-5® high-level disinfectant is compatible with enzymatic detergents (Wavizyme®/Medizime®LF), which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as cleaning agents since improper rinsing could affect the efficacy of **TD-5**® high-level disinfectant solution by altering its pH.

Contraindications

- 1. Use only in the **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector, which has a built-in vapor management system.
- 2. Do not use in any manual or automated disinfecting system for medical devices other than the **TD-100**[®] disinfector or **TEEClean**[®] cleaner disinfector.
- 3. Not for use as a hand rub or hand wash. Do not use as an antiseptic.
- 4. Do not use for a surface cleaning agent for counters and equipment.



Usage

TD-5® high-level disinfectant is only for use in the **TD-100**® disinfector or **TEEClean**® cleaner disinfector. **TD-5**® containers are designed for a single use; reuse is a violation of Federal Law. Please refer to the **TD 100**® or **TEEClean**® cleaner disinfector Operator and Installation Manual for further information. It is a violation of Federal Law to use this product in a manner inconsistent with labeling.

Storage Conditions and Expiration Date

Ready to use **TD-5**[®] high-level disinfectant solution should be stored in its original sealed container at a controlled room temperature of 15°C to 30°C (59°F to 86°F).

Post-Processing Handling and Storage of TEE Probes

Disinfected TEE probes are either to be immediately dried, used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the TEE probe manufacturer's labeling for additional storage and/or handling instructions.

Emergency and Technical Product Information

Emergency, safety, or technical information about **TD-5**® high-level disinfectant solution can be obtained from CS Medical at +1-919-255-9472, 1-877-255-9472 or CHEMTREC Emergency Phone (in US) 1-800-424-9300, Outside US +1-703-527-3887.

User Proficiency

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection of medical devices and the handling of toxic substances, such as liquid chemical germicides. Additional information about **TD-5**[®] high-level disinfectant solution can be obtained from CS Medical at +1-919-255-9472 or 1-877-255-9472.

Disposal Information

Residual solution may usually be flushed down the drain but local ordinances vary. Discard residual solution according to all local, state, and federal regulations. Do not reuse empty container. Rinse thoroughly with water and dispose of in trash.

How Supplied

Manufactured by: Description Case Containers CS Medical

2179 East Lyon Station Rd.

Creedmoor, NC 27522 USA 500 ml (16.9 oz) / bottle One case contains 32 bottles

Website: www.csmedicalllc.com

Technical email: service@csmedicalllc.com General information: sales@csmedicalllc.com

Phone: (877) 255-9472 Phone: +1 (919) 255-9472 Fax: +1 (919) 528-3400

CHEMTREC Emergency Phone (in US) 1-800-424-9300, Outside US +1-703-527-3887

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