CANDELA®

GentleCool Pro Plus™

Safety Data Sheet

Issue Date August 2023 Revision Date June 2025

SECTION 1: IDENTIFICATION

GHS product identifier — **GentleCool Pro Plus**

Other means of identification

Product Code(s) — **FIN101098**
FIN101099
FIN101100

Recommended use of the chemical and restrictions on use

Recommended Use — Refrigerant
Epidermal protection during dermatological or medical laser treatments

Uses advised against — Do not use near eyes

Manufacturer or Supplier's details

Candela Medical
251 Locke Drive
Massachusetts 01752
United States
TEL: +1-508-358-7400

24-Hour Emergency telephone number

CHEMTREC US 1-800-424-9300
INTERNATIONAL +1-703-527-3887

SECTION 2: HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the OSHA Hazard Communication Standard (29 CFR 1910.1200) as amended by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) 2012.

- Gas under pressure
- Liquefied gas
- Simple asphyxiant

GHS Label elements, including precautionary statements

Signal Word	**Warning**
Hazard Statements	H280 - Contains gas under pressure; may explode if heated. May displace oxygen and cause rapid suffocation.



Appearance	Colorless
Physical State	Liquefied gas
Odor	Slight, ether-like

Precautionary Statements

Prevention

- Use personal protective equipment as required.

Storage

- P403 – Store in a well-ventilated place
- P410 – Protect from sunlight

Hazard Not Otherwise Classified (HNOC)

Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP, IARC, or OSHA.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
trans-1,3,3,3-Tetrafluoroprop-1-ene	29118-24-9	100%

SECTION 4: FIRST AID MEASURES

Description of necessary first-aid measures	
General advice	First aider needs to protect himself. Move out of dangerous area. Keep warm and in a quiet place. Show this safety data sheet to the doctor in attendance. Take off all contaminated clothing immediately.
Inhalation	Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Use oxygen as required, provided a qualified operator is present. Call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. In case of frostbite water should be lukewarm, not hot. If symptoms persist, call a physician.
Skin Contact	Rapid evaporation of the liquid may cause frostbite. If there is evidence of frostbite, bathe (do not rub) with lukewarm (not hot) water. If water is not available, cover with a clean, soft cloth or similar covering. Call a physician if irritation develops or persists.
Ingestion	Unlikely route of exposure. As this product is a gas, refer to the inhalation section. Do not induce vomiting without medical advice. Call a physician immediately.
Notes to Physician	Indication of immediate medical attention and special treatment needed, if necessary treat frost-bitten areas as needed.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

- Water mist
- Dry powder
- Foam
- Carbon dioxide (CO2)

Specific Hazards During Firefighting

Contents under pressure.

Heating will cause pressure rise with risk of bursting.

Cool closed containers exposed to fire with water spray.

Product is not combustible under normal conditions.
However, this material can ignite when mixed with air under pressure and exposed to strong ignition sources.

Do not allow run-off from fire fighting to enter drains or water courses.

Vapours are heavier than air and can cause suffocation by reducing oxygen available for breathing.

Some risk may be expected of corrosive and toxic decomposition products.

Fire may cause evolution of:

- Hydrogen fluoride
- Carbon oxides
- Carbonyl halides
- Halogenated compounds

Special Protective Equipment for Firefighters

- In the event of fire and/or explosion do not breathe fumes.
- Wear self-contained breathing apparatus and protective suit.
- No unprotected exposed skin areas.
- Exposure to decomposition products may be a hazard to health.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Immediately evacuate personnel to safe areas.
Keep people away from and upwind of spill/leak.
Wear personal protective equipment.
Unprotected persons must be kept away.
Remove all sources of ignition.
Avoid skin contact with leaking liquid (danger of frostbite).
Ventilate the area.
After release, disperses into the air.
Vapours are heavier than air and can cause suffocation by reducing oxygen available for breathing.
Avoid accumulation of vapours in low areas.
Unprotected personnel should not return until air has been tested and determined safe.

Environmental Precautions	Prevent further leakage or spillage if safe to do so. The product evaporates readily. Prevent spreading over a wide area (e.g. by containment or oil barriers).
Methods and materials for containment and cleaning up	Do not direct water spray at the point of leakage. Allow to evaporate.

SECTION 7. HANDLING AND STORAGE

Handling

Precautions for safe handling

- Handle with care.
- Avoid inhalation of vapour or mist.
- Do not get in eyes, on skin, or on clothing.
- Wear personal protective equipment.
- Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C.
- Follow all standard safety precautions for handling and use of compressed gas cylinders.
- Use authorized cylinders only.
- Protect cylinders from physical damage.
- Do not puncture or drop cylinders, expose them to open flame or excessive heat.
- Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.
- Do not remove screw cap until immediately ready for use. Always replace cap after use.

Advice on protection against fire and explosion

- Do not spray on a naked flame or any incandescent material.
- Keep away from direct sunlight.
- Fire or intense heat may cause violent rupture of packages.
- Vapours may form explosive mixtures with air.
- The product is not easily combustible.

Storage

Conditions for safe storage including any incompatibilities

- Keep containers tightly closed in a cool, well-ventilated place.
- Keep away from direct sunlight.
- Protect cylinders from physical damage.
- Store away from incompatible substances.

Further information on storage conditions

- Keep only in the original container at temperature not exceeding 50°C

Advice on common storage

- Do not store together with oxidizing agents

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Protective measures
Do not breathe vapour.
Avoid contact with skin, eyes and clothing.
Ensure that eyewash stations and safety showers are close to the workstation location.

Engineering measures
Local exhaust

Eye protection
Goggles

Hand protection
Protective gloves

Skin and body protection
Impervious clothing
Wear cold insulating gloves/ face shield/ eye protection.

Respiratory protection
In case of insufficient ventilation wear suitable respiratory equipment.
Wear a positive-pressure supplied-air respirator.

Hygiene measures
Avoid breathing vapours, mist or gas.
Keep working clothes separately.

Exposure Guidelines

Components	CAS-No.	Value	Control Parameters	Update	Basis
trans-1,3,3,3-Tetrafluoroprop-1-ene	29118-24-9	TWA : Time weighted average	(800 ppm)	2012	WEEL:US. OARS. WEELs Workplace Environmental Exposure Level Guide, as amended
trans-1,3,3,3-Tetrafluoroprop-1-ene	29118-24-9	TWA : Time weighted average	(800 ppm)	31.03.11	Honeywell: Limit established by Honeywell International, Inc.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquified gas
Odor	Slight, ether-like
Appearance	Colorless
Odor Threshold	No data available

Property	
pH	Note: neutral
Boiling Point/Boiling Range	-19°C
Flash Point	Note: Not applicable
Evaporation rate	Note: No data available
Flammability (solid, gas)	does not ignite - Method: Flammability (gases)
Lower explosion limit	Note: No LEL and UEL was assigned at standard testing conditions, 20°C., Exhibits flame limits at temperatures in excess of 28°C.
Upper explosion limit	Note: No LEL and UEL was assigned at standard testing conditions, 20°C., Exhibits flame limits at temperatures in excess of 28°C.
Vapor Pressure	4,271 hPa at 20°C(68°F) 11,152 hPa at 54.4°C(129.9°F)
Vapor Density	4 Note: (Air = 1.0)
Density	1.17 g/cm3 at 21.1°C
Water Solubility	0.373 g/l
Partition coefficient: n-octanol/water	log Pow: 1.6
Ignition Temperature	368°C - Method: Auto-ignition temperature
Viscosity, dynamic	Note: No data available
Viscosity, kinematic	Note: No data available
Oxidizing Properties	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	Not classified as a reactivity hazard.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Can form a combustible mixture with air at pressures above atmospheric pressure. Do not mix with oxygen or air above atmospheric pressure.

Incompatible materials	Reactions with alkali metals.
Hazardous decomposition products	Halogenated compounds Carbon oxides Hydrogen fluoride Carbonyl halides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	Note: Not applicable study technically not feasible
Acute inhalation toxicity	Species: Mouse Note: Acute (4-Hour) Inhalation Toxicity Screening Study (mouse): No lethality at >100,000 ppm. Species: Rat LC50: > 207000 ppm Exposure time: 4 h
Acute dermal toxicity	Note: No data available study technically not feasible
Skin irritation	Species: Rabbit Result: No skin irritation Method: OECD Test Guideline 404
Eye irritation	Note: No data available study technically not feasible
Sensitization	Species: dogs Cardiac sensitization Result: Did not cause sensitization on laboratory animals. Species: human Result: Does not cause skin sensitization.
Repeated dose toxicity	Species: Rat Application Route: Inhalation Exposure time: 13 Weeks Note: Causes mild effects on the heart. NOEL 5,000 ppm
Genotoxicity in vitro	Cell type: Human lymphocytes Test Method: Chromosome aberration test in vitro Result: negative Method: OECD Test Guideline 473 Test Method: Ames test Result: negative

Genotoxicity in vivo	Species: Mouse Test Method: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Cell type: Micronucleus Application Route: Inhalation Method: OECD Test Guideline 474 Result: negative
Reproductive toxicity	Species: Rat Test Method: Two-generation study Application Route: Inhalation NOEL: > 20,000 ppm NOEL: > 20,000 ppm Method: OECD Test Guideline 416
Teratogenicity	Species: Rabbit Method: OECD 416 Note: Did not show teratogenic effects in animal experiments. Species: Rat Method: OECD 416 Note: Did not show teratogenic effects in animal experiments.
Teratogenicity	Species: Rat Application Route: Inhalation NOAEC: 15,000 ppm Method: OECD Test Guideline 414
Further information	Note: Excessive exposure may cause central nervous system effects including drowsiness and dizziness. Excessive exposure may also cause cardiac arrhythmia. Rapid evaporation of the liquid may cause frostbite.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Toxicity to fish	Species: Cyprinus carpio (Carp) static test LC0: > 117 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	Species: Daphnia magna (Water flea) static test EC50: > 160 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

Toxicity to algae	Species: Algae Growth rate NOEC: > 170 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Biomass Species: Algae NOEC: > 170 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Elimination information (persistence and degradability)

Bioaccumulation	Note: No bioaccumulation is to be expected (log Pow ≤4).
Biodegradability	aerobic Result: Not readily biodegradable.

Further information on ecology

Additional ecological Information	No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal Methods	Observe all Federal, State, and Local Environmental regulations.

SECTION 14. TRANSPORT INFORMATION

DOT

UN/ID No.	UN 3163
Proper shipping name	LIQUEFIED GAS, N.O.S. (trans-1,3,3,3-Tetrafluoroprop-1-ene)
Class	2.2
Packing group	
Hazard Labels	2.2

IATA

UN/ID No.	UN 3163
Description of the goods	LIQUEFIED GAS, N.O.S. (trans-1,3,3,3-Tetrafluoroprop-1-ene)
Class	2.2
Hazard Labels	2.2
Packing instruction (cargo aircraft)	200
Packing instruction (passenger aircraft)	200

IMDG

UN/ID No.	UN 3163
Description of the goods	LIQUEFIED GAS, N.O.S. (trans-1,3,3,3-Tetrafluoroprop-1-ene)
Class	2.2
Hazard Labels	2.2
EmS Number	F-C, S-V
Marine pollutant	NO

SECTION 15. REGULATORY INFORMATION

Inventories

US. Toxic Substances Control Act	On TSCA Inventory
Australia. Industrial Chemical (Notification and Assessment) Act	On the inventory, or in compliance with the inventory
Canada. Canadian Environmental Protection Act (CEPA). Domestic Substances List (DSL)	All components of this product are on the Canadian DSL
Japan. Kashin-Hou Law List	On the inventory, or in compliance with the inventory
Korea. Existing Chemicals Inventory (KECI)	On the inventory, or in compliance with the inventory
Philippines. Inventory of Chemicals and Chemical Substances (PICCS)	Not in compliance with the inventory
China. Inventory of Existing Chemical Substances (IECSC)	On the inventory, or in compliance with the inventory
New Zealand. Inventory of Chemicals (NZIoC), as published by ERMA New Zealand	On the inventory, or in compliance with the inventory

National regulatory information

SARA 302 Components	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SARA 311/312 Hazards	Acute Health Hazard Sudden Release of Pressure Hazard
California Prop. 65	This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

NFPA

Health Hazard	**1**
Flammability	**1**
Physical Hazard	**0**
Instability	**-**

HMIS III

Health Hazard	**2**
Flammability	**1**
Physical Hazard	**-**
Instability	**0**

Hazard rating and rating systems (e.g. HMIS® III, NFPA): This information is intended solely for the use of individuals trained in the particular system.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. Final determination of suitability of any material is the sole responsibility of the user. This information should not constitute a guarantee for any specific product properties.

End of Safety Data Sheet

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