



SAFETY DATA SHEET

HISTOFREEZER® CRYOSURGICAL SYSTEM

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: HISTOFREEZER® PORTABLE CRYOSURGICAL SYSTEM

PRODUCT USE: Cryosurgical treatment

GENERIC NAME: Mixture of propane, (Iso, n-) butane and dimethyl ether (DME)

MANUFACTURER

OraSure Technologies, Inc.
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Bethlehem, PA 18015
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EMERGENCY CONTACT INFORMATION

INFOTRAC US & CANADA: 1-800-535-5053
INFOTRAC INTERNATIONAL: +1-352-323-3500

COMMENTS: To the best of our knowledge, this Safety Data Sheet conforms to the requirements of the US OSHA 29 CFR 1910.1200, Regulation EC 1907/2006 and Canadian Hazardous Products Act.

2. HAZARD IDENTIFICATION

GHS Classification

Flammable Aerosol (Category 1)

GHS Label:

Signal Word	Danger
Pictogram	
Hazard Statements:	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
Precautionary Statements:	P210: Keep away from heat, sparks, open flames, hot surfaces. No smoking. P211 Do not spray on open flame or other ignition source. P251: Do not pierce or burn, even after use. P410 + P412: Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

POTENTIAL HEALTH EFFECTS:

SKIN: May burn skin or cause irreversible damage if contact is made with chemicals.

EYES: May burn skin or cause irreversible damage if contact is made with chemicals.

INGESTION: May burn or cause irreversible damage if chemical is ingested.

INHALATION: Dizziness and/or headaches.

COMMENTS: For additional toxicological information see section 11.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	WT. %	EINECS nr.	CAS Number	EC Classification
Dimethyl ether (DME)	95	204-065-8	115-10-6	F+, R12
Propane	2	200-827-9	74-98-6	F+, R12
Isobutane / n-butane	3	200-857-2 / 703-448-7	75-28-5 / 106-97-8	F+, R12

4. FIRST AID MEASURES

EYES: Flush with water for 15 minutes, consult a Doctor.

INGESTION: Not Applicable.

SKIN: Flush with water for 15 minutes, consult a Doctor.

INHALATION: Remove from further exposure, move into fresh air and rest.

5. FIRE FIGHTING MEASURE

FLAMMABLE LIMITS:

LEL: dimethyl ether 3.4/ propane 2.1/ (Iso, n-) butane 1.8

UEL: dimethyl ether 18.0/ propane 9.5/ (Iso, n-) butane e 8.4

FLAMMABLE CLASS: 1A

AUTO-IGNITION TEMPERATURE: 350°C (622°F) (DME)

GENERAL HAZARD: Extremely flammable.

EXTINGUISHING AGENT: CO₂, Dry Chemical, Water Fog

FIRE FIGHTING EQUIPMENT: Respiratory and eye protection are required for fire fighting personnel. Full protective equipment (bunker gear) and SCBA should be used for all indoor fires and any significant outdoor fires. For small outdoor fires, which can easily be extinguished with a portable fire extinguisher, use of SCBA may not be required.

SENSITIVE TO STATIC DISCHARGE: Yes, avoid static discharge and strong oxidizing agents.

WHMIS FLAMMABILITY CLASSIFICATION: Class B, Division 5: flammable aerosol.

COMMENTS: Product is highly flammable. The container may explode if exposed to temperatures higher than 50°C (122°F).

6. ACCIDENTAL RELEASE MEASURES

SMALL SPILL/ LEAK: Apply the appropriate personal protective equipment, move leaking container to a vent hood or well ventilated controlled area and allow pressure to dissipate. Once product has stop leaking, carefully check for residual product and dispose of as per section 13.

LARGE SPILL/ LEAK: Large spills or leaks are not anticipated; product is manufactured in 80ml containers.

GENERAL PROCEDURES: Remove container to well ventilated area.

RELEASE NOTES: If spill could potentially enter waterway, including intermittent dry creeks, contact the local authorities.

If in the U.S., contact US COAST GUARD NATIONAL RESPONSE CENTER toll free number 800-424-8802.

In case of accidental or road spill notify INFOTRAC in the USA 800-535-5053, CANUTEC in Canada at 613-996-6666, other countries, at (international code) +1-352-323-3500.

COMMENTS: See Section 13 for disposal information and Section 15 for regulatory requirements. Large and small spills may have a broad definition depending on the user's handling system. Therefore, the spill category must be defined at the point of release by technically qualified personnel.

7. HANDLING AND STORAGE

HANDLING: This product is considered safe under normal and anticipated handling conditions of temperatures and pressure. Avoid static discharge and strong oxidizing agents. No special equipment required for handling. Handle in well ventilated area.

STORAGE: Store canister in a cool, dry, well ventilated location. Do not expose to direct sunlight or temperatures above 50°C (122°F) or store near heat or open flame. Avoid static discharge and strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Name	CAS #	TLV (Units)
DME	115-10-6	Mac 100ppm, LC50; 386ppm (inhalation, mouse, 15 min), LC50; 308000 mg/m ³ (inhalation, rat) AIPH-PEL 1000ppm (TWA)
Propane	74-98-6	MAC>600ppm; OSHA PEL 1000ppm (1800 mg/m ³)(TWA), ACGIH-TWA; 2500ppm
Isobutane / n-butane	75-28-5 / 106-97-8	LC50; 57pph (inhalation, rat, 15 min) NIOSH-REL; 800ppm (1900 mg/m ³)(TWA)

ENGINEERING CONTROLS: Provide adequate ventilation for continuous use.

PERSONAL PROTECTIVE EQUIPMENT: Not normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Liquid under pressure

pH: N/A

VAPOR DENSITY: >1

BOILING POINT: DME -25°C/ propane -41°C/ isobutene -12°C

FLASHPOINT AND METHOD: DME -41°C (TOC)

SPECIFIC GRAVITY (WATER=1): 0.625

% VOLATILE BY VOLUME: 100%

COMMENT: The above physical data are only approximate and do not represent specification values. They should only be utilized in the context of this safety data sheet.

10. STABILITY AND REACTIVITY

STABLE: This material is considered stable under normal and anticipated storage and handling conditions of temperature and pressure. Hazardous polymerization will not occur. Avoid storage in hot, unventilated areas. Protect from light; do not expose to temperatures higher than 50°C (122°F).

STABILITY: This product is considered stable under normal and anticipated handling conditions of temperatures and pressure. No special equipment required for handling. Handle in well ventilated area.

CONDITIONS TO AVOID: Avoid storage in hot, unventilated areas. Avoid static discharge and incompatibilities.

INCOMPATIBLE MATERIALS: May highly react with oxidizing agents.

11. TOXICOLOGICAL INFORMATION

ACUTE: Contact with the eyes or skin can cause frostbite. Inhalation of vapors may cause irritation of the respiratory tract, dizziness and headache.

CHRONIC: No information available.

SKIN EFFECTS: Frostbite/ burn.

EYES EFFECTS: Frostbite/ burn

CARCINOGENICITY: Not considered carcinogenic
Not listed by NTP, IARC or OSHA.

12. ECOLOGICAL INFORMATION

There is no data available on the preparation itself.

13. DISPOSAL CONSIDERATION

DISPOSAL METHOD: Dispose of in accordance with Local, State/ Provincial and Federal Regulations.

GENERAL COMMENTS: Do not puncture or incinerate containers after use even when empty. Dispose of in accordance with Local, State/ Provincial and Federal Regulations. Recycle where appropriate.

14. TRANSPORTATION INFORMATION

U.S. DOT (DEPARTMENT OF TRANSPORTATION)



PROPER SHIPPING NAME:

Limited Quantity

TECHICAL NAME:

N/A

PRIMARY HAZARD CLASS/DIVISION:

N/A

UN/NA NUMBER:

N/A

PACKING GROUP:

N/A

LABEL:

Limited Quantity

AIR (ICAO/IATA)



PROPER SHIPPING NAME:

Consumer Commodity

TECHICAL NAME:

N/A

PRIMARY HAZARD CLASS/DIVISION:

9

UN or ID NUMBER:

ID8000

PACKING GROUP:

None



CANADA TRANSPORT OF DANGEROUS GOODS & VESSEL SHIPMENTS:



PROPER SHIPPING NAME:

Aerosols, Flammable

TECHICAL NAME:

(Dimethyl ether, Propane)

PRIMARY HAZARD CLASS/DIVISION:

2.1

UN/NA NUMBER:

UN1950

NAERG:

126

LABEL:

Flammable Gas, 2, Limited Quantity



EUROPEAN SHIPPING NAME:



PROPER SHIPPING NAME: LAND/SEA: Aerosols,
AIR: Aerosols, Flammable
TECHNICAL NAME: Dimethyl ether, Propane
UN NUMBER: UN1950
PRIMARY HAZARD CLASS: AIR/SEA: 2.1,
LAND: 2, f5



COMMENTS: Avoid shipping in hot, unventilated areas; avoid static discharge and strong oxidizing agents.

15. REGULATORY INFORMATION

CANADIAN COMMUNITY: WHMIS SYMBOLS AND CLASSIFICATIONS

Class A:
(Compressed Gas)

Class B5:
(Flammable Aerosol)

Class D1A:
(Toxic-Immediate and Serious Effect)



EUROPEAN COMMUNITY: EEC LABEL SYMBOL AND CLASSIFICATION

Extremely Flammable



16. OTHER INFORMATION

The information contained herein is accurate to the best of our knowledge. OraSure Technologies Inc. makes no warranty of any kind, expressed or implied, concerning the safe use of this material in the process or in combination with other substances.

SUMMARY OF CHANGES:

- 3/28/2011; Information update and reformatted to comply with the Globally Harmonized System.
- 3/1/2012: Updated Flammable symbol to new standardized symbol.
- 8/21/2013: Updated to include GHS classification and elements.

SUMMARY OF CHANGES: 01/31/14, Removing the Expiration Date.

2/23/15, Added limited quantity labels to section 14, updated Canadian classification from liquefied gas to aerosols, remove risk phases.