

**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, isobutene and dimethyl ether (DME)

**MANUFACTURER**

 OraSure Technologies, Inc.  
 220 East First Street  
 Bethlehem, PA 18015  
 Phone: 800-869-3538  
 www.orasure.com

**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:**

<b>Signal Word</b>	Danger
<b>Pictogram</b>	
<b>Hazard Statements:</b>	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
<b>Precautionary Statements:</b>	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	3	200-857-2	75-28-5	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/ isobutene 1.8

**UEL:** dimethyl ether 18.0/ propane 9.5/ isobutene 8.4

**FLAMMABLE CLASS:** 1A

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

**GENERAL HAZARD:** Extremely flammable.

**EXTINGUISHING AGENT:** CO<sub>2</sub>, 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 <sup>3</sup> (inhalation, rat) AIPH-PEL 1000ppm (twa)
Propane	74-98-6	MAC>600ppm; OSHA PEL 1000ppm (1800 mg/m <sup>3</sup> )(TWA), ACGIH-TWA; 2500ppm
Isobutane	75-28-5	LC50; 57pph (inhalation, rat, 15 min) NIOSH-REL; 800ppm (1900 mg/m <sup>3</sup> )(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)



<b>PROPER SHIPPING NAME:</b>	Consumer Commodity
<b>TECHICAL NAME:</b>	N/A
<b>PRIMARY HAZARD CLASS/DIVISION:</b>	N/A
<b>UN/NA NUMBER:</b>	N/A
<b>PACKING GROUP:</b>	N/A
<b>LABEL:</b>	ORM-D/ Packages comply

### AIR (ICAO/IATA)



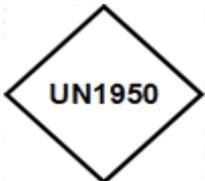
<b>PROPER SHIPPING NAME:</b>	Consumer Commodity
<b>TECHICAL NAME:</b>	N/A
<b>PRIMARY HAZARD CLASS/DIVISION:</b>	9
<b>UN or ID NUMBER:</b>	ID8000
<b>PACKING GROUP:</b>	None

### CANADA TRANSPORT OF DANGEROUS GOODS & VESSEL SHIPMENTS:



<b>PROPER SHIPPING NAME:</b>	Liquefied Gas, Flammable, N.O.S.
<b>TECHICAL NAME:</b>	(Dimethyl ether, Propane)
<b>PRIMARY HAZARD CLASS/DIVISION:</b>	Flammable Gas II
<b>UN/NA NUMBER:</b>	UN3161
<b>NAERG:</b>	115
<b>LABEL:</b>	Flammable Gas, 2

### EUROPEAN SHIPPING NAME:



<b>PROPER SHIPPING NAME: LAND/SEA:</b>	Aerosols,
<b>AIR:</b>	Aerosols, Flammable
<b>TECHICAL NAME:</b>	Dimethyl ether, Propane
<b>UN NUMBER:</b>	UN1950
<b>PRIMARY HAZARD CLASS: AIR/SEA:</b>	2.1,
<b>LAND:</b>	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**



**RISK PHASES (European Union)**

CODE	PHASE
12	Extremely Flammable.

**SAFETY PHASES (European Union)**

CODE	PHASE
2	Keep out of reach from children.
9	Keep container in a well-ventilated place.
16	Keep away from sources of ignition, No smoking.
23	Do not breathe spray.
33	Take precautionary measures against static discharge.

**OTHER:**

PHASES: Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C (122°F). Do not pierce or burn even after use. Do not spray on a naked flame or any incandescent material.

**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.