

Histofreezer® Portable Cryosurgical System

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).
Publication Date: 06/10/20 020MS-NA+Mex-ENG Revision 2

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Histofreezer® Portable Cryosurgical System

Synonyms: mixture of propane, (iso, n-) butane and dimethyl ether (DME)

Intended Use of the Product

Cryosurgical treatment

Name, Address, and Telephone of the Responsible Party

Company

CryoConcepts, LP

205 Webster Street

Bethlehem, PA 18015

Phone: 855-355-2796

www.cryoconcepts.com

Emergency Telephone Number

Emergency Number : INFOTRAC USA: +1-800-535-5053

INFOTRAC INTERNATIONAL: +1-352-323-3500

CANUTEC: 613-996-6666

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS-US/CA Classification

Simple Asphy

Flam. Aerosol 1 H222

Liquefied gas H280

Full text of hazard classes and H-statements: see section 16

Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H222 - Extremely flammable aerosol.

H280 - Contains gas under pressure; may explode if heated.

May displace oxygen and cause rapid suffocation.

Precautionary Statements (GHS-US/CA)

: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P211 - Do not spray on an open flame or other ignition source.

P251 - Do not pierce or burn, even after use.

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

P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

Additional Information

Product is regulated as a medical device and is exempt from the labelling provisions of GHS according to the OSHA Hazard Communication Standard (HCS) and Canadian Hazardous Products Regulations.

Other Hazards

Contact with gas escaping the container can cause frostbite. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Unknown Acute Toxicity Not available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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Mixture

Name	Product Identifier	% *	GHS Ingredient Classification
Dimethyl ether	(CAS No) 115-10-6	95	Simple Asphy Flam. Gas 1, H220 Liquefied gas, H280
Isobutane	(CAS No) 75-28-5	<= 3	Simple Asphy Flam. Gas 1, H220 Liquefied gas, H280
Propane	(CAS No) 74-98-6	2	Simple Asphy Flam. Gas 1, H220 Compressed gas, H280

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If frostbite or unintentional freezing occurs, immediately flush with plenty of lukewarm water to GENTLY warm the affected area. Do not use hot water. Do not rub affected area. Get immediate medical attention.

Inhalation: If a large amount is released, first take proper precautions to ensure your own safety before attempting rescue (e.g. wear appropriate respiratory protective equipment, use the buddy system), then remove the exposed person to fresh air. Keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

Skin Contact: In case of unintentional skin contact, thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: May cause frostbite if there is unintentional contact with the liquid. Asphyxia by lack of oxygen: risk of death with elevated concentrations.

Inhalation: In elevated concentrations may cause asphyxiation, central nervous system effects, and increased breathing rate. Symptoms of asphyxiation include headache, dizziness, rapid breathing, increased pulse, mood changes, tremors, cyanosis, muscular weakness, narcosis, numbness of the extremities, unconsciousness and death.

Skin Contact: Unintentional contact with gas/liquid escaping the container can cause frostbite and freeze burns.

Eye Contact: Contact with gas/liquid escaping the container can cause frostbite, freeze burns, and permanent eye damage or blindness.

Ingestion: Not considered a potential route of exposure, but contact with gas/liquid escaping the container can cause freeze burns and frostbite.

Chronic Symptoms: None expected under normal conditions of use.

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 5: FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, dry chemical, or sand.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Flammable aerosol.

Explosion Hazard: Heat may build pressure, rupturing closed containers, spreading fire and increasing risk of burns and injuries. Containers may explode in heat of fire.

Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion when present in large quantities.

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Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. In case of large fire with mass quantities: DO NOT fight fire when fire reaches containers. Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not get in eyes or on clothing. Do not breathe gas.

For Non-Emergency Personnel

Protective Equipment: Use of personal protective equipment (PPE) is not generally required but should be evaluated based on conditions of accidental release.

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so.

For Emergency Personnel

Protective Equipment: Use of personal protective equipment (PPE) is not generally required but should be evaluated based on conditions of accidental release.

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

Environmental Precautions

Prevent entry to sewers and public waters. 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.

Methods and Materials for Containment and Cleaning Up

For Containment: Stop leak, if possible without risk. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up: If a large amount is released: Stop the source of the release, if safe to do so. Consider the use of water spray to disperse vapors. Isolate the area until gas has dispersed. Ventilate and gas test area before entering. Contact competent authorities after a spill.

Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations. 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.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Additional Hazards When Processed: Asphyxiating gas at high concentrations. Pressurized container: may burst if heated. Do not pierce or burn, even after use. Do not pressurize, cut, or weld containers. Ruptured cylinders may rocket.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Do not spray on an open flame or other ignition source. Do not breathe gas.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high temperatures and incompatible materials. Keep only in the original container in a cool, well ventilated place away from ignition sources. Protect from sunlight. Do not expose to temperatures exceeding 50°C/ 122°F.

Incompatible Materials: Strong oxidizers. Metal hydrides.

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Specific End Use(s)

Cryosurgical treatment

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

Dimethyl ether (115-10-6)		
USA AIHA	WEEL TWA (ppm)	1000 ppm
British Colombia	OEL TWA (ppm)	1000 ppm
Propane (74-98-6)		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1800 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1800 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	2100 ppm (10% LEL)
Alberta	OEL TWA (ppm)	1000 ppm
British Colombia	OEL TWA (ppm)	1000 ppm
Northwest Territories	OEL STEL (ppm)	1250 ppm
Northwest Territories	OEL TWA (ppm)	1000 ppm
Québec	VEMP (mg/m ³)	1800 mg/m ³
Québec	VEMP (ppm)	1000 ppm
Saskatchewan	OEL STEL (ppm)	1250 ppm
Saskatchewan	OEL TWA (ppm)	1000 ppm
Isobutane (75-28-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	800 ppm
Manitoba	OEL STEL (ppm)	1000 ppm
Newfoundland & Labrador	OEL STEL (ppm)	1000 ppm
Nova Scotia	OEL STEL (ppm)	1000 ppm
Northwest Territories	OEL STEL (ppm)	1250 ppm
Northwest Territories	OEL TWA (ppm)	1000 ppm
Ontario	OEL STEL (ppm)	1000 ppm
Ontario	OEL TWA (ppm)	800 ppm
Prince Edward Island	OEL STEL (ppm)	1000 ppm
Saskatchewan	OEL STEL (ppm)	1250 ppm
Saskatchewan	OEL TWA (ppm)	1000 ppm

Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when flammable gases or vapors may be released and may exceed exposure limits. Oxygen detectors should be used when asphyxiating gases may be released in large quantities.

Personal Protective Equipment: Not generally required. The use of the following personal protective equipment may be necessary when handling bulk quantities: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.

Materials for Protective Clothing: Chemically resistant materials and fabrics. Wear fire/flame resistant/retardant clothing.

Hand Protection: If material is cold, wear thermally resistant protective gloves.

Eye Protection: Chemical safety goggles.

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Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use a NIOSH-approved self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Thermal Hazard Protection: Wear thermally resistant protective clothing.

Other Information: When using, do not eat, drink or smoke

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Gas
Appearance	: Not available
Odor	: Not available
Odor Threshold	: Not available
pH	: Not available
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: -25 °C DME; -41 °C (-42 °F) propane; -12 °C (10 °F) isobutane (-13 °F)
Flash Point	: -41 °C DME (TOC) (-41.8 °F)
Auto-ignition Temperature	: 350 °C DME (662 °F)
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: 3.4 % DME; 2.1% propane; 1.8% butane
Upper Flammable Limit	: 18 % DME; 9.5% propane; 8.4% butane
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: > 1 (air = 1)
Specific Gravity	: 0.625
Solubility	: Not available
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available
Explosive Properties	: Contains gas under pressure; may explode if heated

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion.

Chemical Stability: Flammable aerosol. Pressurized container: may burst if heated. Contains gas under pressure; may explode if heated.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Direct sunlight, extremely high temperatures, heat, hot surfaces, sparks, open flames, incompatible materials, and other ignition sources.

Incompatible Materials: Strong oxidizers. Metal hydrides.

Hazardous Decomposition Products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

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Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: In elevated concentrations may cause asphyxiation, central nervous system effects, and increased breathing rate. Symptoms of asphyxiation include headache, dizziness, rapid breathing, increased pulse, mood changes, tremors, cyanosis, muscular weakness, narcosis, numbness of the extremities, unconsciousness and death.

Symptoms/Injuries After Skin Contact: Unintentional contact with gas/liquid escaping the container can cause frostbite and freeze burns.

Symptoms/Injuries After Eye Contact: Contact with gas/liquid escaping the container can cause frostbite, freeze burns, and permanent eye damage or blindness.

Symptoms/Injuries After Ingestion: Not considered a potential route of exposure, but contact with gas/liquid escaping the container can cause freeze burns and frostbite.

Chronic Symptoms: None expected under normal conditions of use.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Dimethyl ether (115-10-6)	
LC50 Inhalation Rat	308.5 mg/l/4h
Propane (74-98-6)	
LC50 Inhalation Rat	658 mg/l/4h
Isobutane (75-28-5)	
LC50 Inhalation Rat	658 mg/l/4h
LC50 Inhalation Rat	11000 ppm

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Not classified.

Persistence and Degradability

Cryosurgical System	
Persistence and Degradability	Not established.

Bioaccumulative Potential

Cryosurgical System	
Bioaccumulative Potential	Not established.

Dimethyl ether (115-10-6)	
Log Pow	-0.18

Propane (74-98-6)	
Log Pow	2.3

Isobutane (75-28-5)	
BCF Fish 1	1.57 - 1.97
Log Pow	2.88 (at 20 °C)

Mobility in Soil Not available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations. Do not pierce or burn, even after use.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions. Empty gas cylinders should be returned to the vendor for recycling or refilling. Do not puncture or incinerate container.

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Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

In Accordance with DOT

Proper Shipping Name : LIQUEFIED GAS, FLAMMABLE, N.O.S. (Contains dimethyl ether, isobutane)
Hazard Class : 2.1
Identification Number : UN3161
Label Codes : 2.1
ERG Number : 115



Limited quantities:



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

In Accordance with IMDG

Proper Shipping Name : AEROSOLS
Hazard Class : 2.1
Identification Number : UN1950
Label Codes : 2.1
EmS-No. (Fire) : F-D
EmS-No. (Spillage) : S-U



Limited quantities:



PROPER SHIPPING NAME:	Aerosols
TECHNICAL NAME:	Dimethyl ether, Propane
UN NUMBER:	UN1950
PRIMARY HAZARD CLASS:	2.1



In Accordance with IATA

Proper Shipping Name : AEROSOLS, FLAMMABLE
Hazard Class : 2.1
Identification Number : UN1950
Label Codes : 2.1
ERG Code (IATA) : 10L

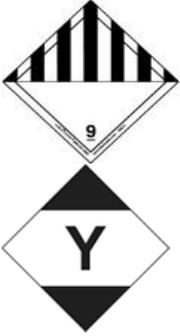


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Limited quantities:



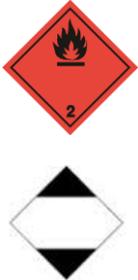
PROPER SHIPPING NAME:	Consumer Commodity
TECHICAL NAME:	N/A
PRIMARY HAZARD CLASS/DIVISION:	9
UN or ID NUMBER:	ID8000
PACKING GROUP:	None

In Accordance with TDG

Proper Shipping Name	: AEROSOLS flammable
Hazard Class	: 2.1
Identification Number	: UN1950
Label Codes	: 2.1



Limited quantities:



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

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

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

Histofreezer® Portable Cryosurgical System	
SARA Section 311/312 Hazard Classes	Fire hazard Sudden release of pressure hazard Immediate (acute) health hazard
Dimethyl ether (115-10-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Propane (74-98-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Isobutane (75-28-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

US State Regulations

Dimethyl ether (115-10-6)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List
Propane (74-98-6)
U.S. - Massachusetts - Right To Know List

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U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Isobutane (75-28-5)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Canadian Regulations

Dimethyl ether (115-10-6)

Listed on the Canadian DSL (Domestic Substances List)

Propane (74-98-6)

Listed on the Canadian DSL (Domestic Substances List)

Isobutane (75-28-5)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Indication of Changes:

01/10/17 - New SDS specific for USA, Canada, Mexico.

Revision Date : 01/10/17

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR).

GHS Full Text Phrases:

Compressed gas	Gases under pressure Compressed gas
Flam. Aerosol 1	Flammable aerosol Category 1
Flam. Gas 1	Flammable gases Category 1
Liquefied gas	Gases under pressure Liquefied gas
Simple Asphy	May displace oxygen and cause rapid suffocation
H220	Extremely flammable gas
H222	Extremely flammable aerosol
H280	Contains gas under pressure; may explode if heated

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS