

Histofreezer® Portable Cryosurgical System

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 10/01/17

Date of issue: 10/01/17

Item 19301-EU-ENG

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product Name : Histofreezer® Portable Cryosurgical System
Synonyms : mixture of propane, (iso, n-) butane and dimethyl ether (DME)

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Cryosurgical treatment

NOTE: This product is a medical device that meets the exemption specified under Article 2 (6)(c) of Regulation (EC) No. 1907/2006 (REACH). As a result, an SDS is not legally required to be made available for this product. However, this SDS is being provided for informational purposes only.

1.2.2. Uses advised against

No additional information available.

1.3. Details of the supplier of the safety data sheet

Company

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

1.4. Emergency telephone number

Emergency number : INFOTRAC INTERNATIONAL: +1-352-323-3500
Other Emergency numbers : Call your local emergency center

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Aerosol 1 H222;H229

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Danger

Hazard statements (CLP) : H222 - Extremely flammable aerosol
H229 - Pressurised container: May burst if heated

Precautionary statements (CLP) : 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+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

2.3. Other hazards

Other hazards not contributing to the classification : Asphyxiant gas, can be fatal in elevated concentrations. May cause damage to the blood, central nervous system, and cardiovascular system. High concentrations of gas can cause unconsciousness and death. Being under the influence of alcohol may enhance the effects of this product. Contact with gas escaping the container can cause frostbite. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dimethyl ether	(CAS No) 115-10-6 (EC no) 204-065-8 (EC index no) 603-019-00-8	95	Flam. Gas 1, H220 Liquefied gas, H280
Isobutane	(CAS No) 75-28-5 (EC no) 200-857-2 (EC index no) 601-004-00-0	<= 3	Flam. Gas 1, H220 Liquefied gas, H280
Propane	(CAS No) 74-98-6 (EC no) 200-827-9 (EC index no) 601-003-00-5	2	Flam. Gas 1, H220 Liquefied gas, H280

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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.
First-aid measures after 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.
First-aid measures after skin contact	: In case of unintentional skin contact, thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.
First-aid measures after 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.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

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

4.3. 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: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray, fog, carbon dioxide (CO ₂), 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.

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5.2. 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.
- Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂).

5.3. 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.

SECTION 6: Accidental release measures

6.1. 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.
- 6.1.1. 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.
- 6.1.2. For emergency responders**
 - 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.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material 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.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Asphyxiating gas at high concentrations. Pressurised 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.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Comply with applicable regulations.

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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 products : Strong oxidizers. Metal hydrides.

7.3. Specific end use(s)

Cryosurgical treatment

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Dimethyl ether (115-10-6)		
EU	IOELV TWA (mg/m ³)	1920 mg/m ³
EU	IOELV TWA (ppm)	1000 ppm
Austria	MAK (mg/m ³)	1910 mg/m ³
Austria	MAK (ppm)	1000 ppm
Austria	MAK Short time value (mg/m ³)	3820 mg/m ³
Austria	MAK Short time value (ppm)	2000 ppm
Belgium	Limit value (mg/m ³)	1920 mg/m ³
Belgium	Limit value (ppm)	1000 ppm
Bulgaria	OEL TWA (mg/m ³)	1920 mg/m ³
Bulgaria	OEL TWA (ppm)	1000 ppm
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	1920 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (ppm)	1000 ppm
Cyprus	OEL TWA (mg/m ³)	1920 mg/m ³
Cyprus	OEL TWA (ppm)	1000 ppm
France	VME (mg/m ³)	1920 mg/m ³ (indicative limit)
France	VME (ppm)	1000 ppm (indicative limit)
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	1900 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (ppm)	1000 ppm
Gibraltar	OEL TWA (mg/m ³)	1920 mg/m ³
Gibraltar	OEL TWA (ppm)	1000 ppm
Greece	OEL TWA (mg/m ³)	1920 mg/m ³
Greece	OEL TWA (ppm)	1000 ppm
Italy	OEL TWA (mg/m ³)	1920 mg/m ³
Italy	OEL TWA (ppm)	1000 ppm
Latvia	OEL TWA (mg/m ³)	1920 mg/m ³
Latvia	OEL TWA (ppm)	1000 ppm
Spain	VLA-ED (mg/m ³)	1920 mg/m ³ (indicative limit value)
Spain	VLA-ED (ppm)	1000 ppm (indicative limit value)
Switzerland	VME (mg/m ³)	1910 mg/m ³
Switzerland	VME (ppm)	1000 ppm
Netherlands	Grenswaarde TGG 8H (mg/m ³)	950 mg/m ³
Netherlands	Grenswaarde TGG 15MIN (mg/m ³)	1500 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	766 mg/m ³
United Kingdom	WEL TWA (ppm)	400 ppm
United Kingdom	WEL STEL (mg/m ³)	958 mg/m ³
United Kingdom	WEL STEL (ppm)	500 ppm

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Dimethyl ether (115-10-6)		
Czech Republic	Expoziční limity (PEL) (mg/m ³)	1000 mg/m ³
Denmark	Grænseværdie (langvarig) (mg/m ³)	1920 mg/m ³
Denmark	Grænseværdie (langvarig) (ppm)	1000 ppm
Estonia	OEL TWA (mg/m ³)	1920 mg/m ³
Estonia	OEL TWA (ppm)	1000 ppm
Finland	HTP-arvo (8h) (mg/m ³)	2000 mg/m ³
Finland	HTP-arvo (8h) (ppm)	1000 ppm
Hungary	AK-érték	1920 mg/m ³
Hungary	CK-érték	7680 mg/m ³ (Substances with European indicative limits (96/94/EC, 2000/39/EC, 2006/15/EC, 2009/161/EU), which currently has no peak limit concentration. In these cases, Annex 3.1. should be used exercised)
Ireland	OEL (8 hours ref) (mg/m ³)	1920 mg/m ³
Ireland	OEL (8 hours ref) (ppm)	1000 ppm
Ireland	OEL (15 min ref) (mg/m ³)	5760 mg/m ³ (calculated)
Ireland	OEL (15 min ref) (ppm)	3000 ppm (calculated)
Lithuania	IPRV (mg/m ³)	1920 mg/m ³
Lithuania	IPRV (ppm)	1000 ppm
Lithuania	TPRV (mg/m ³)	2280 mg/m ³
Lithuania	TPRV (ppm)	1500 ppm
Luxembourg	OEL TWA (mg/m ³)	1920 mg/m ³
Luxembourg	OEL TWA (ppm)	1000 ppm
Malta	OEL TWA (mg/m ³)	1920 mg/m ³
Malta	OEL TWA (ppm)	1000 ppm
Norway	Grenseverdier (AN) (mg/m ³)	384 mg/m ³
Norway	Grenseverdier (AN) (ppm)	200 ppm
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	384 mg/m ³
Norway	Grenseverdier (Korttidsverdi) (ppm)	200 ppm
Poland	NDS (mg/m ³)	1000 mg/m ³
Romania	OEL TWA (mg/m ³)	1920 mg/m ³
Romania	OEL TWA (ppm)	1000 ppm
Slovakia	NPHV (priemerná) (mg/m ³)	1920 mg/m ³
Slovakia	NPHV (priemerná) (ppm)	1000 ppm
Slovenia	OEL TWA (mg/m ³)	1920 mg/m ³
Slovenia	OEL TWA (ppm)	1000 ppm
Sweden	nivågränsvärde (NVG) (mg/m ³)	950 mg/m ³
Sweden	nivågränsvärde (NVG) (ppm)	500 ppm
Sweden	kortidsvärde (KTV) (mg/m ³)	1500 mg/m ³
Sweden	kortidsvärde (KTV) (ppm)	800 ppm
Portugal	OEL TWA (mg/m ³)	1920 mg/m ³ (indicative limit value)
Portugal	OEL TWA (ppm)	1000 ppm (indicative limit value)
Propane (74-98-6)		
Austria	MAK (mg/m ³)	1800 mg/m ³
Austria	MAK (ppm)	1000 ppm
Austria	MAK Short time value (mg/m ³)	3600 mg/m ³
Austria	MAK Short time value (ppm)	2000 ppm

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Propane (74-98-6)		
Belgium	Limit value (ppm)	1000 ppm (gas)
Bulgaria	OEL TWA (mg/m ³)	1800,0 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	1800 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (ppm)	1000 ppm
Greece	OEL TWA (mg/m ³)	1800 mg/m ³
Greece	OEL TWA (ppm)	1000 ppm
Latvia	OEL TWA (mg/m ³)	1800 mg/m ³
Latvia	OEL TWA (ppm)	1000 ppm
Switzerland	VLE (mg/m ³)	7200 mg/m ³
Switzerland	VLE (ppm)	4000 ppm
Switzerland	VME (mg/m ³)	1800 mg/m ³
Switzerland	VME (ppm)	1000 ppm
Denmark	Grænseværdie (langvarig) (mg/m ³)	1800 mg/m ³
Denmark	Grænseværdie (langvarig) (ppm)	1000 ppm
Estonia	OEL TWA (mg/m ³)	1800 mg/m ³
Estonia	OEL TWA (ppm)	1000 ppm
Finland	HTP-arvo (8h) (mg/m ³)	1500 mg/m ³
Finland	HTP-arvo (8h) (ppm)	800 ppm
Finland	HTP-arvo (15 min)	2000 mg/m ³
Finland	HTP-arvo (15 min) (ppm)	1100 ppm
Ireland	OEL (8 hours ref) (ppm)	1000 ppm
Ireland	OEL (15 min ref) (ppm)	3000 ppm (calculated)
Ireland	OEL chemical category (IE)	Simple asphyxiant
Norway	Grenseverdier (AN) (mg/m ³)	900 mg/m ³
Norway	Grenseverdier (AN) (ppm)	500 ppm
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	900 mg/m ³
Norway	Grenseverdier (Korttidsverdi) (ppm)	500 ppm
Poland	NDS (mg/m ³)	1800 mg/m ³
Romania	OEL TWA (mg/m ³)	1400 mg/m ³
Romania	OEL TWA (ppm)	778 ppm
Romania	OEL STEL (mg/m ³)	1800 mg/m ³
Romania	OEL STEL (ppm)	1000 ppm
Slovenia	OEL TWA (mg/m ³)	1800 mg/m ³
Slovenia	OEL TWA (ppm)	1000 ppm
Slovenia	OEL STEL (mg/m ³)	7200 mg/m ³
Slovenia	OEL STEL (ppm)	4000 ppm
Portugal	OEL TWA (ppm)	1000 ppm
Isobutane (75-28-5)		
Austria	MAK (mg/m ³)	1900 mg/m ³
Austria	MAK (ppm)	800 ppm
Austria	MAK Short time value (mg/m ³)	3800 mg/m ³
Austria	MAK Short time value (ppm)	1600 ppm
Belgium	Limit value (ppm)	1000 ppm (gas)
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	2400 mg/m ³

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Isobutane (75-28-5)		
Germany	TRGS 900 Occupational exposure limit value (ppm)	1000 ppm
Switzerland	VLE (mg/m ³)	7200 mg/m ³
Switzerland	VLE (ppm)	3200 ppm
Switzerland	VME (mg/m ³)	1900 mg/m ³
Switzerland	VME (ppm)	800 ppm
Estonia	OEL TWA (mg/m ³)	1900 mg/m ³
Estonia	OEL TWA (ppm)	800 ppm
Finland	HTP-arvo (8h) (ppm)	800 ppm
Finland	HTP-arvo (15 min)	2400 mg/m ³
Finland	HTP-arvo (15 min) (ppm)	1000 ppm
Slovenia	OEL TWA (mg/m ³)	2400 mg/m ³
Slovenia	OEL TWA (ppm)	1000 ppm
Slovenia	OEL STEL (mg/m ³)	9600 mg/m ³
Slovenia	OEL STEL (ppm)	4000 ppm
Slovenia	OEL chemical category (SL)	Category 1A concentration >=0.1% Butadiene, Category 1B containing >=0.1% Butadiene

8.2. 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/flammable resistant/retardant clothing.
Hand protection	: If material is cold, wear thermally resistant protective gloves.
Eye protection	: Chemical safety goggles.
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: Use an 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

9.1. Information on basic physical and chemical properties

Physical state	: Gas
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: -25 °C (-13 °F) DME; -41 °C (-42 °F) propane; -12 °C (10 °F) isobutane
Flash point	: -41 °C (-41,8 °F) DME (TOC)
Auto-ignition temperature	: 350 °C (662 °F) DME
Decomposition temperature	: No data available

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Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: > 1
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: Contains gas under pressure; may explode if heated.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

Gas group	: Liquefied gas
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts violently with strong oxidisers. Increased risk of fire or explosion.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Strong oxidizers. Metal hydrides.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
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Dimethyl ether (115-10-6)	
LC50 inhalation rat (mg/l)	308,5 mg/l/4h
Propane (74-98-6)	
LC50 inhalation rat (mg/l)	658 mg/l/4h
Isobutane (75-28-5)	
LC50 inhalation rat (mg/l)	658 mg/l/4h
LC50 inhalation rat (ppm)	11000 ppm

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: 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.

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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.
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Not classified.

12.2. Persistence and degradability

Histofreezer® Portable Cryosurgical System	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Histofreezer® Portable Cryosurgical System	
Bioaccumulative potential	Not established.

Dimethyl ether (115-10-6)

Log Pow	-0,18
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Propane (74-98-6)

Log Pow	2,3
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Isobutane (75-28-5)

BCF fish 1	1,57 - 1,97
Log Pow	2,88 (at 20 °C)

12.4. Mobility in soil

No additional information available.

12.5. Results of PBT and vPvB assessment

No additional information available.

12.6. Other adverse effects

Other information : Avoid release to the environment.






SECTION 13: Disposal considerations

13.1. Waste treatment methods

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. Do not puncture or incinerate container.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

Refer to shipping papers for additional information. In accordance with ADR / RID / IMDG / IATA / ADN:

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
1950	1950	1950	1950	1950
14.2. UN proper shipping name				
AEROSOLS	AEROSOLS	Aerosols, flammable	AEROSOLS	AEROSOLS
14.3. Transport hazard class(es)				
2.1	2.1	2.1	2.1	2.1
				
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA	ADN	RID
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user

No additional information available.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

14.8 Other information

Limited quantities:

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

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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

Dimethyl ether - Propane - Isobutane - Butane

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

Dimethyl ether (115-10-6)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Propane (74-98-6)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Histofreezer® Portable Cryosurgical System

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Isobutane (75-28-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations

No additional information available.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Indication of Changes:

10/01/17 - New EU-specific SDS.

Revision date : 10/01/17

Data sources : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment
Regulation (EU) 2015/830

Full text of H- and EUH-statements:

Aerosol 1	Aerosol, Category 1
Flam. Gas 1	Flammable gases, Category 1
Liquefied gas	Gases under pressure : Liquefied gas
H220	Extremely flammable gas
H222	Extremely flammable aerosol
H229	Pressurised container: May burst if heated
H280	Contains gas under pressure; may explode if heated

EU GHS SDS

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.