

CRYDOSE

Safety Data Sheet (MSDS)

SEC. 1. PRODUCT & COMPANY IDENTIFICATION

Product name: CryoDose H

Product Use: Cryosurgical treatment

Generic Name: Mixture of propane, isobutane and dimethyl ether (DME)

Manufacturer: Nuance Medical, LLC,
5931 Sea Lion Place, Suite 113, Carlsbad, CA 92010
(760) 585-4849 CryoDose.com

Medical Emergency:

1-800-441-3637

(outside US 1-302-774-1139)

Transport Emergency:

CHEMTREC: 1-800-424-9300

(outside US 1-703-527-3887)

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

SEC. 2. HAZARDS IDENTIFICATION

GHS Classification: Flammable Aerosol (Category 1)

GHS Label:

Signal Word: Danger

Pictogram: (as shown to right)



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.

SEC. 4. FIRST AID MEASURES

Eyes contact: Flush with water for 15 minutes; consult a doctor.

Skin contact: Flush with water for 15 minutes; consult a doctor.

Ingestion: Not applicable.

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

SEC. 5. FIREFIGHTING MEASURES

Flammable Limits:

LEL: dimethyl ether 3.4/ propane 2.1/ isobutane 1.8

UEL: dimethyl ether 18.0/ propane 9.5/ isobutane 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).

SEC. 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 stopped leaking, carefully check for residual product and dispose of as per section 13.

Small spill/leak: Large spills or leaks are not anticipated; product is manufactured in 80 mL 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.

SEC. 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.

SEC. 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Name: DME **CAS #:** 115-10-6

TLV (Units): Mac 100ppm

LC50; 386ppm (inhalation, mouse, 15 min)

LC50; 308000 mg/m3 (inhalation, rat)

AIPH-PEL 1000ppm (twa)

Component Name: Propane **CAS #:** 74-98-6

TLV (Units): MAC>600ppm

OSHA PEL 1000ppm (1800 mg/m3)(TWA)

ACGIH-TWA; 2500ppm

SEC. 3. COMPOSITION/INFORMATION ON INGREDIENTS Components:

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

CRYDOSE H

CRYOSURGICAL SYSTEM

Safety Data Sheet (continued)

Component Name: Isobutane **CAS #:** 75-28-5
TLV (Units): LC50; 57pph (inhalation, rat, 15 min)
NIOSH-REL; 800ppm (1900 mg/m3)(TWA)
Engineering controls: Provide adequate ventilation for continuous use.
Personal protective equipment: Not normally required.

SEC. 9. PHYSICAL & CHEMICAL PROPERTIES

Physical state: Liquid under pressure
pH: N/A **Vapor density:** >1
Boiling point: DME -25° C/ propane -41° C/ isobutane -12° C
Flashpoint & method: DME -41° C (TOC)
Specific gravity (water = 1): 0.625
% volatile by volume: 100%
Vapor density: 3.4 at 25°C (77°F) and 1013 hPa (Air=1.0)

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.

SECTION 10. STABILITY & 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.

SEC. 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.

Eye effects: Frostbite/ burn. **Skin effects:** Frostbite/ burn.

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

SEC. 12. ECOLOGICAL INFORMATION

There is no data available on the preparation itself.

SEC. 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.

SEC. 14. TRANSPORT INFORMATION

US Department Of Transportation

Proper shipping name: Limited Quantity

Technical 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

Technical 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: Liquefied Gas, Flammable, N.O.S.

Technical name: (Dimethyl ether, Propane)

Primary hazard class/division: Flammable Gas II

NAERG: 115 **Label:** Flammable Gas, 2



EUROPEAN SHIPPING NAME

Proper shipping name: AIR/SEA: Aerosols LAND: 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.



SEC. 15. REGULATORY INFORMATION

CANADIAN COMMUNITY: WHMIS SYMBOLS AND CLASSIFICATIONS

Class A: (Compressed Gas).....

Class B5: (Flammable Aerosol).....

Class D1A: (Toxic-Immediate & Serious Effect).....



EUROPEAN COMMUNITY: EEC LABEL SYMBOL AND CLASSIFICATION

Extremely Flammable



RISK PHASES (European Union)

CODE: 12; PHASE: Extremely Flammable.

SAFETY PHASES (European Union)

CODE 2; PHASE: Keep out of reach from children.

CODE 9; PHASE: Keep container in a well-ventilated place.

CODE 16; PHASE: Keep away from sources of ignition, No smoking.

CODE 23; PHASE: Do not breathe spray.

CODE 33; PHASE: 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.

SEC. 16. OTHER INFORMATION

The information contained herein is accurate to the best of our knowledge. Nuance Medical, LLC 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.

This Safety Data Sheet document has been formatted for inclusion in CryoDose H Treatment Kit.