

## Safety Data Sheet<sup>1</sup>

<b>1.</b>	<b>PRODUCT AND COMPANY IDENTIFICATION</b>
<p><b>Trade Name:</b> Hydrozid®</p> <p><b>Substance Name:</b> Norflurane</p> <p><b>Intended use:</b> Cryosurgery and cryotherapy</p> <p><b>Medical Device Classification:</b> IIa (active therapeutical device)<sup>2</sup></p> <p><b>CE mark:</b> 2460</p> <p><b>Manufacturer:</b> BIBAWO Medical A/S</p> <p>Klintehøj Vænge 6 DK 3460 Birkerød Denmark info@hydrozid.eu</p> <p><b>Emergency contact information:</b> (+45) 8140 1843</p>	

<b>2.</b>	<b>HAZARD IDENTIFICATION</b>
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**Regulation 1272/2008:** Not classified

**GHS Classification:** Non-flammable aerosol (Category 3)

<b>Hazard Pictogram</b>	No symbol
<b>Signal word</b>	Warning
<b>Hazard statements</b>	H229: Pressurised container: May burst if heated.
<b>Precautionary statements</b> <b>Prevention</b>	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P251 Do not pierce or burn, ever after use.
<b>Precautionary statements</b> <b>Storage</b>	P410: Protect from sunlight. P412: Do not expose to temperatures exceeding 50°C / 122°F.
<b>Additional Information</b>	Contains fluorinated greenhouse gas HFC-134a (0.248 kg 134a; 0.355 t CO <sub>2</sub> eq; GWP 1430).

<sup>1</sup> To the best of our knowledge this safety data sheet conforms with the requirements of the 1907/2006/EC, Article 31 and United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Seventh revised edition.

<sup>2</sup> Rule 9, Annex VIII of the Medical Device Regulation (EU) 2017/745

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

International Nonproprietary Name (INN)	Norflurane
Molecular Formula	C <sub>2</sub> H <sub>2</sub> F <sub>4</sub>
Chemical Name	HFC-134a, HFA-134a, R-134a, fluorocarbon 134a
Chemical Family	Fluorinated Hydrocarbon
Chemical Abstracts (CAS)	811-97-2

### 4. FIRST-AID MEASURES

**General Information:** No special measures required.

**Symptoms and effects, both acute and delayed:** No further relevant information available.

**Indication of any immediate medical attention and special treatment needed:** No further relevant information available.

**After inhalation:** Supply fresh air; consult doctor in case of complaints.

**After skin contact:** Generally, the product does not irritate the skin.

**After eye contact:** Rinse the opened eye for several minutes under running water.

**After swallowing:** If symptoms persist consult doctor.

### 5. FIRE FIGHTING MEASURE

**Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**Special hazards arising from the substance or mixture:** No further relevant information available.

**Advice for firefighters:**

**Protective equipment:** No special measures required.

**Additional information:** Collect contaminated firefighting water separately. It must not enter the sewage system.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:** Not required.

**Environmental precautions:** Do not allow to enter sewers/surface or ground water.

**Methods and material for containment and cleaning up:** Absorb liquid components with liquid-binding material.

**Reference to other sections:** No dangerous substances are released.

### 7. HANDLING AND STORAGE

**Precautions for safe handling:** No special measures required.

**Information about fire - and explosion protection:** No special measures required.

**Conditions for safe storage, including any incompatibilities:**

**Storage:** Store vertically.

**Requirements to be met by storage rooms and receptacles:** Do not expose to direct sunlight. Do not expose to temperatures exceeding 50°C / 122°F.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** None.

**Specific end use(s):** Cryosurgery and cryotherapy.

8.	<b>EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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**Additional information about design of technical facilities:** No further data; see item 7.

**Control parameters****Ingredients with limit values that require monitoring at the workplace:**

Component Name	CAS	Limit Values
Norflurane	811-97-2	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Exposure controls****Personal protective equipment:**

**General protective and hygienic measures:** The usual precautionary measures are to be taken as when handling chemicals.

**Protection of hands:** Not required.

**Eye protection:** Not required.

**Respiratory protection:** Not required.

9.	<b>PHYSICAL AND CHEMICAL PROPERTIES<sup>3</sup></b>
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<b>Form</b>	Gaseous; liquid under pressure
<b>Colour</b>	Colourless
<b>Odour</b>	Faint ethereal odour
<b>Flammability</b>	Non-flammable
<b>Dangerous of explosion</b>	Product does not present any hazard explosion
<b>pH</b>	-
<b>Flashpoint</b>	-
<b>Ignition temperature</b>	-
<b>Decomposition temperature</b>	-
<b>Melting Point</b>	-103,3°C / -153,4°F

<sup>3</sup> The physical data should only be utilized in the context of this safety data sheet  
Hydrozid® Material Safety Data Sheet

<b>Boiling Point</b>	-26°C / -14,8°F
<b>Vapor pressure at 20°C/ 68°F</b>	5716 hPa
<b>Density at 20°C/ 68°F</b>	1,226 g/cm <sup>3</sup>
<b>Solubility in water at 20°C/ 68°F</b>	1.93 g/l
<b>Organic solvents content</b>	0,0%
<b>Volatile Organic Compound content</b>	0,0%

## 10. STABILITY AND REACTIVITY

**Reactivity (Possibility of hazardous reactions):** No dangerous reactions known.

**Chemical stability:** This product is considered stable under normal and anticipated handling conditions of temperature and pressure. No special protective equipment required.

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**Conditions to avoid:** No further relevant information available.

**Incompatible materials:** No further relevant information available.

**Hazardous decomposition products:** No known dangerous decomposition products.

## 11. TOXICOLOGICAL INFORMATION

**Acute toxicity:** No known acute toxicity effects.

**Primary irritant effect on the skin:** No irritant effect.

**Primary irritant effect on the eye:** No irritant effect.

**Sensitization:** No known sensitizing effects.

**Additional toxicological information:** When used and handled according to specifications, the product does not have any harmful effects in our experience and in the information provided to us.

**Carcinogenicity:** Not considered carcinogenic. The substance is not subject to classification according to the latest version of the EU lists.

## 12. ECOLOGICAL INFORMATION

**Aquatic toxicity:** No further relevant information available.

**Persistence and degradability:** No further relevant information available.

**Bio accumulative potential:** No further relevant information available.

**Mobility in soil:** No further relevant information available.

**Additional ecological information:** HFA-134a contains no chlorine and therefore has no potential to deplete the ozone layer in the stratosphere <sup>4</sup>.

## 13. DISPOSAL CONSIDERATION

### Waste treatment methods

**Recommendation:** Smaller quantities can be disposed of with household waste.

<sup>4</sup> Alexander DJ, Libretto SE. An overview of the toxicology of HFA-134a (1,1,1,2-tetrafluoroethane). Hum Exp Toxicol. 1995;14: 715-20.  
Hydrozid® Material Safety Data Sheet

## European waste catalogue





15 01 10 packaging containing residues of or contaminated by dangerous substances

15 01 04 metallic packaging

### Uncleaned packaging:

**Recommendation:** Disposal must be according to official regulations. Recycle where appropriate.

## 14. TRANSPORT INFORMATION

UN Model Regulations	ADR <sup>5</sup>	IMDG <sup>6</sup>	IATA <sup>7</sup>
UN proper shipping name	UN 1950 Aerosols 	Aerosols	Aerosols, non-flammable
Pictogram			
Transport Hazard Class	2.5A Gases.	2.2.	2.2.
Transport Hazard Label	2.2.	2.2.	2.2.
Packing Group	Not applicable.	Not applicable.	Not applicable.
Environmental hazards Marine pollutant:	No.	No.	No.
Special precautions for user	Warning: Gases.	Warning: Gases.	Warning: Gases.
Limited Quantities	1L	-	1L
Transportation category	3	-	-
Tunnel restriction code	E	-	-

## 15. REGULATORY INFORMATION

**Safety-, health- and environmental regulations/legislation specific for the substance or mixture:** No further relevant information available.

<sup>5</sup> ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

<sup>6</sup> IMDG: International Maritime Code for Dangerous Goods

<sup>7</sup> IATA: International Air Transport Association

<b>16.</b>	<b>OTHER INFORMATION</b>
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The information contained herein is accurate to the best of our knowledge. However, this shall not guarantee for any specific product features and shall not establish a legally valid contractual relationship. BIBAWO Medical A/S makes no warranty of any kind, expressed or implied, concerning the safety and performance incurred through improper use of the product or application of the data.

**For healthcare professionals use only.**

### **Revision History**

CT/Revision 01 2018/03/ 19 Safety Data Sheet.

CT/Revision 02 2018/10/19 Safety Data Sheet issued.

CT/Revision 03 2020/07/01 Safety Data Sheet revised to reflect transfer of Hydrozid to BIBAWO Medical A/S.

SL/Revision 04 2021/11/05 CE mark updated to 2460.

MEP/Revision 05 2022/10/21 Email and phone number updated.