

Safety Data Sheet¹

1.	PRODUCT AND COMPANY IDENTIFICATION
<p>Trade Name: Hydrozid®</p> <p>Substance Name: Norflurane</p> <p>Intended use: Cryosurgery and cryotherapy</p> <p>Medical Device Classification: IIa (active therapeutical device)²</p> <p>CE mark: 0123</p> <p>Manufacturer: BIBAWO Medical A/S</p> <p>Klintehøj Vænge 6 DK 3460 Birkerød Denmark info@hydrozid.eu</p> <p>Emergency contact information: (+45) 8140 1843</p>	

2.	HAZARD IDENTIFICATION
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Regulation 1272/2008: Not classified

GHS Classification: Non-flammable aerosol (Category 3)

Hazard Pictogram	No symbol
Signal word	Warning
Hazard statements	H229: Pressurised container: May burst if heated.
Precautionary statements Prevention	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.
Precautionary statements Storage	P410: Protect from sunlight. P412: Do not expose to temperatures exceeding 50°C / 122°F.
Additional Information	Contains fluorinated greenhouse gas HFC-134a (0.248 kg 134a; 0.355 t CO ₂ eq; GWP 1430).

¹ 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.

² 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 ₂ H ₂ F ₄
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: CO₂, 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. EXPOSURE CONTROLS/PERSONAL PROTECTION****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. PHYSICAL AND CHEMICAL PROPERTIES³**

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

³ The physical data should only be utilized in the context of this safety data sheet
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Boiling Point	-26°C / -14,8°F
Vapor pressure at 20°C/ 68°F	5716 hPa
Density at 20°C/ 68°F	1,226 g/cm ³
Solubility in water at 20°C/ 68°F	1.93 g/l
Organic solvents content	0,0%
Volatile Organic Compound content	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 ⁴.

13. DISPOSAL CONSIDERATION

Waste treatment methods

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

⁴ Alexander DJ, Libretto SE. An overview of the toxicology of HFA-134a (1,1,1,2-tetrafluoroethane). Hum Exp Toxicol. 1995;14: 715-20.
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European waste catalogue

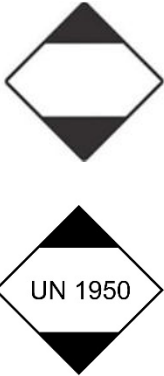



15 01 10 packaging containing residues of or contaminated by dangerous substances

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 ⁵	IMDG ⁶	IATA ⁷
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.

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

⁶ IMDG: International Maritime Code for Dangerous Goods

⁷ IATA: International Air Transport Association

16. OTHER INFORMATION

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.

MEP/Revision 06, 2024/11/14: CE mark updated to 0123.