

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 28.05.2024

Version number 5 (replaces version 4)

Revision: 28.05.2024

- **1.1 Product identifier**
- **Trade name:** **OPTIFLUID® STOMA OIL 25ml**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Technical function**
Medical device with patient contact.
The classification criteria of (EU) 1272/2008 are therefore not applicable.
- **Application of the substance / the mixture** Lubricant
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
PRISMAN GmbH
Otto-Hahn-Ring 6-18
64653 Lorsch
- Vertrieb durch/Distributed by:
Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Str. 4a
51149 Köln-Germany
Phone: +49 (0) 2203/2980-200
- **Further information obtainable from:**
Abteilung Produktsicherheit
Alexander.Metz@prisman.de
- **1.4 Emergency telephone number:** ++49 (0)6251 866980-0, Mo-Fr 9-17 Uhr

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
-

Dangerous components:

CAS: 74-98-6 EINECS: 200-827-9 Index number: 601-003-00-5 RTECS: TX 2275000 Reg.nr.: 01-2119486944-21-xxxx	propane	 Flam. Gas 1, H220 Press. Gas (Comp.), H280	25-50%
CAS: 106-97-8 EINECS: 203-448-7 Index number: 601-004-00-0 RTECS: EJ 4200000 Reg.nr.: 01-2119474691-32-xxxx	butane, pure	 Flam. Gas 1, H220 Press. Gas (Comp.), H280	10-25%

GB

(Contd. on page 2)

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Trade name: **OPTIFLUID® STOMA OIL 25ml**

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Generally the product does not irritate the skin.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Storage class:** 2B
- **7.3 Specific end use(s)** No further relevant information available.

GB

(Contd. on page 3)

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(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

106-97-8 butane, pure

WEL	Short-term value: 1810 mg/m ³ , 750 ppm
	Long-term value: 1450 mg/m ³ , 600 ppm
	Carc (if more than 0.1% of buta-1.3-diene)

· **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not required.

· **Hand protection** Not required.

· **Material of gloves -**

· **Penetration time of glove material -**

· **Eye/face protection** Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· **Physical state**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Nearly odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not applicable

· **Upper:**

Not applicable

· **Flash point:**

>112 °C

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

· **Viscosity:**

· **Kinematic viscosity at 40 °C**

35 mm²/s

· **Dynamic at 40 °C:**

>35 mPas

· **Solubility**

· **water:**

Not miscible or difficult to mix.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**

· **Density at 20 °C:**

0.85 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

(Contd. on page 4)

Safety data sheet

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Version number 5 (replaces version 4)

Revision: 28.05.2024

Trade name: **OPTIFLUID® STOMA OIL 25ml**

(Contd. of page 3)

- **9.2 Other information**
- **Appearance:**
- **Form:** *Aerosol*
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** *Not determined.*
- **Explosive properties:** *Product does not present an explosion hazard.*
- **Solids content:** *0.0 %*
- **Change in condition**
- **Evaporation rate** *Not determined.*
- **Information with regard to physical hazard classes**
- **Explosives** *Void*
- **Flammable gases** *Void*
- **Aerosols** *Void*
- **Oxidising gases** *Void*
- **Gases under pressure** *Void*
- **Flammable liquids** *Void*
- **Flammable solids** *Void*
- **Self-reactive substances and mixtures** *Void*
- **Pyrophoric liquids** *Void*
- **Pyrophoric solids** *Void*
- **Self-heating substances and mixtures** *Void*
- **Substances and mixtures, which emit flammable gases in contact with water** *Void*
- **Oxidising liquids** *Void*
- **Oxidising solids** *Void*
- **Organic peroxides** *Void*
- **Corrosive to metals** *Void*
- **Desensitised explosives** *Void*

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *No dangerous decomposition products known.*

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*

· **LD/LC50 values relevant for classification:**

8042-47-5 White mineral oil, petroleum

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>3,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>5,000 mg/l (rat)

(Contd. on page 5)

GB

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(Contd. of page 4)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· Endocrine disrupting properties
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Substance is not listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· **Aquatic toxicity:**

8042-47-5 White mineral oil, petroleum

EC50 >100 mg/l (daphnia)

LC50/96h >100 mg/l (fish)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of packaging according to regulations on the disposal of packagings.
- **Recommended cleansing agents:** Solvent naphtha

SECTION 14: Transport information

· 14.1 UN number or ID number

· **ADR, IMDG, IATA**

Void

· 14.2 UN proper shipping name

· **ADR**

1950 AEROSOLS

(Contd. on page 6)

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(Contd. of page 5)

· IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** P3a FLAMMABLE AEROSOLS
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H220 Extremely flammable gas.
H280 Contains gas under pressure; may explode if heated.
- **Recommended restriction of use** Product only for professional use
- **Department issuing SDS:** Abteilung Produktsicherheit
- **Contact:** Hr. Dr. Metz
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Gas 1: Flammable gases – Category 1
Press. Gas (Comp.): Gases under pressure – Compressed gas
- *** Data compared to the previous version altered.**