

Safety Data Sheet



(according to Regulation (EC) No. 1907/2006 in its currently valid version)

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 1 of 10

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

1.1. Product identifier

Askina Skin Freeze

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

Use of the substance/mixture

Portable cryosurgical system for the removal of warts and other benign skin lesions

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: Koninklijke Utermöhlen NV
Street: De Overweg 1
Place: NL-8471 ZA Wolvega

Supplier

Company name: B. Braun Melsungen AG
Street: Carl-Braun-Straße 1
Place: D-34212 Melsungen
Responsible Department: Central Services / Logistics and Supply Chain
Telephone: +49 (0) 5661 / 71-4422
E-Mail: logistics.service@bbraun.com
Responsible for the safety data sheet: sds@gbk-ingelheim.de

1.4. Emergency telephone number:

INTERNATIONAL: +49 (0) 6132 / 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Wales: NHS 111; In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Aerosol 1; H222-H229

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Signal word: Danger

Pictograms:



Hazard statements

H222 Extremely flammable aerosol.
H229 Pressurised container: May burst if heated.

Precautionary statements

P102 Keep out of reach of children.
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.
P501 Dispose of contents/container to an approved waste disposal plant. .

Safety Data Sheet

B | BRAUN

(according to Regulation (EC) No. 1907/2006 in its currently valid version)

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 2 of 10

Additional advice on labelling

This product is not subject to labeling obligation according to art. 1 (5) d) of Regulation (EC) no. 1272/2008 under the form of a medical product because it is used under body contact.

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Pictograms:



Hazard statements

H222-H229

Precautionary statements

P102-P210-P211-P251-P410+P412

2.3. Other hazards

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Inhalation of vapours in high concentration can cause narcotic effects.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of the following substances with non-hazardous admixtures

Hazardous components

| CAS No | Chemical name | | | Quantity |
|----------|--|--------------|------------------|----------|
| | EC No | Index No | REACH No | |
| | GHS Classification | | | |
| 115-10-6 | Dimethyl ether | | | < 100 % |
| | 204-065-8 | 603-019-00-8 | 01-2119472128-37 | |
| | Flam. Gas 1, Liquefied gas; H220 H280 | | | |
| 74-98-6 | Propane | | | < 2,5 % |
| | 200-827-9 | 601-003-00-5 | 01-2119486944-21 | |
| | Flam. Gas 1, Compressed gas; H220 H280 | | | |
| 106-97-8 | Butane | | | < 2,5 % |
| | 203-448-7 | 601-004-00-0 | 01-2119474691-32 | |
| | Flam. Gas 1, Compressed gas; H220 H280 | | | |
| 75-28-5 | Isobutane | | | < 2,5 % |
| | 200-857-2 | 601-004-00-0 | 01-2119485395-27 | |
| | Flam. Gas 1, Compressed gas; H220 H280 | | | |

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 3 of 10

General information

Take away from danger area and lay down affected person.

After inhalation

Move to fresh air in case of accidental inhalation of vapours.
In the event of symptoms refer for medical treatment.

After contact with skin

Wash off with soap and plenty of water.
In case of frostbite due to intensive contact, consult a doctor.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
If eye irritation persists, consult a specialist.

After ingestion

Ingestion is not considered a potential route of exposure.
No special measure necessary.

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

Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
May cause eye/skin irritation.
Inhalation of vapours in high concentration can cause narcotic effects.
Rapid evaporation of the liquid may cause frostbite.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Fire may produce:
carbon monoxide and carbon dioxide

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.
Protective suit.

Additional information

Vapours are heavier than air and spread along ground.
The vapour/air mixture is explosive, even in empty, uncleaned receptacles.
Cool containers at risk with water spray jet.
Heating will cause pressure rise with risk of bursting.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Use only explosion-proof equipment.
Keep away from sources of ignition - No smoking.
Vapours are heavier than air and can cause suffocation by reducing oxygen available for breathing.
Ensure adequate ventilation.

For non-emergency personnel

Do not breathe vapours and aerosols.

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 4 of 10

Avoid contact with skin, eyes and clothing.

For emergency responders

In case of vapour formation use respirator.
Use personal protective clothing.

6.2. Environmental precautions

No special environmental precautions required.

6.3. Methods and material for containment and cleaning up**For containment**

No special measures required.

For cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Ensure adequate ventilation.
Keep away from food and drink.
Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.
Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking.
Keep out of the reach of children. Without adequate ventilation formation of explosive mixtures may be possible.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep containers tightly closed in a cool, well-ventilated place.

Hints on joint storage

Incompatible with oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Portable cryosurgical system for the removal of warts and other benign skin lesions

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|----------|----------------|-----|-------------------|-----------|---------------|--------|
| 106-97-8 | Butane | 600 | 1450 | | TWA (8 h) | WEL |
| | | 750 | 1810 | | STEL (15 min) | WEL |
| 115-10-6 | Dimethyl ether | 400 | 766 | | TWA (8 h) | WEL |
| | | 500 | 958 | | STEL (15 min) | WEL |

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 5 of 10

8.2. Exposure controls**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Do not inhale vapours.

Wash hands before breaks and immediately after handling the product.

Keep away from food and drink.

Eye/face protection

Safety goggles with side protection (EN 166).

Hand protection

Impermeable gloves

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection

Long sleeved clothing (DIN EN ISO 6530)

Respiratory protection

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|-----------------|------------|
| Physical state: | Aerosol |
| Colour: | Colourless |
| Odour: | Ethereal |

Test method

| | |
|-----------|------|
| pH-Value: | n.d. |
|-----------|------|

Changes in the physical state

| | |
|-------------------------------|---------------|
| Melting point/freezing point: | - 141,5 °C *) |
|-------------------------------|---------------|

| | |
|---|--------------|
| Boiling point or initial boiling point and boiling range: | - 24,8 °C *) |
|---|--------------|

| | |
|--------------------|------|
| Sublimation point: | n.a. |
|--------------------|------|

| | |
|--------------|--------------|
| Flash point: | - 42,2 °C *) |
|--------------|--------------|

| | |
|------------------------|-----------------------|
| Sustaining combustion: | Sustaining combustion |
|------------------------|-----------------------|

Flammability

| | |
|---------------|------|
| Solid/liquid: | n.a. |
|---------------|------|

| | |
|------|------|
| Gas: | n.d. |
|------|------|

Explosive properties

The product is considered non-explosive; nevertheless explosive vapour/air mixture can be generated.

| | |
|-------------------------|---------------|
| Lower explosion limits: | 2,8 vol. % *) |
|-------------------------|---------------|

| | |
|-------------------------|----------------|
| Upper explosion limits: | 24,4 vol. % *) |
|-------------------------|----------------|

| | |
|----------------------------|-----------|
| Auto-ignition temperature: | 240 °C *) |
|----------------------------|-----------|

Self-ignition temperature

| | |
|--------|------|
| Solid: | n.a. |
|--------|------|

| | |
|------|------|
| Gas: | n.d. |
|------|------|

| | |
|----------------------------|-----------|
| Decomposition temperature: | 226 °C *) |
|----------------------------|-----------|

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 6 of 10

| | |
|--|---------------------------|
| Vapour pressure: (at 20 °C) | 5100 hPa *) |
| Density (at 20 °C): | 0,74 g/cm ³ *) |
| Bulk density: | n.a. |
| Water solubility: | 70 g/L *) |
| Solubility in other solvents | |
| Not oxidising. | |
| Partition coefficient n-octanol/water: | 0,1 *) |
| Viscosity / dynamic: | n.d. |
| Viscosity / kinematic: | n.d. |
| Flow time: | n.d. |
| Relative vapour density: | 1,63 *) |
| Evaporation rate: | n.d. |
| Solvent separation test: | 0 % |
| Solvent content: | 100 % |

9.2. Other information

No data available

*) Dimethylether

SECTION 10: Stability and reactivity**10.1. Reactivity**

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with oxidizing agents.

10.4. Conditions to avoid

Fire or intense heat may cause violent rupture of packages.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

No hazardous decomposition products known.

Fire may produce:

Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in GB CLP Regulation****Acute toxicity**

Based on available data, the classification criteria are not met.

No toxicological data available.

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 7 of 10

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.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

11.2. Information on other hazards**Endocrine disrupting properties**

No data available

Other information

Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

May cause eye/skin irritation.

Inhalation of vapours in high concentration can cause narcotic effects.

Rapid evaporation of the liquid may cause frostbite.

SECTION 12: Ecological information**12.1. Toxicity**

Ecological data are not available.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

Low hazard to waters.

Further information

Ecological injuries are not known or expected under normal use.

Do not flush into surface water or sanitary sewer system.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Can be incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

Contaminated packaging

Offer empty spray cans to an established disposal company.

SECTION 14: Transport information**Land transport (ADR/RID)**

Safety Data Sheet

B | BRAUN

(according to Regulation (EC) No. 1907/2006 in its currently valid version)

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 8 of 10

14.1. UN number: UN 1950
14.2. UN proper shipping name: AEROSOLS
14.3. Transport hazard class(es): 2
14.4. Packing group: -
Hazard label: 2.1



Classification code: 5F
Special Provisions: 190 327 344 625
Limited quantity: 1 L / 30 kg
Excepted quantity: E0
Transport category: 2
Tunnel restriction code: D

Inland waterways transport (ADN)

14.1. UN number: UN 1950
14.2. UN proper shipping name: AEROSOLS
14.3. Transport hazard class(es): 2
14.4. Packing group: -
Hazard label: 2.1



Classification code: 5F
Special Provisions: 190 327 344 625
Limited quantity: 1 L / 30 kg
Excepted quantity: E0

Marine transport (IMDG)

14.1. UN number: UN 1950
14.2. UN proper shipping name: AEROSOLS
14.3. Transport hazard class(es): 2.1
14.4. Packing group: -
Hazard label: 2.1



Marine pollutant: No
Special Provisions: 63, 190, 277, 327, 344, 381, 959
Limited quantity: 1000 mL / 30 kg
Excepted quantity: E0
EmS: F-D, S-U

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1950
14.2. UN proper shipping name: AEROSOLS, FLAMMABLE
14.3. Transport hazard class(es): 2.1
14.4. Packing group: -
Hazard label: 2.1

Safety Data Sheet

B | BRAUN

(according to Regulation (EC) No. 1907/2006 in its currently valid version)

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 9 of 10



| | |
|--|----------------|
| Special Provisions: | A145 A167 A802 |
| Limited quantity Passenger: | 30 kg G |
| Passenger LQ: | Y203 |
| Excepted quantity: | E0 |
| IATA-packing instructions - Passenger: | 203 |
| IATA-max. quantity - Passenger: | 75 kg |
| IATA-packing instructions - Cargo: | 203 |
| IATA-max. quantity - Cargo: | 150 kg |

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No specific precautions required.

14.7. Maritime transport in bulk according to IMO instruments

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 28, Entry 40

2004/42/EC (VOC): 100 %

Information according to 2012/18/EU (SEVESO III): P3a FLAMMABLE AEROSOLS

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,6,7,8,9,10,11,12,14,15.

Safety Data Sheet



(according to Regulation (EC) No. 1907/2006 in its currently valid version)

Askina Skin Freeze

Revision date: 01.02.2022

Product code: 00056-0234

Page 10 of 10

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
IMDG = International Maritime Code for Dangerous Goods
IATA/ICAO = International Air Transport Association / International Civil Aviation Organization
MARPOL = International Convention for the Prevention of Pollution from Ships
IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals
REACH = Registration, Evaluation, Authorization and Restriction of Chemicals
CAS = Chemical Abstract Service
EN = European norm
ISO = International Organization for Standardization
DIN = Deutsche Industrie Norm
PBT = Persistent Bioaccumulative and Toxic
vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose
LC = Lethal concentration
EC = Effect concentration
IC = Median immobilisation concentration or median inhibitory concentration

Classification for mixtures and used evaluation method according to GB CLP Regulation

| Classification | Classification procedure |
|----------------------|--------------------------|
| Aerosol 1; H222-H229 | On basis of test data |

Relevant H and EUH statements (number and full text)

H220 Extremely flammable gas.
H222 Extremely flammable aerosol.
H229 Pressurised container: May burst if heated.
H280 Contains gas under pressure; may explode if heated.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)