

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

1.1. Product identifier

Systemerm B

UFI J6QH-RDRY-V913-C4M2

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

Relevant identified uses: Reserved for industrial and professional use.
Uses advised against: Private households (= general public).

1.3. Details of the supplier of the safety data sheet

Manufacturer

pro3dure medical GmbH
Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax: +49 (0)2374 920050-50

Supplier

pro3dure medical GmbH
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Information contact

pro3dure medical GmbH

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E-mail (competent person) info@pro3dure.com
Website www.pro3dure.com

1.4. Emergency telephone number

pro3dure medical GmbH
This number is serviced during office hours.

Telephone +49 (0)2374 920050-10

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:
Repr. 2, H361; STOT SE 3, H336

2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



GHS07,GHS08
Warning

Signal word:

Hazard statements:

H336 May cause drowsiness or dizziness.
 H361 Suspected of damaging fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).

Precautionary statements:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P271 Use only outdoors or in a well-ventilated area.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P304+340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P308+313 IF exposed or concerned: Get medical advice/attention.
 P312 Call a POISON CENTER/doctor if you feel unwell
 P403+233 Store in a well-ventilated place. Keep container tightly closed.
 P405 Store locked up.
 P501 Dispose of contents/container according to official regulations.

Special labelling of particular preparations:

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2.3. Other hazards

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SECTION 3: Composition / information on ingredients

3.1. Substances

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3.2. Mixtures

Mixture with, among others, the following ingredients and other non-hazardous admixtures

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Propriety glycol 4			<30 %	Repr. 2, H361f	M = 1 ATE (dermal) = Kein Wert ermittelbar ATE (oral) = >2000 mg/kg bw ATE (inhalativ) = Kein Wert ermittelbar
propriety glycol 1			<30 %	Acute Tox. 4, H302; STOT SE 3, H336	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = 500 ATE (inhalativ) = Kein Wert ermittelbar
catalyst			<05 %	Repr. 2, H361; Aquatic Chronic 3, H412	

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: Remove contaminated, saturated clothing immediately. When in doubt or if symptoms are observed, get medical advice.
In case of inhalation: Provide fresh air. Seek medical attention if problems persist.
Following skin contact: After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.
After eye contact: In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Seek medical attention if problems persist.

After ingestion: Rinse mouth immediately and drink plenty of water. No administration in cases of unconsciousness or cramps. Do NOT induce vomiting. Call a physician immediately.

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

No known symptoms to date.

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

No special measures are necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media ABC-powder BC-powder alcohol resistant foam Carbon dioxide (CO₂)

Unsuitable extinguishing media Water spray jet Full water jet Strong water jet

5.2. Special hazards arising from the substance or mixture

Combustible

5.3. Advice for firefighters

General information

In case of fire may be liberated: Carbon monoxide Carbon dioxide (CO₂)

Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Remove persons to safety. Provide adequate ventilation.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. All work processes must always be designed so that the following is as low as possible: Inhalation

Precautions against fire and explosion:

Always close containers tightly after the removal of product. Use only in well-ventilated areas. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Hints on joint storage

none

7.3. Specific end use(s)

none

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
propriety glycol 1		worker inhalative long-term, systemic 136 mg/m ³ worker inhalative short-term, systemic 958 mg/m ³ worker dermal long-term, systemic 19 mg/kg bw/day population oral long-term, systemic 8 mg/kg bw/day
Propriety glycol 4		worker inhalative long-term, systemic 3,3 mg/m ³ worker dermal long-term, systemic 0,94 mg/kg bw/day population inhalative long-term, systemic 0,58 mg/m ³ population dermal long-term, systemic 0,34 mg/kg bw/day population oral long-term, systemic 0,34 mg/kg bw/day

PNEC Value

Substance:	CAS-No.:	PNEC

Additional information

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8.2. Exposure controls

Occupational exposure controls:

Provide adequate ventilation as well as local exhaust at critical locations. Technical measures and the application of suitable work processes have priority over personal protection equipment.

General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Personal protection equipment

Only wear fitting, comfortable and clean protective clothing.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required. Respiratory protection necessary at: insufficient ventilation. Suitable respiratory protection apparatus: Protective respiration apparatus not using surrounding air (breathing apparatus) (DIN EN 133).

Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl rubber.

Eye/face protection

Eye glasses with side protection

Body protection:

lab coat

Environmental exposure controls

refer to chapter 7. No further action is necessary.

Consumer exposure controls

refer to chapter 7. No further action is necessary.

Exposure Scenario:

Skin contact

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
 Colour: diverse
 Odour: -
 Odour threshold: -

Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				No data available
Initial boiling point and boiling range:				No data available
Flammability:				No data available
lower flammability or explosive limits:				No data available
Upper flammability or explosive limits:				No data available
Flash point:				No data available
Ignition temperature:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:				No data available
Water solubility (g/L):				No data available
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,1	g/cm ³	
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

none

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

moisture.

10.5. Incompatible materials

Oxidising agent, strong

10.6. Hazardous decomposition products

Carbon monoxide Carbon dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

none

M-factor: - **Acute toxicity (dermal):** >5000 mg/kg
Acute toxicity (oral): >1525 mg/kg **Acute toxicity (inhalative):** >5,1 mg/l

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Propriety glycol 4		LD50 oral (rat) 14700 mg/kg LD50 dermal (Rabbit) > 10000 mg/kg LC50 inhalation (rat, 4 h) > 850 mg/m ³ NOAEL Repr.-Tox. (Rat) 225 mg/kg bw/day
propriety glycol 1		LD50 oral (rat) 1500 mg/kg LC50 inhalation (rat, 4 h) > 15 mg/L LD50 dermal (rat) > 2000 mg/kg

Skin corrosion/irritation:

Not an irritant.

Serious eye damage/irritation:

Not an irritant.

Respiratory or skin sensitisation:

not sensitising.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

No indications of human carcinogenicity exist.

Germ cell mutagenicity:

No indications of human germ cell mutagenicity exist.

Reproductive toxicity:

No indications of human reproductive toxicity exist.

STOT-single exposure:

none

STOT-repeated exposure:

none

Aspiration hazard:

Not an irritant.

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the mixture itself.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Propriety glycol 4		LC50 (fish, 96 h) 14400 mg/l EC50 (microorganisms, 3h) > 1000 mg/L

12.2. Persistence and degradability

There are no data available on the mixture itself.

12.3. Bioaccumulative potential

There are no data available on the mixture itself.

12.4. Mobility in soil

There are no data available on the mixture itself.

12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself.

12.6 Endocrine disruptive effect

There are no data available on the mixture itself.

12.7. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Waste disposal according to EC Directives 75/442/EEC and 91/689/EEC on waste and hazardous waste in their latest versions. May be disposed of in household waste landfill.

Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

List of proposed waste codes / waste designations according to EWC / AVV

According to EAKV, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

SECTION 14: Transport information

14.1. UN number

UN No.:

14.2. UN proper shipping name

Land transport (ADR/RID)

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

14.3. Transport hazard class(es)

Hazard label(s) / Label:

Classification code: / Classification
Code:

14.4. Packing group

Packing group/ Packing Group:

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR:
Marine pollutant:

Yes

No

14.6. Special precautions for user

Land transport (ADR/RID)

transport category:

Special provisions:

tunnel restriction code:

Limited quantity (LQ):

Sea transport (IMDG)

EmS-No:

Special provisions:

Limited quantity (LQ):

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remark none

SECTION 15: Regulatory information

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

EU legislation

Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:

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Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:

-

Regulation (EC) No. 648/2004 (Detergents regulation)

-

Regulation (EC) No 850/2004 [POP-Regulation]:

-

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:

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Use restriction according to REACH annex XVII, no.:

-

National regulations

Observe in addition any national regulations!

Restrictions of occupation

none

Other regulations, restrictions and prohibition regulations

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15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out.

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SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text):

Hazard statements

H302 Harmful if swallowed.
H336 May cause drowsiness or dizziness.

Training advice

none

Recommended restrictions of use:

refer to chapter 1.

Further remarks:

The information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

Documentation of changes:

Changes compared to version 1.1:

3 Adaptation of the classification of the ingredients and the product.

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

AC: Artikelkategorie (Article Category)
ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)
ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des marchandises dangereuses par route)
AGW: Arbeitsplatzgrenzwert
AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)
Bw: Körpergewicht (Body weight)
CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)
CSR: Stoffsicherheitsbericht (Chemical Safety Report)
DIN: Deutsches Institut für Normung / Deutsche Industrienorm
DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD: Zubereitungsrichtlinie / Richtlinie 1999-45-EC (Dangerous Preparations Directive)
DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU: Nachgeschalteter Anwender (Downstream User)
EC50: Wirksame Konzentration 50% (Effective Concentration 50%)
ECHA: Europäische Chemikalienagentur
EN: Europäische Norm
EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA: Verband für den internationalen Lufttransport (International Air Transport Association)
IBC: Großpackmittel (Intermediate Bulk Container)
ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO: Internationale Seeschiffahrts-Organisation (International Maritime Organization)
ISO: Internationale Normungsorganisation (International Standards Organisation)
LC50: Lethale (Tödliche) Konzentration 50%
LD50: Lethale (Tödliche) Dosis 50%
LEV: Lokale Absaugung (Local exhaust ventilation)
MAK: Maximale Arbeitsplatzkonzentration – DFG
n.a.: nicht anwendbar
n.b.: nicht bestimmt
OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT: persistent, bioakkumulierbar, giftig (persistent, bioaccumulative, toxic)
PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)
PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL: Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)
SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulativ)