

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

1.1. Product identifier

Systemerm SPT-1 Separator

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

Relevant identified uses: Manufacture.
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)274 920050-50

Supplier

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10

Telefax: +49 (0)274 920050-50

Information contact

pro3dure medical GmbH

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Information telefax +49 (0)2374 920050-50

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:

Flam. Liq. 2, H225; Asp. Tox. 1, H304; Skin Irrit. 2, H315; STOT SE 3, H336; Repr. 2, H361; Repr. 2, H361;
STOT RE 2, H373; STOT RE 2, H373; Aquatic Chronic 2, H411

2.2. Label elements

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

Hazard pictograms



GHS02, GHS08, GHS09

Danger

Signal word:

Hazard statements:

- H225 Highly flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
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).
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).
H373 May cause damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

- P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P240 Ground and bond container and receiving equipment.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+352 IF ON SKIN: Wash with plenty of water/soap.
P303+361+353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
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.
P314 Get medical advice/attention if you feel unwell.
P321 Specific treatment (see informations on this label).
P331 Do NOT induce vomiting.
P332+313 If skin irritation occurs: Get medical advice/attention.
P362+364 Take off contaminated clothing and wash it before reuse.
P370+378 In case of fire: Use ABC-powder to extinguish.
P391 Collect spillage.
P403+233 Store in a well-ventilated place. Keep container tightly closed.
P403+235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P501 Dispose of contents/container according to official regulations.

Special labelling of particular preparations:

none

2.3. Other hazards

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SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Petroleum ether	8032-32-4		< 90	-	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar
Dimethylpolysiloxane	63148-62-9		< 50	-	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- General information:** In case of accident or unwellness, seek medical advice immediately Take off immediately all contaminated clothing.
- 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. Subsequently consult an ophthalmologist.
- After ingestion:** Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Consult an ophthalmologist.

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

Aspiration hazard, irritation, drowsiness, drowsiness, narcotic effect.

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media** ABC-powder alcohol resistant foam BC-powder Carbon dioxide (CO₂)
- Unsuitable extinguishing media** Water spray jet Excess water Full water jet

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely. Use water spray jet to protect personnel and to cool endangered containers. Use water spray jet to protect personnel and to cool endangered containers.

Special protective equipment for fire-fighters:

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Remove persons to safety. Remove all sources of ignition. 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 excluded: Inhalation

Precautions against fire and explosion:

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

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Only use the material in places where open light, fire and other flammable sources can be kept away.

Hints on joint storage

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

7.3. Specific end use(s)

Observe instructions for use.

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
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PNEC Value

Substance:	CAS-No.:	PNEC
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Additional information

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8.2. Exposure controls

Occupational exposure controls:

Provide adequate ventilation as well as local exhaustion 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

Respiratory protection necessary at: 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:

For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes). Only wear fitting, comfortable and clean protective clothing. Barrier creams are not substitutes for body protection.

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:

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state:	Liquid
Colour:	colourless
Odour:	characteristic
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:	°C -26
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:	No data available
Relative density:	No data available
Particle properties:	No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

Gas/vapour, highly flammable.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Vapours can form explosive mixtures with air. Violent reaction with: strong oxidants

10.4. Conditions to avoid

heat. Risk of explosion by shock, friction, fire or other sources of ignition.

10.5. Incompatible materials

Rubber products, various plastics

10.6. Hazardous decomposition products

In case of fire may be liberated: Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

There are no data available on the mixture itself.

M-factor:	-	Acute toxicity (dermal):	-
Acute toxicity (oral):	-	Acute toxicity (inhalative):	-

Acute toxicity

Substance:	CAS-No.:	Toxicological information
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Skin corrosion/irritation:

irritant.

Serious eye damage/irritation:

irritant.

Respiratory or skin sensitisation:

There are no data available on the preparation/mixture itself.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

-

Germ cell mutagenicity:

-

Reproductive toxicity:

-

STOT-single exposure:

May cause drowsiness or dizziness.

STOT-repeated exposure:

-

Aspiration hazard:

There are no data available on the preparation/mixture itself.

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the mixture itself.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
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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:

Dispose of waste according to applicable legislation.

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.: 3295

14.2. UN proper shipping name

Land transport (ADR/RID)

KOHLLENWASSERSTOFFE, FLÜSSIG, N.A.G.

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

HYDROCARBONS, LIQUID, N.O.S.

14.3. Transport hazard class(es)

Hazard label(s) / Label: 3

Classification code: / Classification Code: F1



14.4. Packing group

Packing group/ Packing Group: III

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: 3

Special provisions:

tunnel restriction code: D/E

Limited quantity (LQ): 5 L

Sea transport (IMDG)

EmS-No: F-E, S-D

Special provisions: 223 Limited quantity (LQ): 5 L

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

Remark -

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:

-

Use restriction according to REACH annex XVII, no.::

-

National regulations

Observe in addition any national regulations!

Restrictions of occupation

-

Other regulations, restrictions and prohibition regulations

-

15.2. Chemical Safety Assessment

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

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

SECTION 16: Other information

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

Hazard statements

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Training advice

-

Recommended restrictions of use:

refer to chapter 1.

Further remarks:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storag

Documentation of changes:

Changes in comparison to version 3:

- 1.4 Company name added.
- 2 updated according to 3.2
- 3.2 updated
- 4 reworked
- 5 reworked
- 6.3 reworked
- 8.2 reworked
- 10 reworked
- 14 UN-Number changed
- 16 documentation on change added.

Key literature references and sources for data

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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 bioaccumulative)