

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

1.1. Product identifier

Systemerm Cast

UFI H9QH-8DFD-591K-1G64

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)2374 920050-50

Supplier

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10

Telefax: +49 (0)2374 920050-50

Information contact

pro3dure medical GmbH

Information telephone +49 (0)2374 920050-10
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:
Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1/1A/1B, H317; STOT RE 2, H373; Aquatic Chronic 3, H412

2.2. Label elements

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

Hazard pictograms



GHS05, GHS07, GHS08

Signal word:

Danger

Hazard statements:

- H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

- 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.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+352 IF ON SKIN: Wash with plenty of water/soap.
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P314 Get medical advice/attention if you feel unwell.
P321 Specific treatment (see information on this label).
P330 Rinse mouth.
P333+313 If skin irritation or rash occurs: Get medical advice/attention.
P362+364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container according to official regulations.

Special labelling of particular preparations:

-

2.3. Other hazards

-

SECTION 3: Composition / information on ingredients

3.1. Substances

-

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
Acryloyl morpholine	5117-12-4		80-100 %	Acute Tox. 4, H302; STOT RE 2, H373; Eye Dam. 1, H318; Skin Sens. 1/1A/1B, H317	M = keiner ATE (dermal) = > 2000 ATE (oral) = 588 ATE (inhalativ) = Kein Wert ermittelbar
Phenyl-bis(2,4,6-trimethylbenzoyl)phosphine oxide	162881-26-7		< 01 %	Skin Sens. 1/1A/1B, H317; Aquatic Chronic 4, H413	M = 0 ATE (dermal) = 2000 mg/kg ATE (oral) = 2000 mg/kg ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8		< 01 %	Repr. 2, H361; Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	M = 0 ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = 2000

(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. In case of respiratory tract irritation, consult a physician.
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 flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.
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

-

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

-

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	ABC-powder alcohol resistant foam BC-powder Carbon dioxide (CO ₂) Water spray jet
Unsuitable extinguishing media	Excess water Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Pyrolysis products, toxic.

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.

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. Keep away from unprotected people. Keep upwind.

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

Avoid contact with skin and eyes. Do not breathe gas/fumes/vapour/spray. Keep away from sources of ignition - No smoking.

Precautions against fire and explosion:

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place. Only use the material in places where open light, fire and other flammable sources can be kept away. Use only in well-ventilated areas.

Hints on joint storage

-

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
Acryloyl morpholine	5117-12-4	worker inhalative long-term, systemic 132,24 mg/m ³ worker inhalative short-term, systemic 132,24 mg/m ³ worker dermal long-term, systemic 300 mg/kg bw/day worker dermal long-term, systemic 300 mg/kg bw/day
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	worker inhalative long-term, systemic 0,822 mg/m ³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m ³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 mg/kg bw/day
Phenyl-bis(2,4,6-trimethylbenzoyl)phosphine oxide	162881-26-7	worker inhalative long-term, systemic 21 mg/m ³ worker dermal long-term, systemic 3 mg/kg bw/day population inhalative long-term, systemic 5,2 mg/m ³ population dermal long-term, systemic 1,5 mg/kg bw/day population oral long-term, systemic 1,5 mg/kg bw/day

PNEC Value

Substance:	CAS-No.:	PNEC
Acryloyl morpholine	5117-12-4	aquatic, freshwater 12 µg/l sediment, freshwater 9 µg/kg dw soil 1 µg/kg dw
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	aquatic, freshwater 1,4 µg/l aquatic, marine water 0,14 µg/l sediment, freshwater 115 µg/kg dw sediment, marine water 11,5 µg/kg dw soil 22,2 µg/kg dw
Phenyl-bis(2,4,6-trimethylbenzoyl)phosphine oxide	162881-26-7	aquatic, freshwater 1 µg/l intermittent release, freshwater 1 µg/l aquatic, freshwater 1 µg/l sewage treatment plant 1000 µg/l sediment, freshwater 712 µg/kg dw intermittent release, marine water 712 µg/l soil 20000 µg/kg dw

Additional information

-

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

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

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

Suitable gloves type: NBR (Nitrile rubber).

Eye/face protection

Tightly sealed safety glasses. Eye-shade.

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

Do not allow to enter into surface water or drains.

Consumer exposure controls

-

Exposure Scenario:

-

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
Colour: slightly yellowish
Odour: characteristic
Odour threshold: No data available

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:	@25°C	ca. 1,1	g/cm ³	
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

-

SECTION 10: Stability and reactivity

10.1. Reactivity

Sensitivity to light (photosensitive).

10.2. Chemical stability

Can polymerise exothermically if heated, exposed to air, sunlight or by addition of free radical initiators.

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

Heat UV-radiation/sunlight. UV-radiation/sunlight.

10.5. Incompatible materials

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.6. Hazardous decomposition products

In case of fire may be liberated: Pyrolysis products, toxic. 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: none
Acute toxicity (oral): 588

Acute toxicity (dermal): > 2000
Acute toxicity (inhalative): > 2000

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Phenyl-bis(2,4,6-trimethylbenzoyl)phosphine oxide	162881-26-7	LD50 oral (rat) > 2000 mg/kg LD50 dermal (rat) > 2000 mg/kg
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	LC50 inhalation (Rat) 2000 mg/ kg bw LD50 oral (rat) 5000 mg/kg bw LD50 dermal (rat) > 2000 mg/kg bw
Acryloyl morpholine	5117-12-4	LD50 oral (rat) 588 mg/kg LD50 dermal (rat) > 2000 mg/kg

Skin corrosion/irritation:

Not an irritant.

Serious eye damage/irritation:

Risk of serious damage to eyes.

Respiratory or skin sensitisation:

May cause sensitization by inhalation and skin contact.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

No indications of human carcinogenicity exist.

Germ cell mutagenicity:

No data available

Reproductive toxicity:

No data available

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

-

SECTION 12: Ecological information

12.1. Toxicity

-

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Phenyl-bis(2,4,6-trimethylbenzoyl)phosphine oxide	162881-26-7	EC50 Algae (Scenedesmus subspicatus) 72 h > 0,26 mg/l NOEC (algae, 72h) > 0,26 mg/l LC50 (fish, 96 h) > 0,09 mg/L NOEC (fish, 96h) > 0,09 mg/L EC50 (microorganisms, 3h) > 0,1 g/L EC50 (Daphnia, 48 h) > 1,175 mg/L
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	EC50 (Daphnia, 48 h) 3,53 mg/L EC50 (algae, 72 h) > 2,01 mg/L
Acryloyl morpholine	5117-12-4	EC50 (algae, 72 h) > 120 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:

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

-

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 -

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:

-

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

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

Training advice

-

Recommended restrictions of use:

-

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 storage.

Documentation of changes:

Changes compared to version 3:

- 1.1 UFI-code added.

Changes compared to version 2:

- 1.4 Name of the company inserted
- 3.2 Classification of the components of the mixture updated
- 5.1 Extinguishing agent revised
- 8.1 revised according to 3.2
- 8.2 revised
- 10 revised
- 11.1 revised according to 3.2
- 12.1 revised according to 3.2
- 13 revised
- 16 Documentation of changes introduced
- 16 List of abbreviations introduced

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 Kurzzeiteexposition (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)