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

1.1. Product identifier

CORiTEC splint comfort

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

Relevant identified uses: Manufacture.
Uses advised against: Do not use for private purposes (household).

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

prிடெнта GmbH
Meisenweg 37
D 70771 Leinfelden-Echterdingen

Telephone +49 (0)711 320 656-0

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

2.2. Label elements

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

Hazard pictograms

Signal word: -

Hazard statements: -

-

Precautionary statements: -

-

Hazardous component(s) for labelling:

-

Special labelling of particular preparations:

-

2.3. Other hazards

-

SECTION 3: Composition / information on ingredients

3.1. Substances

-

3.2. Mixtures

-

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Polyethylmethacrylat, homopolymer		9003-42-3			>90	-
1,2-Cyclohexandicarbonsäurediisononylester	431-890-2	166412-78-8			<10	-

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: No special measures are necessary.

In case of inhalation: Consult a doctor.

Following skin contact: not applicable.

After eye contact:

Rinse thoroughly with water. Consult an ophthalmologist if symptoms persist.

After ingestion: Contact physician in case of discomfort.

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 Water fog. Carbon dioxide (CO₂). Foam. dry extinguishing powder.

Unsuitable extinguishing media High power water jet.

5.2. Special hazards arising from the substance or mixture

5.3. Advice for firefighters

General information

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

6.2. Environmental precautions

6.3. Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

6.4. Reference to other sections

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

Devices with local exhaust

Precautions against fire and explosion:

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store in a dry place and protect from heat.

Hints on joint storage

7.3. Specific end use(s)

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

PNEC Value

Substance:	CAS-No.:	PNEC

Additional information

-

8.2. Exposure controls

Occupational exposure controls:

-

General protection and hygiene measures:

-

Personal protection equipment

lab coat

Respiratory protection

Devices with local exhaust

Hand protection

protectiv glove

Eye/face protection

Eye glasses with side protection

Body protection:

lab coat

Environmental exposure controls

-

Consumer exposure controls

-

Exposure Scenario:

-

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: solid

Colour:

Odour:

Odour threshold:

Safety relevant basis data

	parameter	Value	unit	Remark
pH:				No data available

Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point:	>250 °C
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Explosivity:	No data available
Upper flammability or explosive limits:	No data available
lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Density:	No data available
Soluble (g/L) in:	No data available
Water solubility (g/L):	No data available
Fat solubility (g/L):	No data available
Partition coefficient: n-octanol/water:	No data available
Ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Oxidizing properties:	No data available

9.2. Other information

-

SECTION 10: Stability and reactivity

10.1. Reactivity

-

10.2. Chemical stability

-

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions. Thermal decomposition can lead to the escape of irritating gases and vapours.

10.4. Conditions to avoid

-

10.5. Incompatible materials

-

10.6. Hazardous decomposition products

-

SECTION 11: Toxicological information

11.1. Information on toxicological effects

-

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

Acute toxicity

Substance:	CAS-No.:	Toxicological information
1,2-Cyclohexandicarbonsäurediisononylester	166412-78-8	
Polyethylmethacrylat, homopolymer	9003-42-3	

Skin corrosion/irritation:

-

Serious eye damage/irritation:

-

Respiratory or skin sensitisation:

-

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

-

Germ cell mutagenicity:

-

Reproductive toxicity:

-

STOT-single exposure:

-

STOT-repeated exposure:

-

Aspiration hazard:

-

SECTION 12: Ecological information

12.1. Toxicity

none

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
1,2-Cyclohexandicarbonsäurediisononylester	166412-78-8	
Polyethylmethacrylat, homopolymer	9003-42-3	

12.2. Persistence and degradability

low water solubility, unlikely bioavailability

12.3. Bioaccumulative potential

not applicable

12.4. Mobility in soil

-

12.5. Results of PBT and vPvB assessment

-

12.6. Other adverse effects

none

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Dispose of waste according to applicable legislation.

Appropriate disposal / Package

Dispose of waste according to applicable legislation.

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

-

Waste key product: -

Waste key packaging: -

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.

-

SECTION 16: Other information

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

Hazard statements

-

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, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Documentation of changes:

-

Key literature references and sources for data

-

Abbreviations and acronyms

-
