

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

### **1.1. Product identifier**

# **PRO3Dent Splint | MSI**

### **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**

pro3dure medical GmbH  
Am Burgberg 13  
D 58624 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**

### **2.2. Label elements**

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

**Hazard pictograms**

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**Signal word:**

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**Hazard statements:**

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**Precautionary statements:**

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Hazardous component(s) for labelling:

-

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

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#### 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 (CO<sub>2</sub>). Foam. dry extinguishing powder.

**Unsuitable extinguishing media** High power water jet.

### 5.2. Special hazards arising from the substance or mixture

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### 5.3. Advice for firefighters

#### General information

-

#### Special protective equipment for fire-fighters:

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

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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

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### 6.2. Environmental precautions

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### 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

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## 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

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### 7.3. Specific end use(s)

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## 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 <sup>3</sup> ]	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/m³]	Limitation of exposure peaks:	Remark:
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**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:**

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**General protection and hygiene measures:**

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**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 / °F
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

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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

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### 10.2. Chemical stability

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### 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

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### 10.5. Incompatible materials

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### 10.6. Hazardous decomposition products

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## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

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

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## 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:

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

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

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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.::

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#### National regulations

Observe in addition any national regulations!

Restrictions of occupation

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Other regulations, restrictions and prohibition regulations

-

### 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

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Training advice

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Recommended restrictions of use:

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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**

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