

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier****SprintRay EU Splint Flex****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**

SprintRay Europe GmbH

Brunnenweg 11
D 64331 Weiterstadt**Telephone** +49 (0)6150 9789480**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

Diese Nummer ist nur zu Bürozeiten erreichbar
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:

Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1/1A/1B, H317; STOT SE 3, H335; Aquatic Chronic 3, H412

2.2. Label elements**Classification according to Regulation (EC) No 1272/2008 [CLP]****Hazard pictograms**GHS07
Warning**Signal word:****Hazard statements:**

- H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264 Wash thoroughly after handling.
 P271 Use only outdoors or in a well-ventilated area.
 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.
 P302+352 IF ON SKIN: Wash with plenty of water/soap.
 P304+340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P312 Call a POISON CENTER/doctor if you feel unwell.
 P321 Specific treatment (see information on this label).
 P332+313 If skin irritation occurs: Get medical advice/attention.
 P333+313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+313 If eye irritation persists: Get medical advice/attention.
 P362+364 Take off contaminated clothing and wash it before reuse.
 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.

Hazardous component(s) for labelling:

-

Special labelling of particular preparations:

Safety data sheet available on request.

2.3. Other hazards

-

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

-

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Methacrylate Monomer 1	-	-	-	-	<60	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
Methacrylate Monomer 2	-	-	-	-	<40	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335
Photoinitiator	-	-	-	-	<2	Repr. 2, H361
Methacrylate Monomer 3	-	-	-	-	<2	-

(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 (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing.
- In case of inhalation:** Move victim to fresh air. Put victim at rest and keep warm. In case of irregular breathing or respiratory arrest provide artificial respiration. Call a physician immediately.
- Following skin contact:** Take off immediately all contaminated clothing. After contact with skin, wash immediately with plenty of water and soap. Call a physician immediately.
- 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. No administration in cases of unconsciousness or cramps. Call a physician immediately.

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

Erythema (redness) Causes skin irritation.

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

Provide fresh air. In case of breathing difficulties administer oxygen.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media** Carbon dioxide (CO₂). Dry extinguishing powder.
- Unsuitable extinguishing media** Water fog. High power water jet. Water. Foam.

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.

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

Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation. Wear personal protection equipment.

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.

Precautions against fire and explosion:

Take precautionary measures against static discharges.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and in a well-ventilated place. Keep container tightly closed in a cool, well-ventilated place. Protect against: UV-radiation/sunlight.

Hints on joint storage

Do not store together with: Oxidizing agent

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
Methacrylate Monomer 2	-	worker inhalative systemic 3,52 mg/m ³ worker dermal systemic 2 mg/m ³ /24h consumer inhalative systemisch 870 µg/m ³ consumer dermal systemic 1 mg/m ³ /24h consumer systemic 500 µg/m ³ /24h

PNEC Value

Substance:	CAS-No.:	PNEC

Additional information

None

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

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

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

Eye/face protection

Tightly sealed safety glasses.

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:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
Colour: colourless light yellow
Odour: Fruity
Odour threshold: No data available

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:				No data available
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:	1,1 g/mL	
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:	°C < 1,5 Pa*s	
Oxidizing properties:		No data available

9.2. Other information

None

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

With proper storage and handling the product is stable.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

heat. UV-radiation/sunlight.

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

Carbon monoxide; carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Methacrylate Monomer 2	-	LD50 oral (rat) 2000 mg/kg LD50 dermal 2000 mg/kg

Skin corrosion/irritation:

Frequently or prolonged contact with skin may cause dermal irritation.

Serious eye damage/irritation:

Strongly irritant. Risk of serious damage to eyes.

Respiratory or skin sensitisation:

May cause sensitisation especially in sensitive humans.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

No information available.

Germ cell mutagenicity:

No information available.

Reproductive toxicity:

No information available.

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

The inhalation of dust/mist or aerosols causes irritation of the respiratory tract.

SECTION 12: Ecological information

12.1. Toxicity

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Methacrylate Monomer 2	-	LC50 (fish, 96 h) 100 mg/l LC50 (crustaceans, 48h) 6 mg/l Ec50 algae 100 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. 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. Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste. Must not be disposed together with household garbage.

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

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Waste key product: 08 04 09 - Waste adhesives and sealants containing organic solvents or other dangerous substances

Waste key packaging: 15 01 10 - packaging containing residues of or contaminated by dangerous substances

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:	Yes	No
Marine pollutant:	<input type="checkbox"/>	<input checked="" type="checkbox"/>

14.6. Special precautions for user

Land transport (ADR/RID)

Transport category:	-	Tunnel restriction code:	-
Special provisions:	-	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

None

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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Training advice

None

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 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:

None

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

None
