

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Version: 3 Revision date: 18.12.2020 Replaces version: 2 from: 25.06.2020

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

1.1. Product identifier

SprintRay EU Surgical Guide

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

Telephone +49 (0)2374 920050-10

Am Burgberg 13 **Telefax**: +49 (0)2374 920050-50

D 58642 Iserlohn

Supplier

SprintRay Europe GmbH

Telephone +49 (0)6150 9789480

Brunnenweg 11

D 64331 Weiterstadt

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

Telephone +49 (0)2374 920050-10

This number is serviced during office hours.

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

2.2. Label elements

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

Hazard pictograms

GHS07

Signal word: Warning

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Hazard statements:

H315 Causes skin irritation.

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

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.
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.

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P312 Call a POISON CENTER/doctor if you feel unwell.
P321 Specific treatment (see information on this label).
P333+313 If skin irritation or rash occurs: Get medical advice/attention.

P337+313 If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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:

Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid

Special labelling of particular preparations:

Safety data sheet available on request.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture with, among others, the following ingredients and other non-hazardous admixtures

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Esterification products of 4,4'- isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	609-946-4	41637-38-1		01- 2119980659- 17-xxxx	> 95	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335
Phenyl bis(2,4,6- trimethylbenzoyl)- phosphine oxide	423-340-5	162881-26- 7		01- 2119489401- 38-xxxx	< 2	Skin Sens. 1, H317; Aquatic Chronic 4, H413

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

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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

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contaminated clothing.

In case of inhalation: Move victim to fresh air. Put victim at rest and keep warm. Seek medical

attention if problems persist.

Following skin After contact with skin, wash immediately with plenty of water and soap. In case

contact: 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. Seek medical attention if problems persist.

After ingestion: Rinse mouth immediately and drink plenty of water. No administration in cases of

unconsciousness or cramps. Do NOT induce vomiting. Seek medical attention if

problems persist.

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

No known symptoms to date.

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 Carbon dioxide (CO2). Dry extinguishing powder.

extinguishing media

Unsuitable Water fog. High power water jet. Water. Foam.

extinguishing media

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

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.

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6.4. Reference to other sections

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

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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 Keep away from food, drink and animal feedingstuffs.

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	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m³]	peaks:	

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	Sou	ırce: Occ	cupational	Occupational	Limitation of	Remark:
			exp	oosure limit	exposure limit	exposure	
			valı	ue:[ppm]	value:[mg/m³]	peaks:	

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	worker inhalative systemic 3,52 mg/m³ worker dermal systemic 2 mg/m3/24h
		consumer inhalative systemic 870 μg/m³ consumer dermal systemic 1 mg/m3/24h
		consumer systemic 500 μg/m3/24h

PNEC Value

Substance:	CAS-No.:	PNEC
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Additional information

none

8.2. Exposure controls

Occupational exposure controls:

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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.

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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

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

Tightly sealed safety glasses.

Body protection:

Suitable protective clothing: Overall. 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.

Environmental exposure controls

See section 7. No additional measures 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: different
Odour: characteristic

Odour threshold: -

Safety relevant basis data

explosive limits:

	parameter	Value	unit	Remark
pH:				No data available
Melting point/freezing point:				No data available
Initial boiling point and boiling				No data available
range:				
Flash point:		113	°C	
Evaporation rate:				No data available
Flammability (solid, gas):				No data available
Explosivity:				No data available
Upper flammability or				No data available

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No data available lower flammability or

explosive limits: Vapour pressure: No data available Vapour density: No data available Relative density: No data available

°C Density: 1,1 g/cm³

Soluble (g/L) in: No data available Water solubility (g/L): No data available Fat solubility (g/L): No data available Partition coefficient: n-No data available

octanol/water:

Ignition temperature: No data available **Decomposition temperature:** No data available

Viscosity: 0,4 - 1,5 Pa*s

Oxidizing properties: No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

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

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

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
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LD50 oral (rat) 2000 mg/kg
and 2-methylprop-2-enoic acid		LD 50 dermal 2000 mg/kg

Skin corrosion/irritation:

EN - 07.2018 Page 6 / 10 May cause an allergic skin reaction.

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)

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Carcinogenicity:

No indication of human carcinogenicity.

Germ cell mutagenicity:

No indications of human germ cell mutagenicity exist.

Reproductive toxicity:

No indications of human reproductive toxicity exist.

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

No data available

SECTION 12: Ecological information

12.1. Toxicity

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	LC50 (fish, 96 h) 0,09 mg/l
		LC50 (crustaceans, 48h) 1,175 mg/l
		EC50 (algae, 96 h) 0,26 mg/l
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LC50 (fish, 96 h) 100 mg/l
and 2-methylprop-2-enoic acid		LC50 (crustaceans, 48h) 6 mg/l
		EC50 (algae, 72h) 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

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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.

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Appropriate disposal / Package

Remark

none

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.

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:	code: / Clas	ssification	-
14.4. Packing group Packing group/ Packing Group:	-			
14.5. Environmental hazards				
ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant:	Yes	No X X		
14.6. Special precautions for user Land transport (ADR/RID) transport category: Special provisions:	tunnel restrictio Limited quantity		- -	
Sea transport (IMDG) EmS-No: - Special provisions: - Limited	quantity (LQ): -			

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

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)

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

none

Other regulations, restrictions and prohibition regulations

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15.2. Chemical Safety Assessment

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

Chemical safety assessments for substances in this mixture were not 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

none

Recommended restrictions of use:

refer to chapter 1.

Further remarks:

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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.

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Documentation of changes:

none

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

none

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