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

Version: 2 Replaces version: 1 Revision date: 21.02.2019 from: 19.02.2018

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

1.1. Product identifier

GR-16 Xray

JV curable resin

CAS No.: EC No.: INDEX No.: **REACH No.:**

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

Supplier

pro3dure medical GmbH

Am Burgberg 13 58642 D Iserlohn Telephone +49 (0)2374 920050-10 Telefax: +49 (0)2374 920050-50

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

Diese Nummer ist nur zu Bürozeiten erreichbar

Telephone +49 (0)2374 920050-10

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008: Identification is not obligatory. Please observe the information on the safety data sheet at all times.

2.2. Label elements

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

Hazard pictograms

EN - 07.2018

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) GR-16 Xray

	GHS07
Signal word:	Warning
Hazard statem	nents:
H317	May cause an allergic skin reaction.
H413	May cause long lasting harmful effects to aquatic life.
Precautionary	statements:
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
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/.?.
P333+313	If skin irritation or rash occurs: Get medical advice/attention.
P362+364	Take off contaminated clothing and wash it before reuse.

Hazardous component(s) for labelling:

Special labelling of particular preparations:

2.3. Other hazards

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentratio n:	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- 17-0000	30 - 90 %	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			< 3 %	-

(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:	No special measures are necessary. 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. Change contaminated, saturated clothing.
After eye contact:	No special measures are necessary. Seek medical attention if problems persist.
After ingestion:	No special measures are necessary. 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 Provide fresh air. Treat symptomatically. First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

SuitableDry extinguishing powder Carbon dioxide (CO2)extinguishing mediaWater spray jet Full water jet Water Foamextinguishing mediaWater spray jet Full water jet Water Foam

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Water mist Carbon monoxide Carbon dioxide (CO2)

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely. Co-ordinate fire-fighting measures to the fire surroundings. 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. Remove all sources of ignition.

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:

Take precautionary measures against static discharges.

EN - 07.2018

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. Protect against direct 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

Subst	ance:	CAS-No.:	Source:	Occupational	Occupational	Limitation of	Remark:
				exposure limit	exposure limit	exposure	
				value:[ppm]	value:[mg/m ³]	peaks:	

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

Substance:	CAS-No.:	Source:	Occupational	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m ³]	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 xxx(systemisch) 3,52 mg/m ³ worker dermal xxx(systemisch) 2 xxx(mg/m3/24h) xxx(Verbraucher) inhalative xxx(systemisch) 870 µg/m ³ xxx(Verbraucher) dermal xxx(systemisch) 1 xxx(mg/m3/24h) xxx(Verbraucher) xxx(systemisch) 500 xxx(µg/m3/24h)

PNEC Value

Substance:	CAS-No.:	PNEC				

Additional information

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

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: Self-contained respirator (breathing apparatus) (DIN EN 133)

Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: DIN EN 374 Suitable gloves type: Suitable material: Butyl caoutchouc (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:

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Physical state: Colour: Odour: Odour: Odour threshold:	Liquid white characteristic			-
Odour threshold:	No data avail	able		
Safety relevant basis data	parameter	Value	unit	Remark
pH:				not applicable
Melting point/freezing point:				No data available
Initial boiling point and boiling				No data available
range:				
Flash point:				No data available
Evaporation rate:				No data available No data available
Flammability (solid, gas): Explosivity:				No data available
Upper flammability or				not applicable
explosive limits:				not applicable
lower flammability or				not applicable
explosive limits:				
Vapour pressure:				No data available
Vapour density:				No data available
Relative density:				No data available
Density:		1,35	g/cm³	Ne dete evelleble
Soluble (g/L) in: Water solubility (g/L):				No data available 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:				No data available
Oxidizing properties:				No data available

9.2. Other information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) GR-16 Xray

ZZZZ (-)

SECTION 10: Stability and reactivity

10.1. Reactivity

No known hazardous reactions.

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Polymerisation

10.4. Conditions to avoid

No special measures are necessary. Seek medical attention if problems persist. Humidity

10.5. Incompatible materials

No information available.

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 preparation/mixture itself.

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

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LD50 oral (rat) 2000 mg/kg
and 2-methylprop-2-enoic acid		XXX 2000 mg/kg

Skin corrosion/irritation:

There are no data available on the preparation/mixture itself. Irritant Bridging principle "Dilution".

Serious eye damage/irritation:

There are no data available on the preparation/mixture itself. Not an irritant. Bridging principle "Dilution".

Respiratory or skin sensitisation:

May cause sensitisation especially in sensitive humans.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

There are no data available on the preparation/mixture itself. No indication of human carcinogenicity. Bridging principle "Dilution".

Germ cell mutagenicity:

There are no data available on the preparation/mixture itself. No indications of human germ cell mutagenicity exist. Bridging principle "Dilution".

Reproductive toxicity:

There are no data available on the preparation/mixture itself. No indications of human reproductive toxicity exist. Bridging principle "Dilution".

STOT-single exposure:

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

STOT-repeated exposure:

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

Aspiration hazard:

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

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
		XXX 100 mg/l

12.2. Persistence and degradability

There are no data available on the preparation/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

This substance does not meet the criteria for classification as PBT or vPvB.

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:

Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.

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

Dispose of waste according to applicable legislation.

Waste key product:	0 11	08 04 09 - waste adhesives and sealants containing organic solvents
Waste key packaging:		or other dangerous substances 15 01 10 - packaging containing residues of or contaminated by dangerous substances

EN - 07.2018

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) GR-16 Xray

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 X X X
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 qu	antity (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: not relevant	
Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:	

not relevant

Regulation (EC) No. 648/2004 (Detergents regulation) not relevant Regulation (EC) No 850/2004 [POP-Regulation]: not relevant

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals: not relevant

Use restriction according to REACH annex XVII, no.:: not relevant

National regulations

Observe in addition any national regulations!

Restrictions of occupation No information available.

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

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

Training advice

none

Recommended restrictions of use:

No special measures are necessary.

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 Data arise from reference works and literature.

Abbreviations and acronyms