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

Version: 1 Replaces version:

Revision date: 21.02.2019 from:

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

1.1. Product identifier

**GR-15** gingiva

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 Iserlohn D

Telephone +49 (0)2374 920050-10 Telefax: +49 (0)2374 920050-50

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Information contact

pro3dure medical GmbH

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# 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: 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
Hazard staten	nents:
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary	v 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/.?.
P304+340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+351+33	B IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
present and ea	asy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/.?/if you feel unwell.
P321	Specific treatment (see .? 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 to .?.

## Hazardous component(s) for labelling:

xxx (Methacrylsäuretetrahydrofurfurylester)

Special labelling of particular preparations: none

## 2.3. Other hazards

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# **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.:	Concentration:	Classification: EC 1272/2008 (CLP):
Bisphenol A-ethoxylat (2 EO/Phenol) Dimethacrylate	609-946-4	41637-38-1		01- 2119980659- 17-0000	< 35 %	-
Methacrylic acid trahydrofurfuryl ester	219-529-5	2455-24-5	607-134-00-4	01- 2120748481- 53-0000	< 35 %	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
Diphenyl-(2,4,6- trimethylbenzoyl)phosp hinoxide	278-355-8	75980-60-8		01- 2119972295- 29-0000	< 2 %	Repr. 2, H361

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

# **SECTION 4: First aid measures**

4.1. Description of fir	rst 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 flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.
After ingestion:	If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

# 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 Water fog. High power water jet. Carbon dioxide (CO2). Foam. dry extinguishing powder. Unsuitable - 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**

In case of fire and/or explosion do not breathe fumes. Co-ordinate fire-fighting measures to the fire surroundings.

## 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

Use personal protection equipment. Remove all sources of ignition. Provide adequate ventilation.

# 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

## 6.3. Methods and material for containment and cleaning up

Suitable material for taking up: Sand Kieselguhr Sawdust Take up mechanically, placing in appropriate containers for disposal.

# 6.4. Reference to other sections

ZZZZ (-)

# **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

Advices on safe handling

When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. All work processes must always be designed so that the following is excluded: Inhalation

## Precautions against fire and explosion:

Always close containers tightly after the removal of product. Use only in well-ventilated areas.

#### 7.2. Conditions for safe storage, including any incompatibilities Requirements for storage rooms and vessels

Only use the material in places where open light, fire and other flammable sources can be kept away.

## Hints on joint storage

-

## 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/m <sup>3</sup> ]	peaks:	

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

Substance:	CAS-No.:	S	Source:	Occupational	Occupational	Limitation of	Remark:
				exposure limit	exposure limit	exposure	
				value:[ppm]	value:[mg/m <sup>3</sup> ]	peaks:	

## **DNEL-/PNEC-values**

DNEL value

Substance:

DNEL/DMEL

## **PNEC** Value

Substance:

CAS-No.: PNEC

CAS-No.:

## **Additional information**

## 8.2. Exposure controls

Occupational exposure controls:

## 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

Only wear fitting, comfortable and clean protective clothing.

#### **Respiratory protection**

Respiratory protection necessary at: Formation of aerosol. Suitable respiratory protection apparatus: Combination filter device (DIN EN 141)..

#### Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: DIN EN 374

#### Eye/face protection

Tightly sealed safety glasses. Eye-shade.

#### **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**

-

**Consumer exposure controls** 

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## **Exposure Scenario:**

-

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

s. i. information on basic p	mysical and chemical propert
Appearance	
Physical state:	Liquid
Colour:	rose opaque
Odour:	ester like
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				No data available
range:				
Flash point:				No data available
Evaporation rate:				No data available
Flammability (solid, gas):				No data available
Explosivity:				No data available
Upper flammability or				No data available
explosive limits:				
lower flammability or				No data available
explosive limits:				
Vapour pressure:				No data available
Vapour density:				No data available
Relative density:				No data available
Density:	at 20°C	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

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Partition coefficient: n- octanol/water:			No data available
Ignition temperature:			No data available
Decomposition temperature:			No data available
Viscosity:	at 20°C	2.5 Pas	
Oxidizing properties:			No data available

## 9.2. Other information

none

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

-

## 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

heat. UV-radiation/sunlight.

## **10.5.** Incompatible materials

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators.

## **10.6. Hazardous decomposition products**

In case of fire may be liberated: Carbon dioxide. Carbon monoxide.

# **SECTION 11: Toxicological information**

## 11.1. Information on toxicological effects

There are no data available on the mixture itself.

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

#### Acute toxicity

Substance:	CAS-No.:	Toxicological information
xxxx(Diphenyl-(2,4,6-trimethylbenzoyl)phosphinoxid)	75980-60-8	
xxxx(Bisphenol A-ethoxylat (2 EO/Phenol) Dimethacrylat)	41637-38-1	
xxxx(Methacrylsäuretetrahydrofurfurylester)	2455-24-5	

## Skin corrosion/irritation:

irritant.

## Serious eye damage/irritation:

irritant.

#### Respiratory or skin sensitisation:

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

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

Germ cell mutagenicity:

Reproductive toxicity:

STOT-single exposure:

## **STOT-repeated exposure:**

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 mixture itself.

#### Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
xxxx(Diphenyl-(2,4,6-trimethylbenzoyl)phosphinoxid)	75980-60-8	
xxxx(Bisphenol A-ethoxylat (2 EO/Phenol) Dimethacrylat)	41637-38-1	
xxxx(Methacrylsäuretetrahydrofurfurylester)	2455-24-5	

## 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.

## Appropriate disposal / Package

Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

## 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.

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Waste key packaging:	08 04 09 - waste adhesives and sealants containing organic solvents or other dangerous substances 15 01 10 - packaging containing residues of or contaminated by dangerous substances				
SECTION 14: Transport inform	nation				
14.1. UN number UN No.:	-				
14.2. UN proper shipping nam Land transport (ADR/RID)	1e				
-					
Sea transport (IMDG), Air transp - -	oort (ICAO-TI / IATA-DGR)				
14.3. Transport hazard class(e Hazard label(s) / Label:	es) - Classification code: / Code:	Classification -			
14.4. Packing group Packing group/ Packing Group:	-				
14.5. Environmental hazards					
ADR/RID / IMDG / ICAO-TI / IATA Marine pollutant:	A-DGR:				
14.6. Special precautions for u Land transport (ADR/RID) transport category: - Special provisions: -	user tunnel restriction code Limited quantity (LQ):				
Sea transport (IMDG) EmS-No: - Special provisions: -	Limited quantity (LQ): -				
	ling to Annex II of MARPOL 73/7	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:

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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Training advice

#### **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:**

#### Key literature references and sources for data

Abbreviations and acronyms