

**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-14.1 denture

UV 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

Telephone +49 (0)2374 920050-10

Telefax: +49 (0)2374 920050-50

Supplier

pro3dure medical GmbH

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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

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



Signal word: GHS07
Warning

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/?.
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 .? 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:

Special labelling of particular preparations:

-

2.3. Other hazards

-

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): |
|--|-----------|------------|------------|-----------------------|----------------|-------------------------------------|
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate | 276-957-5 | 72869-86-4 | | 01-2120751202-68-0000 | < 25 % | Skin Sens. 1/1A/1B, H317 |
| Diphenyl-(2,4,6-trimethylbenzoyl)phosphin oxid) | 278-355-8 | 75980-60-8 | | 01-2119972295-29-0000 | < 2 % | Repr. 2, H361 |
| 3,6,9-trioxaundecamethylene dimethacrylate | 203-653-1 | 109-17-1 | | 01-2120762746-43-0000 | < 15 % | - |
| Bisphenol A-ethoxylat (2 EO/Phenol) Dimethacrylat | 609-946-4 | 41637-38-1 | | 01-2119980659-17-0000 | < 100 % | - |

(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:** After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician. Change contaminated, saturated clothing.
- 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:** Rinse mouth immediately and drink plenty of water. No administration in cases of unconsciousness or cramps. Do NOT induce vomiting. Call a physician immediately.

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

-

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

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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media** 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: Water mist Carbon monoxide Carbon dioxide (CO₂)

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

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. Do not allow to enter into surface water or drains.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Prevent spread over a wide area (e.g. by containment or oil barriers). Retain contaminated washing water and dispose it.

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

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:

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

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

-

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/m³] | 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: |
|------------|----------|---------|---|---|-------------------------------|---------|
| | | | | | | |

DNEL-/PNEC-values

DNEL value

| Substance: | CAS-No.: | DNEL/DMEL |
|--|------------|---|
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | worker inhalative xxx(systemisch) 3,3 mg/m³ worker dermal xxx(systemisch) 1,3 xxx(mg/kg bw /24h) xxx(Verbraucher) inhalative xxx(systemisch) 0,6 mg/m³ xxx(Verbraucher) dermal xxx(systemisch) 0,7 xxx(mg/kg bw/24h) xxx(Verbraucher) xxx(systemisch) 0,3 xxx(mg/kg bw/24h) |

PNEC Value

| Substance: | CAS-No.: | PNEC |
|--|------------|---|
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | xxx(Süßwasser) 0,01 mg/l xxx(Meerwasser) 0,001 mg/l xxx(Kläranlagen) 3,61 mg/l xxx(Süßwassersediment) 4,56 xxx(mg/kg Sediment) xxx(Meeressediment) 0,46 xxx(mg/kg Sediment) soil 0,91 xxx(mg/kg Boden) |

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.

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

-

Exposure Scenario:

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
Colour: various
Odour: weak
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: | 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: | at °C: 1.1 g/cm ³ |
| 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: | at room temperature 0.5 Pas |
| Oxidizing properties: | No data available |

9.2. Other information

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SECTION 10: Stability and reactivity

10.1. Reactivity

-

10.2. Chemical stability

Decomposition with: UV-radiation/sunlight. heat.

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 of free radical initiators.

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 mixture itself.

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

Acute toxicity

| Substance: | CAS-No.: | Toxicological information |
|--|------------|-----------------------------------|
| 3,6,9-trioxaundecamethylene dimethacrylate | 109-17-1 | LD50 dermal (rabbit) > 3000 mg/kg |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | LD50 oral (rat) > 5000 mg/kg |

Skin corrosion/irritation:
irritant.

Serious eye damage/irritation:
irritant.

Respiratory or skin sensitisation:
May cause sensitisation especially in sensitive humans.

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

There are no data available on the mixture itself.

Ecotoxicity

| Substance: | CAS-No.: | Ecotoxicity |
|--|------------|-----------------------------------|
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | XXX > 1,2 mg/l XXX > 0,68 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.

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

Dispose of waste according to applicable legislation.

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:

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 -

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

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. -

-

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

-
