

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

1.1. Product identifier

printodent GR-14.1 denture

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). Observe instructions for use.

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

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10

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Information contact

pro3dure medical GmbH

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Information telefax +49 (0)2374 920050-50

E-mail (competent person) info@pro3dure.com

Website www.pro3dure.com

1.4. Emergency telephone number

pro3dure medical GmbH

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 4, H413

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.
H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements:

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands 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.

Special labelling of particular preparations:

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

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1		< 50 %	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335; Aquatic Chronic 4, H413	ATE (dermal) = 2000 ATE (oral) = 2000 ATE (inhalativ) = Kein Wert ermittelbar
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4		< 25 %	Skin Sens. 1/1A/1B, H317	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1		< 25 %	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335	ATE (dermal) = 2000 ATE (oral) = 2000 ATE (inhalativ) = Kein Wert ermittelbar
3,6,9-trioxaundecamethylenedi methacrylate	109-17-1		< 15 %	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317	M = 0 ATE (dermal) = 3000 mg/kg bw ATE (oral) = 5000 mg/kg bw ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8		< 02 %	Repr. 2, H361; Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	M = 1 ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = 2000

(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 Take off immediately all contaminated clothing.

In case of inhalation: No special measures are necessary. Seek medical attention if problems persist.

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: 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

erythema (redness) Causes skin irritation.

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

Suitable extinguishing media ABC-powder BC-powder alcohol resistant foam Carbon dioxide (CO₂)

Unsuitable extinguishing media Foam Water spray jet Full water jet Water mist

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.

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 Organic peroxides. 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 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:
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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 short-term, systemic 3,52 mg/m ³ worker dermal short-term, systemic 2 mg/m ³ /24h population inhalative short-term, systemic 870 µg/m ³ population dermal short-term, systemic 1 mg/m ³ /24h population short-term, systemic 500 µg/m ³ /24h
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 systemic 3,3 mg/m ³ worker dermal systemic 1,3 mg/kg bw /24h population inhalative systemic 0,6 mg/m ³ population dermal systemic 0,7 mg/kg bw/24h population systemic 0,3 mg/kg bw/24h
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	worker inhalative long-term, systemic 48,5 mg/m ³ worker dermal long-term, systemic 13,9 mg/kg bw/day population inhalative long-term, systemic 14,5 mg/m ³ population dermal long-term, systemic 8,33 mg/kg bw/day population oral long-term, systemic 8,33 mg/kg bw/day
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	worker inhalative long-term, systemic 0,822 mg/m ³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m ³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 mg/kg bw/day
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	worker inhalative short-term, systemic 3,52 mg/m ³ worker dermal short-term, systemic 2 mg/m ³ /24h population inhalative short-term, systemic 870 µg/m ³ population dermal short-term, systemic 1 mg/m ³ /24h population short-term, systemic 500 µg/m ³ /24h

PNEC Value

Substance:	CAS-No.:	PNEC
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	aquatic, freshwater 0,01 µg/l aquatic, marine water 0,001 µg/l sewage treatment plant 3,61 µg/l sediment, freshwater 4,56 µg/kg dw sediment, marine water 0,46 µg/kg dw soil 0,91 µg/kg dw
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	aquatic, freshwater 1,4 µg/l aquatic, marine water 0,14 µg/l sediment, freshwater 115 µg/kg dw sediment, marine water 11,5 µg/kg dw soil 22,2 µg/kg dw

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:

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:	characteristic
Odour threshold:	No data available

Safety relevant basis data

parameter	Value	unit	Remark
Melting point/freezing point:			No data available
Initial boiling point and boiling range:			No data available
Flammability:			No data available
lower flammability or explosive limits:			No data available
Upper flammability or explosive limits:			No data available
Flash point:			No data available
Ignition temperature:			No data available
Decomposition temperature:			No data available
pH:			No data available
Kinematic viscosity:	1.5	Pa*s	
Water solubility (g/L):			
Partition coefficient: n-octanol/water:			No data available
Vapour pressure:			No data available
Density:	1.1	g/cm ³	
Relative density:			No data available
Particle properties:			No data available

9.2. Other information

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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):** 2000
Acute toxicity (oral): 2000 **Acute toxicity (inhalative):** 2000

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LD50 oral (rat) 2000 mg/kg LD50 dermal (rat) 2000 mg/kg
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	LC50 inhalation (Rat) 2000 mg/ kg bw LD50 oral (rat) 5000 mg/kg bw LD50 dermal (rat) > 2000 mg/kg bw
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	LD50 dermal (rat) > 3000 mg/kg LD50 oral (rat) > 5000 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
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LD50 oral (rat) 2000 mg/kg LD50 dermal (rat) 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:

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

Germ cell mutagenicity:

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

Reproductive toxicity:

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

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:

May cause sensitisation especially in sensitive humans.

SECTION 12: Ecological information

12.1. Toxicity

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LC50 (fish, 96 h) 100 mg/l LC50 (crustaceans, 48h) 6 mg/l EC50 (algae, 72 h) 100 mg/l
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	EC50 (Daphnia, 48 h) 3,53 mg/L EC50 (algae, 72 h) > 2,01 mg/L
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	EC50 Daphnia (Daphnia magna) 48 h 381 mg/l
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	LC50 (Daphnia) > 1,2 mg/l EC50 (algae, 72 h) > 0,68 mg/l
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LC50 (fish, 96 h) 100 mg/l LC50 (crustaceans, 48h) 6 mg/l EC50 (algae, 72 h) 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 preparation/mixture itself.

12.4. Mobility in soil

There are no data available on the preparation/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 Endocrine disruptive effect

12.7. Other adverse effects

There are no data available on the preparation/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.

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: - 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 none

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

none

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

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Training advice

none

Recommended restrictions of use:

No special measures are necessary.

Further remarks:

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Documentation of changes:

Changes compared to version 5:

1.1 UFI-code removed.

Changes compared to version 4:

- 1.1 UFI-code added.
- 1.4 Company name added.
- 2.2 Classification revised.
- 3.2 Composition further broken down.
- 4.2 Symptoms added.
- 5.1 Extinguishing media revised.
- 7.2 Storage instructions expanded.
- 8.1 Extended according to 3.2.
- 11.1 Extended according to 3.2.
- 12.1 Extended according to 3.2.
- 16 Documentation of changes introduced.

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

none
