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

1.1. Product identifier

printodent GR-22 flex

UFI 8X41-35G3-3T3F-05UY

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

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
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

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; Repr. 2, H361; STOT SE 3, H335; Aquatic Chronic 2, H411

2.2. Label elements

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

GHS07,GHS08,GHS09

Signal word: Warning

Hazard statements:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
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.
P308+313	IF exposed or concerned: Get medical advice/attention.
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.
P391	Collect spillage.
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:

2.3. Other hazards

-

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
Methacrylate Monomer 1	proprietary		25-45	Skin Sens. 1/1A/1B, H317; Repr. 2, H361d; Aquatic Chronic 2, H411	ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = Kein Wert ermittelbar
Methacrylate Monomer 3	proprietary		25-45	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
Methacrylate Monomer 2	proprietary		10-20	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
Methacrylate Monomer 4	proprietary		07-10	-	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar
Photoinitiator	proprietary		<02	Repr. 2, H361; Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	M = 0 ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = 2000
Methacrylate Monomer 6	proprietary		<02	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335; Aquatic Chronic 3, H412	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = 2000 ATE (inhalativ) = Kein Wert ermittelbar

(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: Provide fresh air. 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.

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. Consult an ophthalmologist.

After ingestion: Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Consult an ophthalmologist.

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. In case of breathing difficulties administer oxygen.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Unsuitable extinguishing media Full water jet Water spray jet Excess water

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. 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
Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation. Wear personal protection equipment.

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
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 as low as possible: 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
Keep container tightly closed and store 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/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
Methacrylate Monomer 3	proprietary	worker inhalative short-term, systemic 3,52 mg/m³ worker dermal short-term, systemic 2 mg/m3/24h population inhalative short-term, systemic 870 µg/m³ population dermal short-term, systemic 1 mg/m3/24h population short-term, systemic 500 µg/m3/24h
Methacrylate Monomer 6	proprietary	worker inhalative long-term, systemic 14,5 mg/m³ worker dermal long-term, systemic 4,2 mg/kg bw/day population inhalative long-term, systemic 4,3 mg/m³ population dermal long-term, systemic 2,5 mg/kg bw/day population oral long-term, systemic 2,5 mg/kg bw/day
Photoinitiator	proprietary	worker inhalative long-term, systemic 0,822 mg/m³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 mg/kg bw/day

PNEC Value

Substance:	CAS-No.:	PNEC
Methacrylate Monomer 1	proprietary	aquatic, freshwater 142 µg/l aquatic, marine water 1,42 µg/l sewage treatment plant 177 mg/l sediment, freshwater 655 µg/kg dw aquatic, marine water 67 µg/l soil 125 µg/kg dw
Methacrylate Monomer 6	proprietary	aquatic, freshwater 4,88 µg/l aquatic, marine water 0,488 µg/l sewage treatment plant 800 mg/l sediment, freshwater 262 µg/kg dw sediment, marine water 26 µg/kg dw soil 50 µg/kg dw
Photoinitiator	proprietary	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
Eye glasses with side protection

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:
Skin contact Inhalation

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state:	Liquid
Colour:	colourless
Odour:	fruity
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:		400	mPa*s	at 23 °C
Water solubility (g/L):				
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,1	g/mL	
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity
No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability
With proper storage and handling the product is stable.

10.3. Possibility of hazardous reactions
Polymerization.

10.4. Conditions to avoid
Heat UV-radiation/sunlight. UV-radiation/sunlight.

10.5. Incompatible materials
Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

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 preparation/mixture itself.

M-factor: -
Acute toxicity (oral): 2000 mg/kg
Acute toxicity (dermal): 2000 mg/kg
Acute toxicity (inhalative): -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Photoinitiator	proprietary	LC50 inhalation (Rat) 2000 mg/ kg bw LD50 oral (rat) 5000 mg/kg bw LD50 dermal (rat) > 2000 mg/kg bw
Methacrylate Monomer 6	proprietary	LD50 oral (rat) 2000 mg/kg LD50 dermal (rat) 2000 mg/kg
Methacrylate Monomer 1	proprietary	LD50 oral (rat) 5000 mg/kg LD50 dermal (rat) 2000 mg/kg
Methacrylate Monomer 3	proprietary	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:
No information available.
Germ cell mutagenicity:
No information available.
Reproductive toxicity:
No information available.

STOT-single exposure:
No information available.

STOT-repeated exposure:
No information available.

Aspiration hazard:
The inhalation of dust/mist or aerosols causes irritation of the respiratory tract.

SECTION 12: Ecological information

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Photoinitiator	proprietary	EC50 (Daphnia, 48 h) 3,53 mg/L EC50 (algae, 72 h) > 2,01 mg/L
Methacrylate Monomer 3	proprietary	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 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 Endocrine disruptive effect
There are no data available on the preparation/mixture itself.

12.7. 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. 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

	Yes	No
ADR/RID / IMDG / ICAO-TI / IATA-DGR:	☐	☒
Marine pollutant:	☐	☒

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 -

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
none

Other regulations, restrictions and prohibition regulations
-

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out. no
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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.

Training advice
Observe instructions for use.

Recommended restrictions of use:
refer to chapter 1.

Further remarks:
The information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

Documentation of changes:
Changes compared to version 2.2:

removed remaining CAS-numbers.

Changes compared to version 1:

1.1 UFI added.
2.2 Added GHS09, updated classification and added ATE values.
8.1 DNEL/PNEC values added.
9.1 Viscosity determined by measurement.
11.1: Acute toxicity values revised.
12.1: Ecotoxicity values revised.

Key literature references and sources for data
Data arise from reference works and literature.

Abbreviations and acronyms

AC: Artikelkategorie (Article Category)
ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)
ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des merchandises dangereuses par route)
AGW: Arbeitsplatzgrenzwert
AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)
Bw: Körpergewicht (Body weight)
CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)
CSR: Stoffsicherheitsbericht (Chemical Safety Report)
DIN: Deutsches Institut für Normung / Deutsche Industrienorm
DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD: Zubereitungsrichtline / Richtline 1999-45-EC (Dangerous Preparations Directive)
DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU: Nachgeschalteter Anwender (Downstream User)
EC50: Wirksame Konzentration 50% (Effective Concentration 50%)
ECHA: Europäische Chemikalienagentur
EN: Europäische Norm
EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA: Verband für den internationalen Lufttransport (International Air Transport Association)
IBC: Großpackmittel (Intermediate Bulk Container)
ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO: Internationale Seeschifffahrts-Organisation (International Maritime Organization)
ISO: Internationale Normungsorganisation (International Standards Organisation)
LC50: Lethale (Tödliche) Konzentration 50%
LD50: Lethale (Tödliche) Dosis 50%
LEV: Lokale Absaugung (Local exhaust ventilation)
MAK: Maximale Arbeitsplatzkonzentration – DFG
n.a.: nicht anwendbar
n.b.: nicht bestimmt
OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT: persistent, bioakkumlierbar, giftig (persistent, bioaccumulative, toxic)
PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)
PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL: Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)
SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulativ