

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

 Version:
 4.1
 Revision date:
 09.01.2023

 Replaces version:
 4
 from:
 15.12.2022

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

1.1. Product identifier

Thermeo Liquid

UFI U2GS-957T-XT3U-QM5D

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

Telephone +49 (0)2374 920050-10

Am Burgberg 13 Telefax: +49 (0)274 920050-50

D 58642 Iserlohn

Supplier

pro3dure medical GmbH

Telephone +49 (0)2374 920050-10

Am Burgberg 13 Telefax: +49 (0)274 920050-50

D 58642 Iserlohn

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 Telephone +49 (0)2374 920050-10

This number is serviced during office hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:

Skin Sens. 1/1A/1B, H317; Repr. 1A/B, H360; Aquatic Chronic 3, H412

2.2. Label elements

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

Hazard pictograms

GHS07,GHS08

Signal word: Danger

Hazard statements:

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May cause an allergic skin reaction.
May damage fertility or the unborn child.
Harmful to aquatic life with long lasting effects.
statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water/soap.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see information on this label).
If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
Store locked up.

Dispose of contents/container according to official regulations.

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Special labelling of particular preparations:

none

P501

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:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
1,2-Cyclohexane dicarboxylic acid diisononyl ester	166412-78-8	01-0000017810- 74-XXXX	10-20 %	-	ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar
Tetrahydrofurfuryl methacrylate	2455-24-5	01-2120748481- 53-XXXX	25-45 %	Skin Sens. 1/1A/1B, H317; Repr. 1A/B, H360D; Aquatic Chronic 3, H412	M = 1 ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar
2-Ethoxyethyl methacrylate	2370-63-0		40-60 %	Repr. 1A/B, H360	M = 1 ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar 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.

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Following skin After contact with skin, wash immediately with plenty of water and soap. In case

contact: 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

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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

May cause sensitization by skin contact.

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

extinguishing media

Unsuitable Excess water Full water jet Water spray jet

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

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

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

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

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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

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Precautions against fire and explosion:

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

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	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m³]	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/m³]	peaks:	

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
2-Ethoxyethyl methacrylate	2370-63-0	worker inhalative short-term, systemic 7,06 mg/m³ worker dermal long-term, systemic 2 mg/kg bw/day population inhalative long-term, systemic 1,74 mg/m³ population dermal long-term, systemic 1 mg/kg bw/day population oral long-term, systemic 1 mg/kg bw/day
1,2-Cyclohexane dicarboxylic acid diisononyl ester	166412-78-8	worker inhalative long-term, systemic 235 mg/m³ worker dermal long-term, systemic 42 mg/kg bw/day

PNEC Value

11120101111		
Substance:	CAS-No.:	PNEC
2-Ethoxyethyl methacrylate	2370-63-0	aquatic, freshwater 48,7 μg/l aquatic, marine water 4,87 μg/l
		sewage treatment plant 7,28 µg/l sediment, freshwater 241 µg/kg dw
		sediment, marine water 24,1 µg/kg dw soil 19.6 µg/kg dw
1,2-Cyclohexane dicarboxylic acid diisononyl ester	166412-78-8	soil 44700 μg/kg dw

Additional information

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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.

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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.

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Personal protection equipment

Only wear fitting, comfortable and clean protective clothing.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Hand protection

Suitable gloves type: NBR (Nitrile 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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: colourless yellow

Odour:

Odour threshold:

Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				No data available
Initial boiling point and boiling				No data available
range:				
Flammability:				No data available
lower flammability or explosive				No data available
limits:				
Upper flammability or explosive				No data available
limits:				
Flash point:				No data available
Ignition temperature:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:				No data available
Water solubility (g/L):				
Partition coefficient: n-				No data available
octanol/water:				

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Vapour pressure: No data available

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Density: at 20°C. 1,1 g/cm³

Relative density:

Particle properties:

No data available

No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Polymerisation

10.4. Conditions to avoid

heat. 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 mixture itself.

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

Acute toxicity

Substance:	CAS-No.:	Toxicological information
1,2-Cyclohexane dicarboxylic acid diisononyl ester	166412-78-8	LD50 oral (rat) > 5000 mg/kg
		LD50 oral (rat) > 2000 mg/kg
Tetrahydrofurfuryl methacrylate	2455-24-5	LD50 oral (rat) 3945 mg/kg
		NOAEL ReprTox. (Rat) 300 mg/kg/d
		NOAEL STOT-RE (rat) 300 mg/kg/d
2-Ethoxyethyl methacrylate	2370-63-0	NOAEL (rat) 40 mg/kg bw/Tag
		LD50 oral (rat) > 2000 mg/kg
		LD50 dermal (rat) > 2000 mg/kg

Skin corrosion/irritation:

sensitising.

Serious eye damage/irritation:

strongly irritant.

Respiratory or skin sensitisation:

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May cause an allergic skin reaction.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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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:

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
Tetrahydrofurfuryl methacrylate	2455-24-5	LC50 (fish, 96 h) 347 mg/L
		EC50 (algae, 72 h) > 72 mg/L
2-Ethoxyethyl methacrylate	2370-63-0	LC50 Fish (Pimephales promelas) 96 h 27 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 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.

Appropriate disposal / Package

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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.

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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.

4.1. UN number UN No.: 4.2. UN proper shipping name Land transport (ADR/RID)		
UN No.: 4.2. UN proper shipping name Land transport (ADR/RID) Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR) 4.3. Transport hazard class(es) Hazard label(s) / Label: Classification code: / Classification Code: 4.4. Packing group Packing group/ Packing Group: 4.5. Environmental hazards ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant: 4.6. Special precautions for user Land transport (ADR/RID) transport category: Special provisions: Limited quantity (LQ): Sea transport (IMDG) EmS-No: Special provisions: Limited quantity (LQ): 4.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	SECTION 14: Transport information	
Land transport (ADR/RID) Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR) 4.3. Transport hazard class(es) Hazard label(s) / Label: Classification code: / Classification Code: 4.4. Packing group Packing group/ Packing Group: 4.5. Environmental hazards ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant: 4.6. Special precautions for user Land transport (ADR/RID) transport category: Special provisions: Limited quantity (LQ): Sea transport (IMDG) EmS-No: Special provisions: Limited quantity (LQ): 4.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	14.1. UN number UN No.: -	
4.3. Transport hazard class(es)	14.2. UN proper shipping name Land transport (ADR/RID) - -	
Hazard label(s) / Label: Classification code: / Classification code	Sea transport (IMDG), Air transport (ICAO-TI/	IATA-DGR)
Hazard label(s) / Label: Classification code: / Classification code	-	
Packing group/ Packing Group: 4.5. Environmental hazards ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant: 4.6. Special precautions for user Land transport (ADR/RID) transport category: Special provisions: Sea transport (IMDG) EmS-No: Special provisions: Limited quantity (LQ):	14.3. Transport hazard class(es) Hazard label(s) / Label: -	
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EmS-No: - Special provisions: - Limited quantity (LQ): - 4.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	transport category: -	
	EmS-No: -	uantity (LQ): -
	14.7. Transport in bulk according to Anne	

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:

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Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:

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Regulation (EC) No. 648/2004 (Detergents regulation)

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Regulation (EC) No 850/2004 [POP-Regulation]:

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Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:

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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.

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.
 H360 May damage fertility or the unborn child.
 H412 Harmful to aquatic life with long lasting effects.

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.

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Documentation of changes:

Changes compared to version 2:

1.1 UFI-code added.

Changes compared to version 1:

- O Aligning the version number to german version
- 1.1 Product identifier adapted
- 2 adapted according to section 3.2
- 3.2 Concentrations adapted and classification updated
- 4.2 revised
- 4.3 revised
- 5.1 revised
- 5.3 revised
- 6.1 revised
- 7 revised
- 8.1 revised
- 8.2 revised
- 9.1 revised
- 10 revised
- 11 revised
- 12 revised
- 16 Documentation of changes introduced
- 16 List of abbreviations inserted.

Key literature references and sources for data

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Abbreviations and acronyms

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AC: Artikelkategorie (Article Category)

ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)

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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 bioaccumulative)

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