


Material Safety Data Sheet according to (EC) 1907/2006 Tradename: <div style="text-align: center;">DURASPLINT® FLEX Monomer</div>	<div style="text-align: center;">  </div> <div style="text-align: right;"> Status: 29.05.2024 Page: 1 von 11 </div>
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SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Name of product: DURASPLINT® FLEX Monomer

UFI: U2GS-957T-XT3U-QM5D

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Manufacture

Uses advised against

Private households (= general public)

1.3. Details of the supplier of the safety data sheet

Distributor

SCHEU-DENTAL GmbH
 Am Burgberg 20
 58642 Iserlohn
 Tel.-No. +49 (0) 2374/ 9288-0
 Fax-No. +49 (0) 2374/ 9288-90

Email: service@SCHEU-DENTAL.com
 Internet: www.SCHEU-DENTAL.com

Manufacturer

pro3dure medical GmbH
 Am Burgberg 13
 D-58642 Iserlohn

Telephone: +49 (0)2374 920050-10
 Telefax: +49 (0)2374 920050-50
 E-Mail (fachkundige Person) info@pro3dure.com
 Webseite: www.pro3dure.com

1.4. Emergency telephone number: +49 (2374) 920050-10

pro3dure medical GmbH

This number is serviced during office hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

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]

Signal word: Danger

Pictograms: GHS07 / GHS08



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.

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Precautionary statements

P261	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.
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.
P308+313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see information on this label).
P333+313	If skin irritation or rash occurs: Get medical advice/attention.
P362+364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container according to official regulations

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

Stoff:	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) = No value determined ATE (oral) = No value determined ATE (inhalative) = No value determined
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) = No value determined ATE (oral) = No value determined ATE (inhalativ) = No value determined
2-Ethoxyethyl methacrylate	2370-63-0		40 - 60 %	Repr. 1A/B, H360	M = 1 ATE (dermal) = No value determined ATE (oral) = No value determined ATE (inhalativ) = No value determined

Full text of H- and EUH-phrases: 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 eyes 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 a physician.

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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 extinguishing media

ABC-powder. Alcohol resistant foam. BC-powder. Carbon dioxide (CO₂). Nitrogen.

Unsuitable extinguishing media

Excess water. Full water jet. Water spray jet.

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 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

Advice 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

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and 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.

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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:
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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:
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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

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 exhaust 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

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.

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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 yellow
Odour:	
Odour threshold:	

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
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:				No data available
Water solubility (g/l):				No data available
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,1	g/cm ³	At 20 °C
Relative density:				No data available
Particle properties:				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


Polymerization

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.

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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 (dermal): -

Acute toxicity (oral): -

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 dermal (rat) > 2000 mg/kg
Tetrahydrofurfuryl methacrylate	2455-24-5	LD50 oral (rat) 3945 mg/kg NOAEL Repr.-Tox. (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 of skin sensitisation:

May cause an allergic skin reaction.

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:

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

SECTION 12: Ecological Information

12.1. Toxicity

There are no data available on the preparation/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.

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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

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 in accordance with 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.

SECTION 14: Transport Information**Land transport (ADR/RID)**

14.1. UN number:	No hazardous material according to transport regulations.
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packing group:	
Hazard label:	
Classification code:	
Special Provisions:	
Limited quantity:	
Transport category:	
Hazard No:	
Tunnel restriction code:	
Other applicable information (land transport)	


Inland waterways transport (ADN)

14.1. UN number:	No hazardous material according to transport regulations.
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packing group:	
Hazard label:	
Classification code:	
Special Provisions:	
Limited quantity:	
Other applicable information (inland waterways transport)	

Marine transport (IMDG)

14.1. UN number:	
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packaging group:	

No hazardous material according to transport regulations.

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Hazard label:	
Special Provisions:	
Limited quantity:	
EmS:	
Other applicable information (marine transport):	

Air transport (ICAO)	
14.1. UN number:	No hazardous material according to transport regulations.
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packaging group:	
Hazard label:	
Special Provisions:	
Limited quantity Passenger:	
IATA-packing instructions - Passenger:	
IATA-max. quantity - Passenger:	
IATA-packing instructions - Cargo:	
IATA-max. quantity - Cargo:	
Other applicable information (air transport)	
Passenger-LQ:	

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR: no
Marine pollutant: 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 MARPOL73/78 and the IBC Code

Remark none

SECTION 15: Regulatory Information

15.1. Safety, health an 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 (EC) No. 649/2012 on the export and import of dangerous chemicals:
-

Use restriction according to REACH annex XVII, no.:
-

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National regulatory information

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. -

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 information

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.

Key literature references and sources for data

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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 marchandises dangereuses par route)

AGW: Arbeitsplatzgrenzwert

AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)

Bw: Körpergewicht (Body weight)

CMR: Stoffe klassifiziert als Krebs erzeugend, 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: Zubereitungsrichtlinie / Richtlinie 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

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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 Seeschiffahrts-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, bioakkumulierbar, 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 Kurzzeiteexposition (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)