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

### 1.1. Product identifier Name of product: DURASPLINT<sup>®</sup> FLEX Polymer

UFI: DTFS-S55N-1T3C-QKE6

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

### 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) <u>info@pro3dure.com</u> Webseite: www.pro3dure.com

Email: <a href="mailto:service@SCHEU-DENTAL.com">service@SCHEU-DENTAL.com</a>

Internet: www.SCHEU-DENTAL.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] Aquatic Chronic 3, H412

### 2.2. Label elements

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

Signal word: Pictograms:

### Hazard statements

EUH208	Contains dibenzoyl peroxide. May produce an allergic reaction.
H412	Harmful to aquatic life with long lasting effects.

### **Precautionary statements**

P273	Avoid release to the environment.
P501	Dispose of contents/container acc. 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
Polyethylmethacrylate	9003-42-3		80 - 100 %	Aquatic Chronic 3, H412	

Full text of H- and EUH-phrases: see Section 16.

### **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

General Information:	Avoid contact with eyes, skin and clothing. Remove contaminated, soaked clothing. Medical attention is required in case of symptoms obviously due to exposure of skin, eyes to the product or inhalation of its vapours. Remove contaminated, soaked clothing.
In case of inhalation:	After inhalation of product dust: Provide fresh air. If symptoms occur, seek medical treatment.
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:	Not considered a possible route of exposure. If symptoms occur, seek medical treatment.

### 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. Foam. Water spray jet.

### Unsuitable extinguishing media

Excess water. Full water jet. Carbon dioxide (CO2). BC-powder.

### 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.

### Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus. Wear chemical resistant suit.

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### **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust. Avoid contact with eyes, skin and clothing. Personal Use personal protective clothing. Use respiratory protection when exposed to vapours/dust/aerosol. For Provide suitable exhaust/ventilation at the workplace or at the working machines. Increased

Increased risk of slipping due to leaked/spilled product.

### 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

Do not inhale dust. Avoid contact with eyes, skin and clothing. Emergency shower and eye wash should be available. Take measures against electrostatic discharge.

#### Precautions against fire and explosion

In case of fire, cool containers with water. Dust may form an explosive mixture with air. Ensure adequate ventilation. Dust and vapours: Do not breathe. Avoid contact with skin and eyes. Open container with care. Avoid dust accumulation. Avoid dust formation. Danger of dust explosion. Take measures against electrostatic discharge.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Avoid dust accumulation. Store tightly closed, cool and dry in the original container. Keep container closed when not in use.

### Hints on joint storage

None.

#### 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	exposure	exposure	
			limit value:	limit value:	peaks:	
			[ppm]	[mg/m³]		

### Substance with a common (EC) occupational exposure limit value

Substance	CAS-No.	Source	Occupational	Occupational	Limitation of	Remark:
			exposure	exposure	exposure	
			limit value:	limit value:	peaks:	
			[ppm]	[mg/m <sup>3</sup> ]		

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### DNEL/PNEC values

Substance:	CAS-No.:	DNEL/DMEL
PNEC-Wert		PNEC

### Additional information

-

### 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

Only wear fitting, comfortable and clean protective clothing.

### **Respiratory protection**

Respiratory protection necessary at: In the case of the formation of dust. Suitable respiratory protection apparatus: particulates filter device (DIN EN 143).

### Hand protection

Material: Protective gloves against mechanical risks according to EN 388 Additional information: Protective gloves should be changed regularly, especially after intensive contact with the product, Gloves must be removed and replaced when they show signs of wear or chemical breakthrough, A suitable type of glove must be selected for each workplace, Please follow the glove supplier's instructions regarding permeability and breakthrough time. Also consider the specific local conditions in which the product will be used, such as cut hazard, abrasion and contact time.

### 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 an clean protective clothing. Barrier creams are not substitutes for body protection.

### Environmental exposure controls.

See section 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:	solid
Colour:	white
Odour:	
Odour threshold:	

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Safety relevant basis data

	Parameter	Value	Unit	Remark
Melting point/freezing point:	about	70	°C	Softening point
Initial boiling point and boiling range:				No data available
Flammability:				No data available
Lower flammability or explosive limits:	>	400	°C	No data available
Upper flammability or explosive limits:				No data available
Flash point:	>	250	°C	none
Decomposition temperature:	>	250	°C	Start of depolymerisation
pH:				No data available
Kinematic viscosity:	At 20 °C	500	mPa*s	none
Water solubility (g/l):				
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:	At 20 °C	1,16	g/cm <sup>3</sup>	none
Relative density:				No data available
Particle properties:				No data available

### 9.2. Other information

None.

### **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

No information available.

### 10.2. Chemical stability

Start of depolymerisation 250 °C.

### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

### 10.4. Conditions to avoid

Avoid dust formation.

### 10.5. Incompatible materials

Oxidizing agents.

### 10.6. Hazardous decomposition products

Thermal decomposition produces flammable vapours which are irritating to the eyes and respiratory organs, mainly consisting of: Ethyl methacrylate.

### **SECTION 11: Toxicological Information**

### 11.1. Information on toxicological effects

There are no data available on the mixture itself.

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

Acute toxicity	
Substance:	CAS-No.

Toxicological information

### Skin corrosion/irritation:

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

### Serious eye damage/irritation:

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

### Respiratory of skin sensitisation:

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

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### 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
 CAS-No.:
 Ecotoxicity

### 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 an 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.

#### 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 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.



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**SECTION 14: Transport Information** 

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

### Air transport (ICAO)

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.
Hazard label:	
Special Provisions:	
Limited quantity Passenger:	
IATA-packing instructions - Passenger:	
IATA-max. quantity - Passenger:	
IATA-packing instructions - Cargo:	
IATA-max. quantitiy - 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: -

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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.:

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

EUH208Contains dibenzoyol peroxide. May produce an allergic reaction.H412Harmful to aquatic life with long lasting effects.

### **Training advice**

Observe instructions for use.

### 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

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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

### 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