
SECTION 1: IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE COMPANY

1.1. Product identifier

Trade name flexisplint (powder)

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

Application of the substance/preparation:

Powder/liquid system for the production of functional therapeutic bite splints

1.3. Details of the supplier of the safety data sheet

Name of manufacturer/supplier: dentona AG

Street/P.O. Box: Otto-Hahn-str. 27

Country code/Post code/City: D-44227 Dortmund, Germany

Telephone: +49 231 5556 0

Fax: +49 231 5556 30

Email: sdb@dentona.de

1.4. Emergency telephone number: Weekdays from 8am – 5pm: +49 (0)231 5556-0

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

The product is a mixture

Hazard designation

Inhalation and ingestion may cause nausea

Intensive skin contact may cause a rash

R phrases

R phrases	Hazard statements
R 43	May cause sensitisation by skin contact
R36/R37/R38	Irritating to eyes, respiratory system and skin

S phrases

-

2.2. Label elements

Labelling (GHS)

GHS07

Hazard pictogram(s):



Signal word:

Warning

H phrases

H code	Hazard statements
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H335	May cause respiratory irritation

P phrases

-

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

N/A

3.2. Mixtures

The product is a mixture

3.2.1 Chemical characterisation (preparation)

EMA copolymer powder

3.2.2 Hazardous components

Substance:	EC No.:	CAS No.:	INDEX No.:	REACH No.:	Concentration:	Classification: EC 1272/2008(CLP):	Classification: 67/548/EEC:
Barbituric acid	200-658-0	67-52-7			< 2 %	Skin Irrit. 2, H315, Eye Irrit. 2, H319 STOT SE. 3, H335	Xi; R36/37/38
Acrylic acid and ethyl acrylate polymer		25085-35-2			90-100 %		

PBT substance(s): No information available

vPvB substance(s): no information available

The precise wording of the R, H, and P sentences is explained in Section 16

SECTION 4: FIRST AID MEASURES:

4.1. Description of first aid measures

General: Immediately remove all soiled and contaminated clothing. If the person is likely to become unconscious, place and transport in a stable sideways position.

In case of inhalation: Ensure that sufficient fresh air is available and the person is not disturbed. If respiratory arrest occurs, perform mouth-to-mouth resuscitation. If unconscious place in recovery position. Seek medical advice.

Skin contact: Wash with plenty of water or soap and water; immediately remove all soiled and contaminated clothing. If the person feels unwell, seek medical advice

If swallowed: Have the person drink plenty of water in small sips, but only when the person is conscious. Do not induce vomiting. Seek medical advice.

Eye contact: Immediately rinse with plenty of water for 10-15 minutes and seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

No information is available.

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

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Extinguishing powder, foam, carbon dioxide, water spray, water

Unsuitable extinguishing media:

High pressure water jet

5.2. Special hazards arising from the substance or mixture

The following may be released in the event of a fire: carbon monoxide, carbon dioxide, hazardous decomposition products

5.3. Advice for firefighters

Specific hazards posed by the substance or the preparation itself, its combustion products or emitted gases.

Closed containers can break open at high temperatures - risk of explosion due to polymerisation - fumes are heavier than air.

Special protective equipment for firefighters

Use self-contained breathing apparatus.

5.4. Additional Information

Damp down gases/fumes/haze with water spray jets.

Collect contaminated fire fighting water separately. Do not allow to enter drains or watercourses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures.

Wear personal protective equipment (see Section 8). Avoid inhaling vapour and fumes. Avoid contact with skin and eyes.

6.2. Environmental precautions

Do not allow to enter drains, sewers or watercourses. Absorb spillage with a suitable material (e.g. earth). Contain contaminated water/firefighting water. Dispose of in duly identified containers.

6.3. Methods and material for containment and cleaning up

Do not rinse away with water. Pick up mechanically and dispose of properly. For liquid-binding material, such as diatomaceous earth, pick up and dispose of properly. For larger quantities:

contain spillage and pump into suitable containers. Extract fumes.

Additional Information:

Eliminate ignition sources

6.4. Reference to other sections

Relevant information in other sections must be observed. This applies in particular to information on personal protective equipment (Section 8) and disposal (Section 13)

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe storage

Information on safe handling:

Ensure good ventilation in the room and workplace. Extraction required at the property.

Precautions for preventing fire and explosion

Keep away from ignition sources –No smoking. Take precautionary measures against static discharge. Keep containers cool with water. Fumes may build up in closed rooms with air mixtures that lead to explosion in the presence of ignition sources, also in empty, uncleaned containers. Keep away from open flames, heat sources and sparks.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and containers.

Store in a cool, dry place, away from ignition sources

Storage instructions:

No special precautions necessary.

Additional information on delivery requirements:

Keep container tightly sealed and store in a cool, well-ventilated place.

7.3. Specific end-uses:

Always use according to packing instructions

**SECTION 8: EXPOSURE CONTROLS/
PERSONAL PROTECTION**

**8.1. Occupational exposure limits in the workplace and/or biological limit values
Occupational exposure limit (AGW) Germany**

For fumes above 10 ppm, hermetically sealed breathing apparatus should be worn!

8.2. Personal protective equipment

8.2.1 Respiratory equipment

For fumes above 10 ppm, self-contained breathing apparatus should be worn.

8.2.2 Hand protection:

Impermeable neoprene gloves

8.2.3 Eye protection:

Close fitting safety goggles

8.2.4 Body protection:

Protective work clothing

8.2.5 General precautions:

Do not eat, drink or smoke.

8.2.6 Other protective clothing or equipment

Eye Wash

8.2.7 General occupational hygiene

Observe general hygiene requirements

8.2.8 Ventilation

Local ventilation:
Mechanical (general)

Concentration above 100 ppm
none

Specific: none
Other: none

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information

Appearance: Powder
Colour: White
Odour: characteristic

Safety-related data

Parameters	Value	Method	Remarks
Melting point/Melting range	The powder decomposes when heated		
Decomposition temperature	> 250°C		
Flash point	> 150°C		Refers to measurement in closed crucible.
Ignition temperature	N/A		
Lower explosion limit	not determined		
Upper explosion limit	not determined		
Vapour pressure at 20°C	not determined		
Vapour pressure at 50°C	not determined		
Density	1.1 g/cm ³ at 23°C		
Water solubility/miscibility	11.45 g/l		
pH value	2 – 3 <	<	
Viscosity (dynamic)	N/A		
Viscosity (kinematic)			

9.2. Miscellaneous Information

No information is available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

When handled and stored appropriately no dangerous reactions are known
Relevant information may be found in other parts of this section.

10.2. Chemical stability

When handled and stored appropriately no dangerous reactions are known
Relevant information may be found in other parts of this section.

10.3. Possibility of hazardous reactions

When handled and stored appropriately no dangerous reactions are known
Relevant information may be found in other parts of this section.

10.4. Conditions to avoid

Protect from exposure to the light. Keep only in the original container at a temperature of between 4 - 25°C. Can polymerize when exposed to excessive heat.

10.5. Incompatible materials

Oxidizing agents, reducing agents, heavy metals, acids, alkalis (lyes).

10.6. Hazardous decomposition products

When handled and stored appropriately none known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1 General

Data obtained for the complete product takes precedence over data on single ingredients

11.1.2 Acute toxicity:

Description Exposure routes	Method	Dose	Species	Source
Acute toxicity	oral/LD50	> 5000mg/kg	Rat	Toxicology and Applied Pharmacology. Vol. 18, p. 185, 1971.
Skin corrosion/irritation	Prolonged exposure may cause eye and skin irritation, nausea, headaches and, in some cases, even lead to loss of consciousness.			
Skin and eye sensitisation	Possible			
Germ cell mutagenicity	None known			

11.1.3 Other observations:

None known

11.1.4 General notes:

No further information

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Acute toxicity

Fish toxicity	Not known
Daphnia toxicity	Not known
Algae toxicity	Not known
Bacteria toxicity	Not known

Persistence and degradability

Physical/Chemical

Procedure	Not known
Analytical procedure	Not known
Elimination level	Not known
Validation	Not known
Additional Information	Not known

Biological

Procedure	Not known
Analytical procedure	Not known
Elimination level	Not known
Validation	Not known
Additional Information	Not known

Occurrence in the environment

Mobility and accumulation	Not known
Additional Information	Not known

12.2. Occurrence in sewage treatment plant

No data available

12.3. Persistence and degradability

No data available

12.5. Behaviour in the sewage treatment plant

No data available

12.6. Other information

Do not allow large quantities to enter drains.

SECTION 13: DISPOSAL CONSIDERATIONS

Substance/preparation

13.1. Recommendation:

Follow the packing instructions.
Dispose of in accordance with applicable local and national regulations.

13.2. Disposal method

Do not allow to enter drains. Dispose of in accordance with applicable local and national regulations.

13.3 Packaging

Uncleaned packaging

Empty the packaging as completely as possible. Pick up mechanically and dispose of in a suitable container

SECTION 14: TRANSPORT INFORMATION

14.1. UN number; 14.2 UN proper shipping name; 14.3 Transport hazard class; 14.4 Packing group

Road ADR	
Assessment	Not hazardous material
14.1 UN No.	
14.2 Assessment	
14.3 Class	
14.4 Packing group	

Rail RID	
Assessment	Not hazardous material
14.1 UN No.	
14.2 Assessment	
14.3 Class	
14.4 Packing group	

Maritime transport IMDG Code	
Assessment	Not hazardous material
14.1 UN No.	
14.2 Assessment	
14.3 Class	
14.4 Packing group	

Air transport ICAO-TI/IATA-DGR	
Assessment	Not hazardous material
14.1 UN No.	
14.2 Assessment	
14.3 Class	
14.4 Packing group	

14.5. Environmental hazards

Environmental hazard labelling: Yes No

14.6. Special precautions for users:

Relevant information in other sections must be observed

14.7. Transport in bulk in accordance with Annex II of MARPOL 73/78 and the IBC Code

No bulk cargo transportation in tankers is intended

Additional notes:

Classification code:

No information

Tunnel restriction code (road):

No information

SECTION 15: STATUTORY REGULATIONS

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National and local regulations must be observed.
Information on labelling can be found in Section 2 of this document.

Water hazard class:

not hazardous to water (VwVwS, German Administrative Regulation Regarding Water Pollutants)
Annex 4, no. 3 of 27/07/2005

15.2. Substance description

No chemical safety assessment in accordance with Regulation (EC) 1907/2006 (REACH) was conducted for this product.

15.3 Information about the international registration status

If there is any relevant information on individual substance inventories, this is listed below.

European Economic Area (EEA)

REACH (Regulation (EC) No. 1907/2006):

General notes: Registration obligations arising from manufacture in the EEA or import into the EEA by the supplier referred to in Section 1, are fulfilled by this. Registration obligations arising from import into the EEA by the customer or other derivative users, must be performed by these.

SECTION 16: OTHER INFORMATION

16.1 Product

The information in this document is based on our knowledge at the time of the revision. It is not to be considered as a warranty of the properties of the described product within the meaning of the statutory warranty provisions.

The provision of this document does not release the purchaser of the product from fulfilling their responsibility regarding the laws and regulations applicable to the product. This applies in particular to the further distribution of the product or mixtures or articles derived therefrom to other jurisdictions, as well as the property rights of third parties. If the

product described is processed or mixed with other products, the information in this document may not be transferred to the manufactured product, unless this is expressly stated. When the product is repackaged, the buyer is responsible for attaching the required safety information.

All deliveries are subject to the general terms and conditions of dentona AG, Otto-Hahn-Str. 27, 44227 Dortmund

16.2 Additional Information:

Full stops indicate the decimal point in numeric values. Vertical lines in the lefthand margin indicate changes to the previous version. This version replaces all previous versions.

Safety Data Sheet in accordance with Regulation (EC) No 1907/2006

Trade name: flexisplint (powder)



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Version: 03/2016

replaces the pre-2016 version

Revised on: 01/03/2016

Effective from: 01/03/2016

Information regarding the GHS regulation:

H code	Hazard statements
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H335	May cause respiratory irritation

R phrases	Hazard statements
R 43	May cause sensitisation by skin contact
R36/R37/R38	Irritating to eyes, respiratory system and skin

- End of safety data sheet -
