

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 7

Revision: 09.03.2022

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

- **1.1 Product identifier**
- **Trade name:** BioHPP, BioHPP for2press
- **Article number:**  
540 F2PB 2, 540 F2PB 3, 540 F2PB 4, 540 F2PB 5, 540 F2PB 6, 540 F2PB 7, 540 F2P2 2, 540 F2P2 3, 540 F2P2 4, 540 F2P2 5, 540 F2P2 6, 540 F2P2 7, 540 F2P3 2, 540 F2P3 3, 54F2PP01, 54F2PP02, 54F2PP03, 54F2PP04, 54F2PP05, 54F2PP06, 54F2PP07, 54F2PP08, 54F2PP09, 54F2PP10, 54F2PP11, 54F2PP12, 54F2PP13, 54F2PP14, 54F2PP15, 54F2PP16, 54F2PP17, 54F2PP18
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
No further relevant information available.
- **Application of the substance / the mixture:**  
Thermoplastic material for the "for 2 press" vacuum press system.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
bredent GmbH & Co.KG  
Weißenhornher Straße 2  
89250 Senden  
Tel: +49 (0) 7309/872-0  
Fax: +49 (0) 7309/872-24
- **Further information obtainable from:**  
R & D  
e-mail: R.D@bredent.com
- **1.4 Emergency telephone number:**  
Tel: +49 (0) 7309/872-0 (Mo. - Fr. 7:00 - 17:00)  
(001) 352 323 3500

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Remark**  
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
- **Classification according to Regulation (EC) No 1272/2008**  
The substance is not classified, according to the CLP regulation.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**  
Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.  
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**  
Polyether ether ketone, modified

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Personal protection for the First Aider.  
Take affected persons out of danger area and lay down.  
Keep warm, position comfortably and cover well.  
Do not leave affected persons unattended.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
After contact with the molten product, cool rapidly with cold water.  
Do not pull solidified product off the skin.  
Cover wound with a sterile dressing.  
Call a doctor immediately.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**  
In case of fire, the following can be released:  
Carbon monoxide (CO)  
Under certain fire conditions, traces of other toxic gases cannot be excluded.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Ensure adequate ventilation  
Keep away from ignition sources.
- **6.2 Environmental precautions:** Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Store in cool, dry place in tightly closed receptacles.  
Provide suction extractors if dust is formed.

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- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Do not eat, drink, smoke or sniff while working.  
Use skin protection cream for skin protection.  
The usual precautionary measures are to be adhered to when handling chemicals.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:**  
Heat protection gloves  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Granulate
- **Colour:** Different according to colouring
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** 343 °C
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Product is not flammable.

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· <b>Ignition temperature:</b>	575 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Not determined.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	1.3 g/cm <sup>3</sup>
· <b>Relative density at 20 °C</b>	1.3 - 1.5 g/cm <sup>3</sup>
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
<b>VOC (EC)</b>	0,00 %
<b>Solids content:</b>	100.0 %
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
Stable at environment temperature.  
No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** Reacts with strong acids and oxidising agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
Carbon monoxide and carbon dioxide  
Poisonous gases/vapours

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** No data available.
- **Serious eye damage/irritation** No data available.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.

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- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must be specially treated adhering to official regulations.  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**  
Packagings that may not be cleansed are to be disposed of in the same manner as the product.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No              |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>   | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008** Void

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- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** *Substance is not listed.*
- **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

### SECTION 16: Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Department issuing SDS:** *R & D*
- **Contact:** *R & D*
- **Abbreviations and acronyms:**
  - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*
  - ICAO: International Civil Aviation Organisation*
  - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)*
  - IMDG: International Maritime Code for Dangerous Goods*
  - IATA: International Air Transport Association*
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals*
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)*
  - VOC: Volatile Organic Compounds (USA, EU)*
  - PBT: Persistent, Bioaccumulative and Toxic*
  - vPvB: very Persistent and very Bioaccumulative*
- **\* Data compared to the previous version altered.**

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