

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

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

- **1.1 Product identifier**
- **Trade name:** Pi-Ku-Plast HP 36 Polymer
- **Article number:** 540 0021 5
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:** -
- **Application of the substance / the mixture:** Cold-Polymerizing resin
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhornener 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:** (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**



environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS07, GHS09
- **Signal word** Warning
- **Hazard-determining components of labelling:**
dibenzoyl peroxide
methyl methacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 1)

P391 Collect spillage.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:** Powder based on polymethyl methacrylate.**· Dangerous components:**

CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide Org. Perox. B, H241 Aquatic Chronic 1, H410 Eye Irrit. 2, H319; Skin Sens. 1, H317	≤3%
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≤1%

· Additional information: For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.**· After swallowing:** Call a doctor immediately.**· 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:**

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· For safety reasons unsuitable extinguishing agents: Water with full jet**· 5.2 Special hazards arising from the substance or mixture** No further relevant information available.**· 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** Wear protective clothing.**· 6.2 Environmental precautions:**

Do not allow to penetrate the ground/soil.

Do not allow to enter sewers/ surface or ground water.

· 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.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 2)

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** Prevent formation of dust.
- **Information about fire - and explosion protection:** Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **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:**

94-36-0 dibenzoyl peroxide ($\leq 3\%$)

WEL (Great Britain) Long-term value: 5 mg/m³

80-62-6 methyl methacrylate ($\leq 1\%$)

WEL (Great Britain) Short-term value: 416 mg/m³, 100 ppm

Long-term value: 208 mg/m³, 50 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Do not eat, drink, smoke or sniff while working.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Immediately remove all soiled and contaminated clothing
- **Respiratory protection:** Use suitable respiratory protective device when high concentrations are present.
- **Protection of hands:**



Protective 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.

· **Material of gloves**

Butyl rubber, BR

Recommended thickness of the material: ≥ 0.5 mm

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 penetration time has to be at least 60 minutes (Permeation according to EN 374 Part 3: Level 3).

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 3)

· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Powder
Colour:	White
Odour:	Odourless

· **pH-value:** Not applicable.· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	not applicable

· **Flash point:** Not applicable.· **Flammability (solid, gas):** May cause fire.· **Ignition temperature:** > 400 °C· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Density:** Not determined.· **Solubility in / Miscibility with water:**

Insoluble.

· **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· **Solvent content:**

Organic solvents:	0.0 %
VOC (EC)	0.00 %

Solids content: 100.0 %

· **9.2 Other information** 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:**

No decomposition if used according to specifications.
To avoid thermal decomposition do not overheat.

· **10.3 Possibility of hazardous reactions** No dangerous reactions known.· **10.4 Conditions to avoid** No further relevant information available.· **10.5 Incompatible materials:** No further relevant information available.

(Contd. on page 5)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 4)

· **10.6 Hazardous decomposition products:** Irritant 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** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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.
- **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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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**
Can be burned with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-------------|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, IMDG, IATA | <p>Void</p> |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR | <p>Void</p> |

(Contd. on page 6)

GB

*

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 5)

· **IMDG, IATA** Void· **14.3 Transport hazard class(es)**· **ADR, IMDG, IATA**· **Class** Void· **14.4 Packing group**· **ADR, IMDG, IATA** Void· **14.5 Environmental hazards:**

· **Marine pollutant:** No
 Symbol (fish and tree)

· **Special marking (ADR):** Symbol (fish and tree)

· **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user** Not applicable.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **UN "Model Regulation":** 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**

The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms** GHS07, GHS09· **Signal word** Warning· **Hazard-determining components of labelling:**

dibenzoyl peroxide

methyl methacrylate

· **Hazard statements**

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P391 Collect spillage.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is 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.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

(Contd. on page 7)

GB

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

Printing date 09.03.2022

Version number 4

Revision: 09.03.2022

Trade name: Pi-Ku-Plast HP 36 Polymer

(Contd. of page 6)

H241 Heating may cause a fire or explosion.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** R & D

· **Contact:** R & D

· **Abbreviations and acronyms:**

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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

Flam. Liq. 2: Flammable liquids – Category 2

Org. Perox. B: Organic peroxides – Type B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· *** Data compared to the previous version altered.**

GB