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

Printing date 09.03.2022 *Version number 6* *Revision: 12.08.2021*

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

· **1.1 Product identifier**

· **Trade name: Pi-Ku-Plast HP 36 Monomer**

· **Article number:** 540 0021 0, 540 0021 1, 540 0021 2, 540 0021 3, 540 0021 4
· **1.2 Relevant identified uses of the substance or mixture and uses advised against:** -
· **Application of the substance / the mixture:** Monomer solution for Pi-Ku-Plast HP 36.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhorner 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**

flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

· **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** GHS02, GHS07
· **Signal word** Danger

· **Hazard-determining components of labelling:**
methyl methacrylate
ethylene dimethacrylate
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

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· ***Precautionary statements***

P210	*Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*
P233	*Keep container tightly closed.*
P261	*Avoid breathing dust/fume/gas/mist/vapours/spray.*
P280	*Wear protective gloves/protective clothing/eye protection/face protection.*
P303+P361+P353	*IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*
P403+P235	*Store in a well-ventilated place. Keep cool.*

· ***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:*** *Mixture of methacrylates, initiators and stabilizers.*

· ***Dangerous components:***

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*	*50-100%*
CAS: 97-90-5 *EINECS: 202-617-2*	*ethylene dimethacrylate* *Skin Sens. 1, H317; STOT SE 3, H335*	*2.5-10%*
CAS: 1330-20-7 *EINECS: 215-535-7*	*xylene* *Flam. Liq. 3, H226* *Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315*	*≤3%*
CAS: 99-97-8 *EINECS: 202-805-4*	*N,N-dimethyl-p-toluidine* *Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331* *STOT RE 2, H373* *Aquatic Chronic 3, H412*	*≤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***
· ***General information:***
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· ***After inhalation:***
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· ***After skin contact:***
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
· ***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.

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SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** CO2, sand, extinguishing powder. Do not use water.
· **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:**
Wear self-contained respiratory protective device.
Mouth respiratory protective device.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective clothing.
Keep away from ignition sources.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Wear protective equipment. Keep unprotected persons away.
· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
· **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**
Keep receptacles tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:**
Fumes can combine with air to form an explosive mixture.
Use explosion-proof apparatus / fittings and spark-proof tools.
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Store in a cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
· **7.3 Specific end use(s)** No further relevant information available.

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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:***	
80-62-6 methyl methacrylate (50-100%)	
WEL (Great Britain)	*Short-term value: 416 mg/m³, 100 ppm* *Long-term value: 208 mg/m³, 50 ppm*
1330-20-7 xylene (≤3%)	
WEL (Great Britain)	*Short-term value: 441 mg/m³, 100 ppm* *Long-term value: 220 mg/m³, 50 ppm* *Sk; BMGV*

· ***Ingredients with biological limit values:***	
1330-20-7 xylene (≤3%)	
BMGV (Great Britain)	*650 mmol/mol creatinine* *Medium: urine* *Sampling time: post shift* *Parameter: methyl hippuric acid*

· ***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.
The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the skin.
Avoid contact with the eyes and skin.
· ***Respiratory protection:***
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
· ***Protection of hands:***
Preventive skin protection by use of skin-protecting agents is recommended.

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.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **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:	*Fluid*
Colour:	*According to product specification*
· **Odour:**	*Characteristic*
· **Odour threshold:**	*Not determined.*
· **pH-value:**	*Not determined.*
· **Change in condition**	
Melting point/freezing point:	*Undetermined.*
Initial boiling point and boiling range:	*101 °C*
· **Flash point:**	*10 °C*
· **Flammability (solid, gas):**	*Not applicable.*
· **Ignition temperature:**	*430 °C*
· **Decomposition temperature:**	*Not determined.*
· **Auto-ignition temperature:**	*Product is not selfigniting.*
· **Explosive properties:**	*Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.*
· **Explosion limits:**	
Lower:	*2.1 Vol %*
Upper:	*12.5 Vol %*
· **Vapour pressure at 20 °C:**	*47 hPa*
· **Density at 20 °C:**	*0.94521 g/cm³*
· **Relative density**	*Not determined.*
· **Vapour density**	*Not determined.*
· **Evaporation rate**	*Not determined.*
· **Solubility in / Miscibility with water:**	*Not miscible or difficult to mix.*
· **Partition coefficient: n-octanol/water:**	*Not determined.*
· **Viscosity:**	
Kinematic:	*Not determined.*
· **Solvent content:**	
Organic solvents:	*2.1 %*
Solids content:	*0.0 %*
· **9.2 Other information**	*No further relevant information available.*

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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.
· **10.3 Possibility of hazardous reactions**
Reacts with peroxides and other radical forming substances.
Reacts with reducing agents.
Reacts with heavy metals.
Exothermic polymerisation.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
80-62-6 methyl methacrylate		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4h	29.8 mg/l (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation** No data available.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **Additional toxicological information:**
· **CMR effects (carcinogenity, 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**
May cause respiratory irritation.
· **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.

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· **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:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1247
· **14.2 UN proper shipping name**	
· **ADR**	1247 METHYL METHACRYLATE MONOMER, STABILIZED
· **IMDG, IATA**	METHYL METHACRYLATE MONOMER, STABILIZED
· **14.3 Transport hazard class(es)**	
· **ADR, IMDG, IATA**	

· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	33
· **EMS Number:**	F-E,S-D
· **Stowage Category**	C
· **Stowage Code**	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E

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· ***IMDG***	
· ***Limited quantities (LQ)***	*1L*
· ***Excepted quantities (EQ)***	*Code: E2* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 500 ml*
· ***UN "Model Regulation":***	*UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II*

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*** *GHS02, GHS07*
· ***Signal word*** *Danger*

· ***Hazard-determining components of labelling:***
methyl methacrylate
ethylene dimethacrylate
· ***Hazard statements***
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
· ***Precautionary statements***

P210	*Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*
P233	*Keep container tightly closed.*
P261	*Avoid breathing dust/fume/gas/mist/vapours/spray.*
P280	*Wear protective gloves/protective clothing/eye protection/face protection.*
P303+P361+P353	*IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*
P403+P235	*Store in a well-ventilated place. Keep cool.*

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *None of the ingredients is listed.*
· ***Seveso category*** *P5c FLAMMABLE LIQUIDS*
· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** *5.000 t*
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *50.000 t*
· ***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.
H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.

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H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

· ***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
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· **** Data compared to the previous version altered.***