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

· 1.1 Product identifier

· Trade name: breCAM.HIPC

· Article number:

 $540\ 0339\ 8,\ 540\ 0339\ 9,\ 540\ 0340\ 0,\ 540\ 0340\ 1,\ 540\ 0340\ 2,\ 540\ 0340\ 3,\ 540\ 0340\ 4,\ 540\ 0340\ 5,\ 540\ 0340$

· 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:

Milling blank for the fabrication of crowns and bridges made of synthetic polymer.

· 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 & L

e-mail: R.D@bredent.com

• 1.4 Emergency telephone number: Tel: +49 (0) 7309/872-0 (Mo. - Fr. 7:00 - 17:00)

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.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances
- · CAS No. Description

acrylic polymers

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- $\cdot \textit{After inhalation:} \ \textit{Supply fresh air; consult doctor in case of complaints.}$

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- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Rinse out mouth and then drink plenty of water.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 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.

- · 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 Not required.
- 6.2 Environmental precautions: 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.

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

Use only in well ventilated areas.

No special measures required.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store in dry conditions.

Store under lock and key and out of the reach of children.

· 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.

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

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· Protection of hands: Not required.

· Eye protection: Not required.

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and	cnemicai	properties
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· General Information

· Appearance:

Form: Solid material

Colour: Different according to colouring

· Odour: Characteristic
· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined.
 Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.
Upper: Not determined.

• Vapour pressure: Not applicable.

Density: Not determined.
 Relative density Not determined.
 Vapour density Not applicable.

• Vapour density Not applicable. • Evaporation rate Not applicable.

· Solubility in / Miscibility with

water: Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic:Not applicable.Kinematic:Not applicable.Organic solvents:0.0 %

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.
- · 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.

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· 10.6 Hazardous decomposition products:

At temperatures above 250°C, depolymerisation and the release of starting monomers can arise.

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 Based on available data, the classification criteria are not met.
- · 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 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:

Negative ecological effects are, according to the current state of knowledge, not expected.

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

Must be specially treated adhering to official regulations.

Smaller quantities can be disposed of with household waste.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- · 14.1 UN-Number
- · ADR, ADN, IMDG, IATA

Void

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· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
14.5 Environmental hazards: Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of 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 Void
- · 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:

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)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.

