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

· 1.1 Product identifier

· Trade name: KATANA AVENCIA Block

· Article number: 207

· Registration number Not applicable

· 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 Dental CAD/CAM material

· 1.3 Details of the supplier of the safety data sheet

· Supplier:

Kuraray Europe GmbH Philipp-Reis-Str. 4, 65795 Hattersheim am Main

Germany

Phone: +49 (0)69 305 35 835 E-mail: dental.eu@kuraray.com

· Further information obtainable from: Supplier

· 1.4 Emergency telephone number:

(UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166

* 3E Company

* Kuraray Access Code:334674

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

· Additional information

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/GHS) usually if they are in the finished state and intended for the final user.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· Precautionary statements

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of water. P321 Specific treatment (see on this label).

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

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P362+P364 Take off contaminated clothing and wash it before reuse. P337+P313 If eye irritation persists: Get medical advice/attention.

- · 2.3 Other hazards Dust generation.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

	· Dangerous components:		
Γ			10-30%
	EINECS: 276-957-5	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
Γ		Triethyleneglycol dimethacrylate	5-20%
	EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

Other ingredients:

Amorphous silica

Silane coupling agent

Pigments

· Additional information: Silicon oxide; Nanoform, Amorphous silica, particle size 1 - 100 nm

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: Generally the product does not irritate the skin.
- · 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:

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 See Section 8.
- 6.2 Environmental precautions: No special measures required.
- · 6.3 Methods and material for containment and cleaning up:

Pick up mechanically. Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

- · 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 at room temperature.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Personal protective equipment:
- · General protective and hygienic measures: Do not inhale dust / smoke / mist.
- · Respiratory protection: Not required.
- · Hand protection



Protective gloves

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

· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Physical state Solid

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Coloured
 Odour:
 Odourless
 Odour threshold:
 Melting point/freezing point:
 Not determined

 \cdot Boiling point or initial boiling point and boiling

range Not determined

• Flammability Product is not flammable.

Lower and upper explosion limit

Lower: Not determined
 Upper: Not determined
 Flash point: Not determined
 Auto-ignition temperature: Not determined
 Decomposition temperature: Not determined
 pH Not determined
 Viscosity: Not determined

• Kinematic viscosity
• Dynamic:

Not determined

Not determined

Solubility

water: Insoluble.
 Partition coefficient n-octanol/water (log value)
 Vapour pressure: Not determined

Density and/or relative density

Density at 20 °C:
 Relative density
 Relative vapour density
 Particle characteristics

1.7 g/cm³
Not determined
Not determined
See item 3.

· 9.2 Other information

· Appearance:

· Form: Solid

Important information on protection of health and environment, and on safety.

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

· Solvent separation test:

· Solids content: 100.0 %

· Change in condition

· Evaporation rate Not determined

· Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void

Substances and mixtures
Substances and mixtures, which emit flammable
gases in contact with water
Void
Oxidising liquids
Oxidising solids
Organic peroxides
Void
Corrosive to metals
Desensitised explosives
Void

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- · 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.
- · 10.6 Hazardous decomposition products: Carbon dioxide

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB:** Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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14.1 UN number or ID number	V. 1	
ADR, ADN, IMDG, IATA	Void	
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 Maritime transport in bulk according to IMO		
instruments	Not applicable.	
UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 94/33/EC: Care should be taken when people under 18 handle this product.
- · Directive 94/85/EEC: No further relevant information available.
- · Chemical safety assessment
- · Named dangerous substances ANNEX I None of the ingredient is listed.
- · Regulation (EU) No 649/2012
- · Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

 \cdot Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

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

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

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

* * Data compared to the previous version altered.