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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 materials

· 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:

[United Kingdom] National Poisons Information Service (NPIS): +44 (0)344 892 0111 Only for NHS and other healthcare professionals

3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 *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 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.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.

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- · 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:			
	Urethane dimethacrylate	10 - 30%	
EINECS: 276-957-5	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319		
	Triethyleneglycol dimethacrylate	5 - 20%	
EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335		
	titanium dioxide	< 1%	
EINECS: 236-675-5	& Carc. 2, H351		

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:

13463-67-7 titanium dioxide

WEL (Great Britain) Long-term value: 10* 4** mg/m³ *total inhalable **respirable

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 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
- · Physical state So

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· Colour:	Colored
· Odour:	Odourless
· Melting point/freezing point:	Not determined
· Roiling point or initial hoiling point and hoiling	

Boiling point or initial boiling point and boiling

range Not determined
• Flammability Product is not flammable.

Lower and upper explosion limit

Lower:

Vot determined

Upper:

Not determined

Viscosity: Not determined
 Kinematic viscosity Not determined
 Dynamic: Not determined

· Dynamic: · Solubility

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

· Density and/or relative density

Density: 1.7 g/cm³
 Relative density Not determined
 Relative vapour density Not determined

· Particle characteristics

See section 3.

· 9.2 Other information

· 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

Void · Oxidising gases · 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, which emit flammable gases in contact with water Void Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability

· Corrosive to metals

· Desensitised explosives

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Void

Void

· 10.3 Possibility of hazardous reactions No dangerous reactions known.

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- · 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.

SECTION 14: Transport information

- · 14.1 UN number or ID 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, ADN, 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 instruments	to IMO Not applicable.	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Poisons Act
- · Directive 94/33/EC: Care should be taken when people under 18 handle this product.
- · Directive 94/85/EEC: No further relevant information available.
- · 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.

· 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.

H351 Suspected of causing cancer.

· 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

Carc. 2: Carcinogenicity - Category 2

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

* * Data compared to the previous version altered.

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