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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****· 1.1 Product identifier****· Trade name:** KATANA Cleaner**· Article number:** 234**· 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] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566

For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)

3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 \*Kuraray Access Code: 334674

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**SECTION 2: Hazards identification****· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008**

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

**· 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-determining components of labelling:**

Triethanolamine

**· Hazard statements**

H317 May cause an allergic skin reaction.

**· Precautionary statements**

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

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

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

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P321 Specific treatment (see on this label).  
 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 Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

**· Dangerous components:**

CAS: 102-71-6	Triethanolamine		Skin Sens. 1, H317	< 3%
EINECS: 203-049-8				

**· Other ingredients:**

- Water
- Polyethyleneglycol
- 10-Methacryloyloxydecyl dihydrogen phosphate
- Dyes

**\* SECTION 4: First aid measures**

**· 4.1 Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.

**· 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:** 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.

**SECTION 5: Firefighting measures**

**· 5.1 Extinguishing media**

**· Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

**· 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:**

Dilute with plenty of water.

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

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**· 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 section 13.

Ensure adequate ventilation.

Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.

Vacuum or sweep material and place in a disposal container. Provide ventilation.

Use appropriate Personal Protective Equipment (PPE).

**· 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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.

**· 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: Store in a cool location (2-25°C).

· Information about storage in one common storage facility: Not required.

**· Further information about storage conditions:**

Keep container tightly sealed.

Protect from heat and direct sunlight.

Store in cool, dry conditions in well sealed receptacles.

**· 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 section 7.

**· Personal protective equipment:****· General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection: Suitable respiratory protective device recommended.

**· Hand protection**

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.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**· 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** Safety glasses

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**SECTION 9: Physical and chemical properties****· 9.1 Information on basic physical and chemical properties****· General Information****· Physical state**

Liquid

**· Colour:**

Violet

**· Odour:**

Odourless

**· Melting point/freezing point:**

Not determined.

**· Boiling point or initial boiling point and boiling range**

100 °C (7732-18-5 water, distilled, conductivity or of similar purity)

Not determined.

**· Flammability****· Lower and upper explosion limit**

Not determined.

**· Lower:**

Not determined.

**· Upper:**

Not determined.

**· Flash point:**

270 °C (25322-68-3 Polyethylene glycol)

**· Auto-ignition temperature:**

360 °C (25322-68-3 Polyethylene glycol)

**· Decomposition temperature:**

Not applicable.

**· pH at 20 °C**

4.5 ± 1.0

**· Kinematic viscosity**

Not determined.

**· Solubility**

Fully miscible.

**· water:**

Not applicable.

**· Partition coefficient n-octanol/water (log value)**

23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)

**· Vapour pressure at 20 °C:**1.1 g/cm<sup>3</sup>**· Density at 20 °C:**

Not determined.

**· Relative vapour density**

Not applicable.

**· Particle characteristics**

Not applicable.

**· 9.2 Other information****· Information with regard to physical hazard classes****· Explosives**

Product does not present an explosion hazard.

**· Flammable gases**

Void

**· Aerosols**

Void

**· 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

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

## 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.
- 10.6 Hazardous decomposition products: Carbon monoxide and 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.

- LD/LC50 values relevant for classification:

**102-71-6 Triethanolamine**

Oral	LD50	8,000 mg/kg (rat)
Dermal	LD50	>22,500 mg/kg (rabbit)

- 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.
- 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.

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**· 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:**

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.

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**SECTION 13: Disposal considerations****· 13.1 Waste treatment methods****· Recommendation**

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.**· Recommended cleansing agents:** Water, if necessary together with cleansing agents.**SECTION 14: Transport information****· 14.1 UN number or ID number**

· ADR, ADN, IMDG, IATA Void

**· 14.2 UN proper shipping name**

· ADR, ADN, IMDG, IATA Void

**· 14.3 Transport hazard class(es)****· ADR, IMDG, IATA**

· Class Void

**· 14.4 Packing group**

· ADR, ADN, IMDG, IATA Void

**· 14.5 Environmental hazards:**

Not applicable.

**· 14.6 Special precautions for user**

Not applicable.

**· 14.7 Maritime transport in bulk according to IMO**

instruments

Not applicable.

**· UN "Model Regulation":**

Void

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**SECTION 15: Regulatory information****· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****· Regulated explosives precursors**

None of the ingredients is listed.

**· Regulated poisons**

None of the ingredients is listed.

**· Reportable explosives precursors**

None of the ingredients is listed.

**· Reportable poisons**

None of the ingredients is listed.

**· Directive 94/33/EC:** Care should be taken when people under 18 handle this product.**· Directive 94/85/EEC:** No further relevant information available.

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- **Named dangerous substances - ANNEX I** None of the ingredient is listed.

- **Regulation (EU) No 649/2012**

- None of the ingredients is listed.

- **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.

- **Regulation (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

- None of the ingredients is listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**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.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Relevant phrases**

- H317 May cause an allergic skin reaction.

- **Classification according to Regulation (EC) No 1272/2008**

- The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

- **Abbreviations and acronyms:**

- ELINCS: European List of Notified Chemical Substances

- Skin Sens. 1: Skin sensitisation – Category 1

- \* Data compared to the previous version altered.

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