



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

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

- **1.1 Product identifier**
 - Trade name: **RetraXil**
- **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 retraction paste
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
 - **Informing department:** E-Mail: msds@kulzer-dental.com
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

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

Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
STOT RE 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- **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**



GHS05 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**

aluminum chloride hexahydrate
Quartz (SiO₂)
- **Hazard statements**

H314 Causes severe skin burns and eye damage.
H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Precautionary statements**

P260 Do not breathe mist/vapours/spray.
P280 Wear protective gloves / eye protection.
P280 Wear protective clothing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 Specific treatment (see on this label).
P332+P313 If skin irritation occurs: Get medical advice/attention.

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- **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:** -

· **Dangerous components:**

CAS: 1332-58-7 EC number: 310-194-1	Kaolin substance with a Community workplace exposure limit	25-50%
CAS: 7784-13-6 EINECS: 231-208-1	aluminum chloride hexahydrate Skin Corr. 1B, H314; Eye Dam. 1, H318 EUH071	10-25%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO ₂) STOT RE 1, H372	≥0-≤5%

- **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**
- **After inhalation** Supply fresh air; consult doctor in case of symptoms.
- **After skin contact** If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
Rinse opened eye for several minutes under running water. Then consult doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms 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** Use fire fighting measures that suit the environment.
- **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.
- **Additional information -**

GB

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SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective clothing.
Avoid contact with eyes and skin.

· **6.2 Environmental precautions:**

Dilute with much water.
Do not allow to enter the ground/soil.

· **6.3 Methods and material for containment and cleaning up:**

Dispose of the material collected according to regulations.

· **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 information on disposal.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Store in cool, dry place in tightly closed containers.
No special precautions necessary if used correctly.
· **Information about protection against explosions and fires:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and containers:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**

1332-58-7 Kaolin

WEL (Great Britain) Long-term value: 2 mg/m³

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

Wash hands during breaks and at the end of the work.
· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Hand protection**

Check protective gloves prior to each use for their proper condition.
recommended

· **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

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- and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
- **Eye/face protection** Tightly sealed safety glasses.
- **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

- **Physical state** Fluid
- **Colour:** Whitish
- **Smell:** Odourless
 - **Odour threshold:** Not determined.
- **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 applicable.
- **Flammability** Not applicable.
- **Lower and upper explosion limit** Not determined.
- **Lower:** Not determined.
- **Upper:** Not applicable
- **Flash point:** Not determined.
- **Decomposition temperature:** Not determined.
- **SADT** Not determined.
- **pH** Not determined.
- **Viscosity:** Not determined.
 - **Kinematic viscosity** Not determined.
- **Kinematic viscosity** Not determined.
 - **dynamic:** Not determined.
- **Solubility** Fully miscible
 - **Water:** Fully miscible
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure at 20 °C:** 23 hPa (7732-18-5 water, distilled, conductivity or of similar purity)
- **Vapour pressure:** Not determined.
- **Density and/or relative density** Not determined.
 - **Density at 20 °C** 1 g/cm³
 - **Relative density** Not determined.
 - **Vapour density** Not determined.

· **9.2 Other information**

No further relevant information available.

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- **Appearance:**
 - **Form:** Pasty
- **Important information on protection of health and environment, and on safety.**
 - **Self-inflammability:** Product is not selfigniting.
 - **Explosive properties:** Product is not explosive.
- **Change in condition**
 - **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
 - **Explosives** Void
 - **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
 - **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**
 - **Conditions to be avoided:** No decomposition if used and stored 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:** None
 - **Additional information:** -

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.

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· LD/LC50 values that are relevant for classification:

7784-13-6 aluminum chloride hexahydrate

Oral	LD50	3,311 mg/kg (rat)
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- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **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**
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

· 11.2 Information on other hazards

· Endocrine disrupting properties

556-67-2	octamethylcyclotetrasiloxane	List II; III
540-97-6	Dodecamethylcyclohexasiloxane	List II

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**
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Must not be disposed together with household garbage.
Disposal must be made according to official regulations.
Small amounts may be diluted with plenty of water and washed away. Dispose of bigger amounts in accordance with Local Authority requirements.
 - **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

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· Recommended cleaning agent: Water, if necessary with cleaning agent.

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SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN2581
· 14.2 UN proper shipping name · ADR · IMDG, IATA	2581 ALUMINIUM CHLORIDE SOLUTION ALUMINIUM CHLORIDE SOLUTION
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	8 (C1) Corrosive substances. 8
· IMDG, IATA	
	
· Class · Label	8 Corrosive substances. 8
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Warning: Corrosive substances.
· Kemler Number:	80
· EMS Number:	F-A, S-B
· Segregation groups	Acids
· Stowage Category	A
· Segregation Code	SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml

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<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	<p>Maximum net quantity per outer packaging: 1000 ml</p> <p>3</p> <p>E</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5L</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 ml</p> <p>Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 2581 ALUMINIUM CHLORIDE SOLUTION, 8, III</p>

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H372 Causes damage to organs through prolonged or repeated exposure.
- EUH071 Corrosive to the respiratory tract.

· **Abbreviations and acronyms:**

- SADT: Self Accelerating Decomposition Temperature
- 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
- Skin Corr. 1B: Skin corrosion/irritation – Category 1B
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
- STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

· *** Data compared to the previous version altered.**