



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

Printing date 13.04.2021

Version number 1

Revision: 13.04.2021

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. 1C 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 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 dust.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
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.
P337+P313 If eye irritation persists: Get medical advice/attention.
 - **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: 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. 1C, H314; Eye Dam. 1, H318	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** -

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:** Prevent material from reaching sewage system, holes and cellars.

· **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.

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See Section 13 for information on disposal.

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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

· **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.

· **Protection of hands:**

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 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 protection:** Tightly sealed safety glasses.

· **Body protection:** Light weight protective clothing

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SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** Whitish
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** 100 °C

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure at 20 °C:** 23 hPa

· **Density at 20 °C** 1 g/cm³

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

· **Water:** Fully miscible

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

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **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**

· **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:** -

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

7784-13-6 aluminum chloride hexahydrate

Oral LD50 3,311 mg/kg (rat)

· **Primary irritant effect:**

· **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.

· **Additional toxicological information:**

· **CMR effects (carcinogenicity, 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**

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.

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:** Not known to be hazardous to water.

· **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 not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

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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
· ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, 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: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

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.

· **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

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. 1C: Skin corrosion/irritation – Category 1C

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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.**

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