



**Safety Data Sheet
acc. to OSHA HCS**

Printing date 04/22/2024

Reviewed on 04/22/2024

1 Identification

· **Product identifier**

· Trade name: **RetraXil**

· -

· **Application of the substance / the mixture dental retraction paste**

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Corrosion 1B

H314 Causes severe skin burns and eye damage.

Eye Damage 1

H318 Causes serious eye damage.

Carcinogenicity 1A

H350 May cause cancer.

Specific Target Organ Toxicity - Repeated Exposure
1

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS05 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

aluminum chloride hexahydrate

Quartz (SiO₂)

· **Hazard statements**

Causes severe skin burns and eye damage.

May cause cancer.

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**

Do not breathe mist/vapours/spray.

Wear protective gloves / eye protection.

Wear protective clothing.

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If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Get medical advice/attention if you feel unwell.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



· **HMIS-Ratings (Scale 0-4)**



· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** -

· **Dangerous components:**

1332-58-7	Kaolin	25-50%
7784-13-6	aluminum chloride hexahydrate Skin Corrosion 1B, H314; Eye Damage 1, H318	10-25%
14808-60-7	Quartz (SiO ₂) Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	≥0.1-≤5%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

· **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 a doctor.

Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

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- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information -**

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Avoid contact with eyes and skin.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Dispose of the collected material according to regulations.
- **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.

· **Protective Action Criteria for Chemicals**

· PAC-1:		
7784-13-6	aluminum chloride hexahydrate	54 mg/m ³
14808-60-7	Quartz (SiO ₂)	0.075 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m ³
· PAC-2:		
7784-13-6	aluminum chloride hexahydrate	110 mg/m ³
14808-60-7	Quartz (SiO ₂)	33 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
540-97-6	Dodecamethylcyclohexasiloxane	1,700 mg/m ³
· PAC-3:		
7784-13-6	aluminum chloride hexahydrate	650 mg/m ³
14808-60-7	Quartz (SiO ₂)	200 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	130 ppm

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540-97-6 Dodecamethylcyclohexasiloxane

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9,900 mg/m³

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.
 - **Information about protection against explosions and fires:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

1332-58-7 Kaolin

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 2* mg/m ³ E; as respirable fraction

14808-60-7 Quartz (SiO₂)

PEL	Long-term value: 0.05* mg/m ³ *resp. dust; 30mg/m ³ /%SiO ₂ +2
REL	Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m ³ *as respirable fraction

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

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures** Wash hands before breaks and at the end of work.
 - **Breathing equipment:** Not necessary if room is well-ventilated.
 - **Protection of hands:**
Check protective gloves prior to each use for their proper condition.

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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 goggles.

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

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Color:**

Whitish

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

100 °C (212 °F)

· **Flash point:**

Not applicable

· **Flammability (solid, gaseous)**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Ignition temperature:**

Product is not selfigniting.

· **Danger of explosion:**

Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Vapor pressure at 20 °C (68 °F):**

23 hPa (17.3 mm Hg)

· **Density at 20 °C (68 °F):**

1 g/cm³ (8.345 lbs/gal)

· **Relative density**

Not determined.

· **Vapor density**

Not determined.

· **Evaporation rate**

Not determined.

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· Solubility in / Miscibility with	
· Water:	Fully miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:	
7784-13-6 aluminum chloride hexahydrate	
Oral	LD50 3,311 mg/kg (rat)

- **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop mycobacterial infections (tuberculous and non-tuberculous) and fungal infections. Inhalation of air with a very high concentration of respirable silica dust can cause the most serious forms of silicosis in a matter of months or a few years. Some epidemiologic studies have concluded that there is significant risk of developing silicosis even at airborne exposure levels that are equal to the recommended NIOSH REL, the ACGIH TLV.

Cancer Status: The International Agency for Research on Cancer has determined that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1 - carcinogenic to humans). Refer to IARC Monograph 100C, A Review of Human Carcinogens: Arsenic, Fibres and Dusts (published in 2011) in conjunction

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with the use of these materials. The National Toxicology Program (NTP) classifies respirable crystalline silica as "known to be a human carcinogen". Refer to the Twelfth Report on Carcinogens (2011). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies crystalline silica, quartz, as a suspected human carcinogen (A2).

14808-60-7	Quartz (SiO ₂)	1
· NTP (National Toxicology Program)		
14808-60-7	Quartz (SiO ₂)	K
· OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients is listed.		
· Reproductive toxicity Based on available data, the classification criteria are not met.		

12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **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.
 - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· UN-Number	
· DOT, ADR, IMDG, IATA	UN2581
· UN proper shipping name	
· DOT	Aluminum chloride, solution
· ADR	2581 ALUMINIUM CHLORIDE SOLUTION
· IMDG, IATA	ALUMINIUM CHLORIDE SOLUTION

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· **Transport hazard class(es)**

· **DOT**



· **Class**
· **Label**

8 Corrosive substances
8

· **ADR**



· **Class**
· **Label**

8 (C1) Corrosive substances
8

· **IMDG, IATA**



· **Class**
· **Label**

8 Corrosive substances
8

· **Packing group**

· **DOT, ADR, IMDG, IATA**

III

· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Warning: Corrosive substances

· **Hazard identification number (Kemler code):** 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

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **Excepted quantities (EQ)**

Code: E1
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 1000 ml

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<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml 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>

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

<ul style="list-style-type: none"> · SARA Section 355 (extremely hazardous substances) 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · SARA Section 313 (specific toxic chemical listings) 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · Hazardous Air Pollutants 	<p>None of the ingredients is listed.</p>
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- **Proposition 65**

- **Prop 65 - Chemicals known to cause cancer**

The listing is for silica, crystalline as "airborne particles of respirable size". Silica, crystalline of this product is within a product matrix.

14808-60-7	Quartz (SiO ₂)
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<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for females: 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for males: 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · Chemicals known to cause developmental toxicity: 	<p>None of the ingredients is listed.</p>
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- **Carcinogeny categories**

<ul style="list-style-type: none"> · EPA (Environmental Protection Agency) 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · TLV (Threshold Limit Value) 		
1332-58-7	Kaolin	A4
14808-60-7	Quartz (SiO ₂)	A2

<ul style="list-style-type: none"> · NIOSH-Ca (National Institute for Occupational Safety and Health) 		
14808-60-7	Quartz (SiO ₂)	

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



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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.

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· **Date of preparation / last revision 04/22/2024**

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Corrosion 1B: Skin corrosion/irritation – Category 1B

Eye Damage 1: Serious eye damage/eye irritation – Category 1

Carcinogenicity 1A: Carcinogenicity – Category 1A

Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) – Category 1

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