



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 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.

(Contd. on page 2)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

- **2.3 Other hazards -**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
 - **Description:** -

- **Dangerous components:**

CAS: 7784-13-6	aluminum chloride hexahydrate	10-25%
EINECS: 231-208-1	Skin Corr. 1B, H314; Eye Dam. 1, H318 EUH071	
CAS: 14808-60-7	Quartz (SiO ₂)	≥0-≤5%
EINECS: 238-878-4	STOT RE 1, H372	

- **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.

(Contd. on page 3)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 2)

- **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

OEL (Ireland)	Long-term value: 2 mg/m ³
---------------	--------------------------------------

14808-60-7 Quartz (SiO₂)

OEL (Ireland)	Long-term value: 0.1 mg/m ³
AGW (European Union)	Long-term value: 0.1 mg/m ³
BOELV (European Union)	Long-term value: 0.1* mg/m ³ *respirable fraction

· **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

(Contd. on page 4)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 3)

- **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/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) |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable |
| · Decomposition temperature: | Not determined. |
| · SADT | |
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Kinematic viscosity | |
| · dynamic: | Not determined. |
| · Solubility | |
| · 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: | |
| · Density and/or relative density | |
| · Density at 20 °C | 1 g/cm ³ |

(Contd. on page 5)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 4)

· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	No further relevant information available.
· 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:** -

IE
(Contd. on page 6)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 5)

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 that are relevant for classification:**

7784-13-6 aluminum chloride hexahydrate

Oral	LD50	3,311 mg/kg (rat)
------	------	-------------------

- **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.

(Contd. on page 7)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 6)

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 cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

· 14.1 UN number or ID number

· **ADR, IMDG, IATA** UN2581

· 14.2 UN proper shipping name

· **ADR** 2581 ALUMINIUM CHLORIDE SOLUTION
· **IMDG, IATA** ALUMINIUM CHLORIDE SOLUTION

· 14.3 Transport hazard class(es)

· **ADR**



· **Class** 8 (C1) Corrosive substances.
· **Label** 8

· **IMDG, IATA**



· **Class** 8 Corrosive substances.
· **Label** 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:**

-

(Contd. on page 8)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 7)

· ADR	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	E
<hr/>	
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 2581 ALUMINIUM CHLORIDE SOLUTION, 8, III

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.

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

no information available

· 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.

(Contd. on page 9)



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

Printing date 22.04.2024

Version number 1

Revision: 22.04.2024

Trade name: RetraXil

(Contd. of page 8)

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.

· **Date of previous version: 13.04.2021**

· **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.**