

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

1.1. Product identifier

Product description Aqueous inorganic mineral paste with stabilizers.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use Industrial application: It insulates gips, acrylic and orthodontic products during soldering works.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 48/50

e-mail: research@leone.it – <http://www.leone.it>

Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.

www.leone.it/emergency (EU and international telephone numbers).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

Upon a correct use, according to our experience no significant hazards to man or environment are reasonably foreseen.

2.2. Label elements

Not applicable.

2.3. Other hazards

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

The product does not contain substances with endocrine-disrupting properties in a concentration ≥ 0.1 %.

SECTION 3: Composition/information on ingredients



3.2. Mixtures

Aqueous inorganic mineral paste with stabilizers.

According to Regulation (EC) no. 1272/2008 [CLP], this product does not meet the criteria for classification as hazardous in accordance with Titles I and II. Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below. Note that the concentration of hazardous goods in the mixture are too low to give the mixture some of their specific hazard.

Mixture of the following substances with non-hazardous additives.

According to Regulation (EC) no. 1272/2008 [CLP].

Hazardous Ingredients	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hydrochloric acid	EINECS: 231-595-7 CAS-No.: 7647-01-0	1,5-5%	 Skin corrosion/irritation, Hazard Category 1, Sub-Category 1B, H314 Serious eye damage/eye irritation, Hazard Category 1, H318  Acute toxicity (oral), Hazard Category 4, H302 STOT SE 3, H335 Specific concentration limits: -Skin corrosion/irritation, Hazard Category 1, Sub-Category 1B, H314: $C \geq 25\%$ -Skin corrosion/irritation, Hazard Category 2, H315: $10\% \leq C < 25\%$ -Serious eye damage/eye irritation, Hazard Category 1, H318: $C \geq 25\%$ -Serious eye damage/eye irritation, Hazard Category 2, H319: $10\% \leq C < 25\%$ - STOT SE 3, H335: $C \geq 10\%$

Further indications: the text of the hazard warning mentioned can be learned from Chapter 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Take to a well-ventilated area, consult a doctor in case of complaints.
Skin contact	The product is generally not irritating to the skin.
Eye contact	Wash with running water for several minutes while holding the eyelids wide open and consult a doctor.
Ingestion	If the pain persists, consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

No other information is available.

4.3. Indication of any immediate medical attention and special treatment needed

No other information is available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media	Take fire-fighting measures around the affected area.
Unsuitable extinguishing Media	Water jets.

5.2. Special hazards arising from the substance or mixture

Carbon monoxide (CO₂).

5.3. Advice for firefighters

Specific protective equipment	No special measures are required.
Other indications	Collect the contaminated water used for extinguishing, do not, under any circumstances, direct it into the sewage system.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unequipped people away.

6.2. Environmental precautions

Prevent infiltration into the sewer system/surface water/groundwater.

6.3. Methods and material for containment and cleaning up

Use neutralising means.

Dispose of contaminated material in accordance with point 13.

6.4. Reference to other sections

For information on safe handling, see Chapter 7.

For information on protective equipment for personal use, see Chapter 8.

See Chapter 13 for information on disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Accurate dust collection.

Information in case of fire and explosion: The product is not flammable

7.2. Conditions for safe storage, including any incompatibilities

Requirements for warehouses and containers:	There are no special requirements.
Information on mixed storage:	Not necessary.
Further information on storage conditions:	Keep containers tightly closed.

7.3. Specific end use(s)

No other information is available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Components whose limit values must be kept under control in the workplace:

7647-01-0 Hydrochloric acid

TWA	Ceiling limit: 2.9 mg/m ³ , 2 ppm
	A4
VL	Short-term value: 15 mg/m ³ , 10 ppm
	Long-term value: 8 mg/m ³ , 5 ppm

Further indications: Lists valid at the date of compilation were used as a basis.



8.2. Exposure controls

8.2.1. Appropriate engineering controls

No further data, see point 7.

8.2.2. Individual protection measures, such as personal protective equipment

General protective and occupational hygiene standards	Keep away from food, drink and fodder. Remove contaminated clothing immediately. Wash hands before breaks or when finished work.
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	Avoid contact with the eyes. Avoid contact with eyes and skin.
Respiratory protection	Not necessary.
Hand protection	 Protective gloves. <i>Glove material:</i> the choice of suitable gloves depends not only on the material but also on other quality characteristics that vary from one manufacturer to another. As the product represents a formulation of several substances, the stability of glove materials cannot be calculated in advance and must be tested before use. <i>Permeation time of the glove material:</i> request from the glove supplier the precise passage time which must be respected.
Eye/face protection	 Tightly sealed protective goggles.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Colour	In accordance with the product name.
Odour	Characteristic.
Odour threshold	Not defined.
Melting point/freezing point	Not defined.
Boiling point or initial boiling point and boiling range	100-110 °C (7647-01-0 hydrogen chloride)
Flammability	Not defined.
Lower and upper explosion limit	Not defined.
Flash point	Not applicable.
Auto-ignition temperature	/
Decomposition temperature	Not defined.
pH at 20 °C	8
Kinematic viscosity	Not applicable.
Solubility in water	Soluble.
Partition coefficient n-octanol/water (log value)	Not defined.
Vapour pressure	Not applicable.
Density at 20 °C	0,82759-2,14611 g/cm ³
Relative density	Not defined.
Relative vapour density	Not applicable.
Particle characteristics	See point 3.

9.2. Other information

Appearance	/
Form	Pasty

Important information on health and environmental protection as well as safety:

Ignition temperature	Non-self-flammable product.
Explosive properties	Non-explosive product.
Solvent content	/
Solids content	100,0%
Change of status	/
Evaporation rate	Not applicable.

9.2.1. Information with regard to physical hazard classes

Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material.

10.2. Chemical stability

Thermal decomposition/ conditions to be avoided: The product does not decompose when used according to regulations.

10.3. Possibility of hazardous reactions

No dangerous reactions are known.

10.4. Conditions to avoid

No other information is available.

10.5. Incompatible materials

No other information is available.

10.6. Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	Based on the available data, the classification criteria are not met
Skin corrosion/irritation	Based on the available data, the classification criteria are not met
Serious eye damage/irritation	Based on the available data, the classification criteria are not met
Respiratory or skin sensitisation	Based on the available data, the classification criteria are not met
Germ cell mutagenicity	Based on the available data, the classification criteria are not met
Carcinogenicity	Based on the available data, the classification criteria are not met
Reproductive toxicity	Based on the available data, the classification criteria are not met
STOT-single exposure	Based on the available data, the classification criteria are not met
STOT-repeated exposure	Based on the available data, the classification criteria are not met
Aspiration hazard.	Based on the available data, the classification criteria are not met

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

None of the components are included.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: No further information available.

12.2. Persistence and degradability

No further information is available.

12.3. Bioaccumulative potential

No further information is available.

12.4. Mobility in soil

No further information is available.

12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

12.6. Endocrine disrupting properties

The product does not contain substances with harmful properties for the endocrine system.

12.7. Other adverse effects

Additional information: Water hazard class 1 (D) (Self-classification): slightly hazardous.

Do not allow to enter groundwater, watercourses or drains undiluted or in large quantities.

SECTION 13: Disposal considerations

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations including those of Decree-Law No. 153 of 17 October 2024.

13.1. Waste treatment methods

Recommendations: Must not be disposed of with household waste.

Waste code: 070199, waste not otherwise specified.

Uncleaned packaging:

Recommendations: Dispose of in accordance with administrative regulations.

Recommended cleaning agent: Water, possibly with the addition of detergents.

SECTION 14: Transport information

14.1. UN number or ID number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

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" not applicable.

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

Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

15.2. Chemical safety assessment

Not performed.

SECTION 16: Other information

This safety data sheet has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of the mixture.

The product is intended for orthodontic and odontological use only. The use of the product has to be restricted to skilled and licensed professionals. The information relates only to specific product designated and is not intended as a warranty of quality.

Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.

The present information does not imply any liberty to break patent rights.

Previous safety data sheet no. R05-6E dated 31/01/2023 is to be considered obsolete. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheets.

Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

H phrases

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Legend

CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

EINECS: European Inventory of Existing Commercial Substances.

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative And Toxic Substances.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

STOT SE 3: Specific target organ toxicity — Single exposure, Hazard Category 3, Respiratory tract irritation

TWA: Time-Weighted Average.

VL: Occupational Exposure Limit Values.

vPvB: Very Persistent And Very Bioaccumulative Substances.