

1. SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product description: Polishing fluid for resin.

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

Identified Use Professional use: Polishing fluid for acrylic plates.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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

The information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to the final user.

2.2. Label elements**Hazard Statement:** No Hazard Statement**2.3. Other hazards**No PBT, vPvB or endocrine disrupting substances present in concentration $\geq 0.1\%$ **SECTION 3: Composition/information on ingredients****3.2. Mixtures**

Hazardous substances according to CLP (EC) No 1272/2008:

Sostanze pericolose no. CAS	EINECS	REACH-Reg No.	Contenuto	Classificazione
Ammonium oleate 544-60-5	208-873-1	*	$\geq 5 - < 7\%$	Eye irritation 2 H319
Triammoniocitrato 3458-72-8	222-394-5	*	$\geq 1 - < 3\%$	Eye irritation 2 H319

SECTION 4: First aid measures**4.1. Description of first aid measures**

No special measures are required.

Inhalation	Transport the casualty to fresh air. In case of difficulty in breathing, seek medical attention immediately.
Skin contact	Rinse with water. Discard contaminated clothing.
Eye contact	Rinse under running water (for at least 10 minutes); consult a doctor if necessary.
Ingestion	Rinse the mouth with water (only if the person is conscious). Do not induce vomiting; seek medical attention immediately.
General information	In case of discomfort, consult a physician

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

In case of inhalation: Irritation of the respiratory tract, coughing. Inhalation of larger amounts may cause laryngospasm with shortness of breath.

In case of skin contact: Temporary skin irritation (redness, swelling, burning)

In case of eye contact: Temporary eye irritation (redness, swelling, burning, tearing)

In case of ingestion: Ingestion may cause irritation of the mouth, throat, digestive system, diarrhea and vomiting. Vomiting may enter the lungs causing damage (aspiration)

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

In case of inhalation: No special warning.

In case of skin contact: No special warnings.

In case of eye contact: No special warnings.

In case of ingestion: In case of ingestion of large or unknown quantities administer an antifoam agent (Dimethicone or Simethicone). Do not induce vomiting. Administer, if necessary, only non-carbonated beverages (water, tea)

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water jet (if possible, avoid maximum power). Adapt fire-fighting measures to environmental conditions. Commercially available extinguishing agents are suitable for extinguishing fires in their initial state. The product itself does not burn.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products and/or carbon monoxide may be formed by pyrolysis.

5.3. Advice for firefighters

Wear full personal protective equipment and mask with self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Danger of slipping on the spilled product. Avoid contact with eyes and skin. Ensure adequate ventilation.

6.2. Environmental precautions

Do not discharge into sewers, surface or ground water

6.3. Methods and material for containment and cleaning up

Mechanical removal. Rinse the remains with plenty of water.

6.4. Reference to other sections

See the warnings in section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

If used according to regulations, it does not require special precautions.

Hygiene measures:

Avoid contact with skin and eyes. Remove contaminated clothing immediately . Remove contaminant from skin with plenty of water, take care of skin.

Protective equipment required only in the case of industrial or high-volume use

7.2. Conditions for safe storage, including any incompatibilities

Store dry between +5°C and +40°C.

Follow the good rules of common storage.

7.3 Specific end use(s)

Metal and ceramic cleaners

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Valid for Italy

Ingrediente (sostanza regolamentata)	ppm	mg/m3	Tipo di valore	Annotazioni	Annotazioni
quartz (SiO ₂) 14808-60-7		0.1	Weighted average (8 ore)		EU OELIII
Silicone, crystalline - α -Quartz, respirable fraction 14808-60-7		0,025	Weighted average (8 ore)	Source of the limit value: ACGIH	OEL (IT)
ALUMINUM METAL AND INSOLUBLE COMPOUNDS, RESPIRABLE FRACTION 1318-74-7		1	Weighted average (8 ore)		OEL (IT)
ALUMINUM METAL AND INSOLUBLE COMPOUNDS, RESPIRABLE FRACTION 1318-74-7		1	Weighted average (8 ore)	Source of the limit value: ACGIH	OEL (IT)

8.2. Exposure controls

Eye/face protection

Hand protection

Tightly sealed goggles.

or contact with the product it is recommended according to EN 374 to use protective gloves of special nitrile (with thickness > 0.1mm and penetration time of the chemical > 480 min. in class 6). It should be noted that, for repeated and prolonged contacts, the above-mentioned penetration time in practice may be considerably shorter than that stipulated in EN 374. Regarding their adaptability to the specific workplace, protective gloves must be tested in any case (e.g. mechanical and thermal resistance, antistatic.....). At the first signs left after use (degradation of the glove in progress) the glove must be replaced immediately

Respiratory protection

Not necessary.

Body protection

Chemical protective clothing. Follow the manufacturer's instructions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Viscous emulsion and murky
Colour	Beige/Grey.
Odour	Pungent.
Melting point/freezing point	No data available / Not applicable
Boiling point or initial boiling point and boiling range	No data available / Not applicable
Flammability	No data available / Not applicable
Lower and upper explosion limit	No data available / Not applicable
Flash point	>100 °C (> 212 °F) The product does not fuel combustion in any way.
Auto-ignition temperature	No data available / Not applicable
Decomposition temperature	No data available / Not applicable
pH	9,8 - 10,2 (20 °C (68 °F));
Kinematic viscosity	2.200 mPa s
Water solubility	water soluble
Partition coefficient n-octanol/water (log value)	No data available / Not applicable
Vapour pressure	No data available / Not applicable
Density and/or relative density	1,100 G/cmc (20 °C (68 °F))
Relative vapour density	No data available / Not applicable
Particle characteristics	/.

9.2. Other information

Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

Not known under normal usage conditions.

10.2. Chemical stability

Stable under normal temperature and pressure conditions.

10.3. Possibility of hazardous reactions

See the responsiveness section.

10.4. Conditions to avoid

The product does not decompose when used properly.

10.5. Incompatible materials

The product is not dangerous when used in accordance with the recommendations for use

10.6. Hazardous decomposition products

The product does not decompose if used properly.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	The mixture is classified by means of a calculation method that considers the classified substances present in the mixture.
Acute toxicity (dermal)	No data available.
Acute toxicity (inhalation)	No data available.
Skin corrosion/irritation	The mixture is classified by a calculation method that considers the classified substances present in the mixture.
Serious eye damage/irritation	The mixture is classified by a calculation method that considers the classified substances present in the mixture
Respiratory or skin sensitisation	The mixture is classified according to the threshold limits of the classified substances in the mixture.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available.

11.2 Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

Toxicity (Fish):

The mixture is classified by means of a calculation method that considers the classified substances present in the mixture

Sostanze pericolose no. CAS	Valore tipico	Valore	Tempo di esposizione	Specie	Metodo
Ammonium Oleate 544-60-5	LC50	160 mg/L	96 H	Brachydanio rerio (nuovo nome: Danio rerio)	OECD Guideline 203 (Fish, acute toxicity testing).
Diammonium citrate 3458-72-8	LC50	>10-100 mg/L	96 H	not specified	OECD Guideline 203 (Fish, acute toxicity testing).

Toxicity (Daphnia):

The mixture is classified by a calculation method that considers the classified substances present in the mixture.

Sostanze pericolose no. CAS	Valore tipico	Valore	Tempo di esposizione	Specie	Metodo
Ammonium Oleate 544-60-5	EC50	88,5 mg/L	48 H	Daphnia magna	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test).
Diammonium citrate 3458-72-8	EC50	>10-100 mg/L	48 H	Daphnia magna	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test).

Chronic toxicity to aquatic invertebrate organisms

No data available.

Toxicity (Algae):

The mixture is classified by a calculation method that considers the classified substances present in the mixture.

Sostanze pericolose no. CAS	Valore tipico	Valore	Tempo di esposizione	Specie	Metodo
Ammonium Oleate 544-60-5	EC50	27 mg/L	72 H	Scenedesmus subspicatus (new name: Desmodesmus subspicatus)	DIN 38412-09
Ammonium Oleate 544-60-5	EC10	10 mg/L	72 H	Scenedesmus subspicatus (new name: Desmodesmus subspicatus)	DIN 38412-09
Diammonium citrate 3458-72-8	EC50	>10-100 mg/L	72 H	not specified	OECD Guideline 201 (Alga, growth inhibition test).

Toxicity to micro-organisms

The mixture is classified by means of a calculation method that considers the classified substances present in the mixture.

Sostanze pericolose no. CAS	Valore tipico	Valore	Tempo di esposizione	Specie	Metodo
Ammonium Oleate 544-60-5	EC0	500 mg/L	16 H	not specified	DIN 38412, part 8 (Pseudomonas Zellvermehrungshemm-Test)
Diammonium citrate 3458-72-8	EC0	>10-100 mg/L	3 H	not specified	OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)

12.2. Persistence and degradability

Sostanze pericolose no. CAS	Risultato	Tipo di test	Degradabilità	Tempo di esposizione	Metodo
Ammonium Oleate 544-60-5	easily biodegradable	aerobic	87 %	30 days	EU Method C.4-E (Determination of "ready" biodegradability - Closed Bottle Test)
Diammonium citrate 3458-72-8	easily biodegradable	aerobic	79 %	30 days	OECD Guideline 301 D (Rapid biodegradability: closed bottle test).

12.3. Bioaccumulative potential

Does not bioaccumulate.

Substance data not available.

12.4. Mobility in soil

Sostanze pericolose	LogPow	Temperatura	Metodo
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no. CAS			
Ammonium Oleate 544-60-5	4,85		not specified
Diammonium citrate 3458-72-8	-1,43	25 °C	QSAR (Quantitative Structure Activity Relationship)

12.5. Results of PBT and vPvB assessment

This mixture contains no substances evaluated as PBT or vPvB

12.6. Endocrine disrupting properties

Based on available data, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Other negative environmental effects of this product are not known to us.

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 October 17, 2024.

13.1. Waste treatment methods

Product disposal:

Dispose of in accordance with specific local and national regulations.

Disposal of contaminated packaging:

Dispose of only completely empty packaging as recyclable material.

SECTION 14: Transport information

14.1. UN number or ID number

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR.

14.2. UN proper shipping name

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

14.3. Transport hazard class(es)

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

14.4. Packing group

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

14.5. Environmental hazards

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

14.6. Special precautions for user

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

14.7. Maritime transport in bulk according to IMO instruments

Non-dangerous substance under RID, ADR, ADN, IMDG, IATA-DGR

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).

This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

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. R12/6E 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.

Hazard statements

H319: Causes serious eye irritation.

Legend

ACGIH: Association Advancing Occupational and Environmental Health.

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

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

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

EC50: The concentration such that 50% of the maximum effect is produced.

LC50, Lethal Concentration 50: lethal concentration for 50% of the organisms in a given population for a given exposure time.

EC-n.: European Registry of Chemical Substances on the Market.

ISO: International Organization for Training.

OEL: Occupational Exposure Limit.

PBT: Persistent, Bioaccumulative and Toxic: hazardous chemicals.

vPvB: mole Persistent very Bioaccumulative.

STOT: Specific target organ toxicity.

IMO: International Maritime Organization.

EN 374: Protective gloves against dangerous chemicals and micro-organisms.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods.

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

EC10: Effect concentration for 10% of the sample.