

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

1.1. Product identifier

Product description: Gloss for plaster models.

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

Identified Use Professional use: Product for the final polishing of plaster models.

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

Classification according to Regulation (EC) No 1272/2008

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2. Label elements

Not applicable.

2.3. Other hazards

Results of PBT and vPvB assessment:

Not classified as PBT or vPvB.




Determination of endocrine-disrupting properties:

Environmental information: There is no information available on endocrine disrupting properties for the environment.

Toxicological information: There is no information available on endocrine disrupting properties for human health.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
propan-2-ol	EINECS No. 200-661-7 CAS No. 67-63-0	2.5-10%	 Flammable liquids, Hazard Category 2, H225  Serious eye damage/eye irritation, Hazard Category 2, H319 STOT SE 3, H336
sodium carbonate	EINECS No. 207-838-8 CAS No. 497-19-8	≤2.5%	 Serious eye damage/eye irritation, Hazard Category 2, H319

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 complaints.

After skin contact: Immediately rinse with water. 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.

After swallowing: Rinse out mouth and then drink plenty of water. If symptoms persist 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 Media CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant

foam.

Unsuitable extinguishing Media None.

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not required.

6.2. Environmental precautions

Dilute with plenty of water. Do not allow to enter sewers/ surface or ground water.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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 disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep receptacles tightly sealed.

Information about fire - and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: Store only in the original receptacle.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Store in upright position. Keep container tightly sealed.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

67-63-0 propan-2-ol

WEL	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm
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Additional information: The lists valid during the making were used as basis.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No further data; see item 7.

8.2.2. Individual protection measures, such as personal protective equipment

General protective and hygienic measures: Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.

Respiratory protection:

Not required.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Fluid
Colour	Light yellow
Odour	Fruit-like
Odour threshold:	Not determined
Melting point/freezing point	Undetermined

Boiling point or initial boiling point and boiling range	82 °C
Flammability	Not applicable
Lower and upper explosion limit	Not determined
Flash point	>60 °C
Auto-ignition temperature	425 °C
Decomposition temperature	Not determined
pH at 20 °C:	11.3
Kinematic viscosity	Not determined
Water solubility	Fully miscible
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure	Not determined
Density at 20 °C:	0.98 g/cm ³
Relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	/

9.2. Other information

9.2.1. 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

9.2.2. Other safety characteristics

Form	Fluid
Auto-ignition temperature:	Product is not selfigniting
Explosive properties:	Product does not present an explosion hazard
Organic solvents:	4%
VOC (EC):	4%
Evaporation rate:	Not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No further relevant information available.

10.2. Chemical stability

No decomposition if used 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

No dangerous decomposition products known.

SECTION 11: Toxicological information

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

According to Regulation (EC) no. 1272/2008 [CLP], the risks related to the product's exposure can be summarized as follows:

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

LD/LC50 values relevant for classification:		
67-63-0 propan-2-ol		
Oral	LD50	5,840 mg/kg (rat)
Dermal	LD50	13,900 mg/kg (rabbit)
Inhalative	LC50/4 h	>25 mg/l (rat)
497-19-8 sodium carbonate		
Oral	LD50	2,800 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	2,300 mg/l (rat)

Skin corrosion/irritation:

Serious eye damage/irritation:

Respiratory or skin sensitisation:

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

STOT-single exposure:

STOT-repeated exposure:

Aspiration hazard:

Additional toxicological information

Sensitisation:

Based on available data, the classification criteria are not met.

Causes serious eye irritation.

Based on available data, the classification criteria are not met.

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11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity:	
67-63-0 propan-2-ol	
EC50	>100 mg/l (A) >100 mg/l (B)
LC50/96h	9,640 mg/l (fish)
497-19-8 sodium carbonate	
EC50	200-227 mg/l (daphnia)
EC50	300 mg/l (fish)

12.2. Persistence and degradability

Biodegradable.

12.3. Bioaccumulative potential

Does not accumulate in organisms.

12.4. Mobility in soil

No further relevant information available.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high

pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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

Recommendation:

Must not be disposed together with the household garbage. Do not allow product to reach sewage system.

European waste catalogue	
07 00 00	WASTES FROM ORGANIC CHEMICAL PROCESSES

07 06 00	wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics
07 06 99	wastes not otherwise specified

Uncleaned packaging – Recommendation: Disposal must be made according to official regulations.
Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN number or ID number

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14.2. UN proper shipping name

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14.3. Transport hazard class(es)

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14.4. Packing group

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14.5. Environmental hazards

No.

14.6. Special precautions for user

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14.7. Maritime transport in bulk according to IMO instruments

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).

Restrictions relating to the product or substances contained therein according to Annex XVII of Regulation (EC) 1907/2006

Conditions of restriction: 3.

National regulations:

Other regulations, limitations and prohibitive regulations:

Customs tariff number: 3402 19 00

Regulation 648/2004/EC: Contains 5-15% soap, fragrances

15.2. Chemical safety assessment

A Chemical Safety Assessment has not 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. R19-5E 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 and precautionary statements

H319: Causes serious eye irritation.

H225: Highly flammable liquid and vapour.

H336: May cause drowsiness or dizziness.

P280: Wear 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.

P337+P313: If eye irritation persists: Get medical advice/attention.

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.

EC50: 50 % effective concentration. Corresponds to the concentration of a tested substance capable of causing 50 % effect changes (e.g. on growth) during a specified time interval.

EINECS No.: European Inventory of Existing Commercial Substances.

GHS: World Harmonised System of Classification and Labelling of Chemicals.

IBE: Biological Exposure Index.

IMO: International Maritime Organization.

LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

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

TWA: Time-weighted average concentration of a chemical agent in the air within the breathing zone of a worker for an 8-hour working day.

VOC: Volatile Organic Compounds.

vPvB: Very Persistent And Very Bioaccumulative Substances.