

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

Product description: Utility wax, modelling wax, quadrangular wax sticks, sticky wax, thermo-wax for undercuts, wax for typodont.

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

Identified Use Professional use: Waxes for use in dentistry or dental laboratory.

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 under Regulation (EC) No. 1272/2008.

2.2. Label elements

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2.3. Other hazards

The preparation poses no danger to either humans or the environment.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

The preparation contains synthetic or natural waxes and food dyes.

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

Inhalation	Pure wax or wax containing no oil at all shows almost no vapor pressure when fluid, so inhalation absorption of any toxicologically relevant component can be ruled out.
Skin contact	Contact with molten/fluid product may cause burns. Cool immediately with cold water, if necessary treat the wound in a sterile manner, consult a physician. Absorption of kerosene components through the skin is not to be expected when the wax is solid.
Eye contact	Rinse thoroughly with water, consult a doctor if necessary (when wax is hot/fluid).
Ingestion	Rinse the mouth-no other measures are necessary. Waxes can be applied as components of pharmaceutical or food products, so the issue of absorption in the digestive tract after accidental ingestion is irrelevant.

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

None.

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

None.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing Media Foam, dry powder, carbon dioxide (CO₂), water jet.

Unsuitable extinguishing Media Full water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire, fumes are possible: carbon monoxide (CO).

5.3. Advice for firefighters

Respiratory protection independent of surroundings - in case of fumes.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid contact with melted wax.

6.2. Environmental precautions

Curb the leak and allow the product to cool. Do not enter surface water or sewage.

6.3. Methods and material for containment and cleaning up

Scrape and/or shovel the solidified material and then clean the area with absorbent material. Collect in closed containers suitable for disposal.

6.4. Reference to other sections

See protective measures in sections 7 and 8.

Disposal: see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

In case of powdered wax and ventilated room, use gloves and goggles.

Fire and explosion protection tips: No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and containers:

Store in a cool, dry place.

Store/store only in original container.

Protect from direct sunlight.

7.3 Specific end use(s)

No other relevant information is available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances according to EU common lists that must be monitored in workplaces.

8.2. Exposure controls

Protective measures and hygiene: Work in well-ventilated areas or use appropriate respiratory protection. Wear only tight-fitting, comfortable and clean protective clothing.

Wash hands before breaks and after work. Store work clothes separately.

Eye/face protection: In case of molten product, use face mask and goggles.

Hand protection: No special measures are needed.

Skin protection: Protective clothing.

Respiratory protection: Particle filtering device (DIN EN 143)

8.2.1. Appropriate engineering controls

Provide good ventilation.

8.2.3. Environmental exposure controls

Keep in mind point 6.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid, wax of different shapes and colors
Colour	Various.
Odour	Characteristic, differing according to type
Melting point	60 +/- 2 °C
Freezing point	< 50°C
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	The substance is flammable, but it does not intensify fires.
Lower and upper explosion limit	None
Flash point	> 130°C
Auto-ignition temperature	> 220 °C
Decomposition temperature	Not determined
pH	Not available
Kinematic viscosity	Not available
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	Not applicable
Density and/or relative density	ca. 0,93 g/cm ³
Relative vapour density	Not applicable
Particle characteristics	/.

9.2. Other information

There is no additional information.

SECTION 10: Stability and reactivity

10.1. Reactivity

No unusual reactivity is known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No known dangerous reactions.

10.4. Conditions to avoid

Heat dissipation.

10.5. Incompatible materials

Not indicated.

10.6. Hazardous decomposition products

Carbon monoxide, carbon dioxide.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity (oral)

Skin corrosion/irritation

Serious eye damage/irritation

Respiratory or skin sensitisation

Germ cell mutagenicity

Carcinogenicity

No information is available on systemic effects.

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

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The vapors have a very weak irritant effect.

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

An extensive program already carried out in 1958 to clarify the absence of carcinogenic properties in pure waxes was followed by its approval as a food ingredient.

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

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Reproductive toxicity

STOT-single exposure

STOT-repeated exposure

Aspiration hazard

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

Not applicable

SECTION 12: Ecological information**12.1. Toxicity**

No information available

12.2. Persistence and degradability

No data available. Given its consistency and insolubility, bioavailability is highly unlikely.

12.3. Bioaccumulative potential

It is not significantly accumulable in living organisms.

12.4. Mobility in soil

No information available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, Annex XIII.

12.6. Endocrine disrupting properties

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

12.7 Other adverse effects

Not hazardous to water - no further quantitative data on ecotoxic effects are available.

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

Disposal of contaminated packaging

Recycle in accordance with official regulations.

Dispose of waste in accordance with current legislation.

SECTION 14: Transport information**14.1. UN number or ID number**

No dangerous goods as defined by this transport regulation.

14.2. UN proper shipping name

No dangerous goods as defined by this transport regulation.

14.3. Transport hazard class(es)

No dangerous goods as defined by this transport regulation.

14.4. Packing group

No dangerous goods as defined by this transport regulation.

14.5. Environmental hazards

None

14.6. Special precautions for user

No dangerous goods as defined by this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous goods as defined by this transport regulation.

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).

Some products are 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 assessments have been carried out for the substances contained in this mixture.

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. R18/4E 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.

Legend

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.

CLP: Regulation on the classification, labelling and packaging of substances and mixtures.

IMO: International Maritime Organization.

DIN EN 143: Respiratory protective devices - Particle filters - Requirements, testing, marking.