



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, 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.

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.

For potential health hazards: See Section 11 below.

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

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

The product in solid form does not require particular first aid measures: if the product is in a melted state, act as follows:

Inhalation If inhaled: ensure the place is well ventilated. If feeling unwell, consult a doctor.

Skin contact Immediately dip the affected area in cold water and consult a doctor.

Eye contact Wash eyes immediately with plenty of water for at least 15 minutes and consult a doctor.

Ingestion No specific data.

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

Not available.

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

No specific data.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Carbon dioxide, chemical powders, foam, sand, nebulised water.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

If large amounts of the product are involved in the fire, CO and CO₂ may develop.

5.3. Advice for firefighters

Not combustible.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with melted wax.

6.2. Environmental precautions

Contain the loss and allow the product to cool.

**6.3. Methods and material for containment and cleaning up**

Scrape and/or sweep away the solidified material and afterwards clean the area with absorbent material.

6.4. Reference to other sections

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SECTION 7: Handling and storage**7.1. Precautions for safe handling**

In ventilated place, when using wax in powder, wear glasses and gloves.

7.2. Conditions for safe storage, including any incompatibilities

Store the product away from the heat sources and open flames, in ventilated and dry places.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The European Union has not issued max values for professional exposure relevant to the principal ingredients of the product.

8.2. Exposure controls

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	When using melted product, wear face mask and safety glasses.
Skin protection	Not necessary; eventually wear an apron.
Hand protection	Gloves.
Respiratory protection	Not necessary.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

	Utility wax	Modelling Wax	Quadrangular wax sticks	Sticky wax	Thermo-wax for undercuts	Wax for Typodont
Appearance	Solid.	Solid.	Solid.	Solid.	Solid.	Solid.
Odour	Odourless.	Odourless.	Odourless.	Odourless.	Odourless.	Odourless.
Colour	Blue.	Pink.	Blue.	Blue.	Blue.	Pink.
pH	Not determinable.	Not determinable.	Not determinable.	Not determinable.	Not determinable.	Not determinable.
Melting point	58±2°C.	65±2°C.	60±2°C.	62±2°C.	103±2°C.	67±2°C.
Burning temperature	> 220°C.	> 220°C.	> 220°C.	> 220°C.	> 220°C.	> 220°C.
Explosive properties	Not explosive.	Not explosive.	Not explosive.	Not explosive.	Not explosive.	Not explosive.
Relative density	0.78-0.86 at 60°C.	0.78-0.86 at 60°C.	0.78-0.86 at 60°C.	0.78-0.86 at 60°C.	0.78-0.86 at 60°C.	0.78-0.86 at 60°C.
Solubility in water	Insoluble.	Insoluble.	Insoluble.	Insoluble.	Insoluble.	Insoluble.
Volatile substances	No specific data.	No specific data.	No specific data.	No specific data.	No specific data.	No specific data.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity**10.1. Reactivity**

Information not available.

10.2. Chemical stability

Stable, it will not decompose in common conditions of use and storage.



10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition product(s)

Information not available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Paraffin are generally considered non-toxic. In mice, the high concentrations vapors, can cause pulmonary edema and hemorrhage. For prolonged contacts, these effects were observed on animals: irritation and ulceration of the skin.

Potential Acute Health Effects

Skin corrosion/irritation: not available.

Ocular damage/irritation: not available.

Skin and respiratory system sensitization: not available.

Signs and Symptoms of Exposure

Not known.

Medical Conditions Generally Aggravated by Exposure

Not known.

Carcinogenic or Potential Carcinogenic Effects

Not available.

Other Potential Health Effects

Not known.

Potential Chronic Health Effects

Not known.

SECTION 12: Ecological information

12.1. Toxicity

Paraffin degrades, in sediments and grounds, at a speed that depends on the micro organisms present. In water, it tends to absorb itself to hanging solids and sediments.

12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

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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.

13.1. Waste treatment methods

The product is classified as non dangerous special waste, and it can be disposed of in controlled dumps. Sometimes, on the decision of individual town councils, it can be disposed of with domestic waste.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN-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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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).

The utility wax, the modelling wax and the quadrangular wax sticks 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

Not applicable.

SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

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. R18/2E dated 29/05/2009 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 sheet.

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

Legend

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.