

Safety data sheet

Under Regulation (EC) No 2020/878

unidesa - odi

ARTIFICIAL TEETH

Odilux, Odipal, Odident, Odimax, Ortolux Top and Eledent

Date of revision 11.10.2022

Revision number 11

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

1.1. Product identifier

Trade product name: **Artificial teeth of the brands Odilux, Odipal, Odident, Odimax, Ortolux Top and Eledent**

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

Use of the substance or mixture: Material for dental prostheses.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier	Unión Dental, S.A. "unidesa - odi".
Address	Pº de la Estación, 4. 28550, Tielmes, Madrid, Spain
Telephone	0034 91 873 76 30
Fax	0034 91 874 64 90
Email	unidesa@unidesa-odi.com
Web	www.unidesa-odi.com
Information area	Regulatory Affairs

1.4. Emergency telephone number

0034 91 874 60 00 / Spanish Toxicology Information Service: 0034 91 562 04 20

SECTION 2 Hazard identification

2.1. Classification of the substance or mixture

According to Regulation (EC) No 1272/2008

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2. Label elements

Not applicable, product not classified as hazardous according to Regulation (EC) No 1272/2008

2.3. Other hazards

Avoid inhalation of grinding dust. No risks under normal conditions of use.

Results of PBT and vPvB assessment PBT: Not applicable vPvB: Not applicable

SECTION 3 Composition / information on ingredients

3.1. Substances

3.2. Mixtures

Chemical formulation: Mixture.

Description: Acrylic copolymer based on Polymethylmethacrylate (PMMA)

Hazardous ingredients: None.

ARTIFICIAL TEETH

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SECTION 4 First aid measures

4.1. Description of first aid measures

General instructions	No special measures required
Inhalation	Supply fresh air in case of inhalation of milling dust.
Skin contact	Not necessary. Generally, the product does not irritate the skin.
Eye contact	Rinse with water.
Ingestion	Seek medical attention.

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

No further relevant information is available.

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

No further relevant information is available.

SECTION 5 Firefighting measures

5.1. Extinguishing media

Extinguishing media dry, foam, CO₂, extinguishing powder and water spray.

5.2. Special hazards arising from the substance or mixture

The combustion gases are mostly methyl methacrylate vapours and carbon monoxide.

5.3. Advice for firefighters

Protective equipment: Protective equipment with breathing system, avoiding inhalation of fumes.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid inhalation of dust generated during milling.

6.2. Environmental precautions

No special measures are necessary.

6.3. Methods and material for containment and cleaning up

Collect the product mechanically.

6.4. Reference to other sections

See section 7 for safe handling.

See section 8 for personal protection.

See section 13 for product disposal.

ARTIFICIAL TEETH

Odilux, Odipal, Odident, Odimax, Ortolux Top and Eledent

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SECTION 7 Handling and storage

7.1. Precautions for safe handling

This product should only be handled by trained personnel. For use in dentistry only. In case of dust formation, provide a suction system.

7.2. Conditions for safe storage, including any incompatibilities

Requirements to be met by warehouses and containers

Normal temperature and humidity. The packaging contains wax which may melt.

Indications in case of joint storage

No special measures are necessary.

Additional information on storage

Avoid high temperatures and exposure to direct sunlight.

7.3. Specific end use(s)

Auxiliary agents for the production of dental prostheses.

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Components with limit values that require monitoring in the workplace: Does not contain.

8.2. Exposure controls

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

Eye protection Wear protective goggles when trimming, reworking or polishing the product with a rotating instrument.

Skin protection Not necessary.

Respiratory protection If dust is produced wear filter mask.

Hand protection Not necessary.

Additional information

Always work under hygienic conditions.

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid
Colour	Similar to natural teeth
Odour	Odourless
Boiling point	Not determined
Melting point	Not determined

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ARTIFICIAL TEETH

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Revision number 11

Flash point	Not applicable
Explosion hazard	Not foreseen
Self-flammability	-
Oxidising properties	-
Viscosity	-
Density	-
Solubility (Water)	Insoluble
pH value	-
Vapour pressure at 20°C	-

9.2. Other information

No further relevant information is available.

SECTION 10 Stability and reactivity

10.1. Reactivity

No further relevant information is available.

10.2. Chemical stability

The product is stable, does not decompose under normal handling and storage conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

No further relevant information is available.

10.5. Incompatible materials

Avoid exposure to strong oxidising agents, acids and alkalis.

10.6. Hazardous decomposition products

Not considered during normal storage. In case of thermal decomposition, combustible and irritating vapours of mainly methyl methacrylate are released, with release of toxic vapours.

SECTION 11 Toxicological information

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

Acute toxicity

On the basis of the available data, the classification criteria are not met.

Skin corrosion or irritation

On the basis of the available data, the classification criteria are not met.

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Serious eye damage or irritation

On the basis of the available data, the classification criteria are not met.

Sensitising effects

On the basis of the available data, the classification criteria are not met.

Inhalation hazard

On the basis of the available data, the classification criteria are not met.

11.2. Information on other hazards

Toxicological data have been determined specifically for this type of product. These products have been evaluated and declared as biocompatible and non-toxic.

SECTION 12 Ecological information

12.1. Toxicity

Not covered. The product is insoluble in water. No environmental hazards are foreseen.

12.2. Persistence and degradability

The product is not considered to be readily biodegradable.

12.3. Bioaccumulation potential

No further relevant information is available.

12.4. Mobility in soil

No further relevant information is available.

12.5. Results of PBT and vPvB assesment

PBT: Not applicable **vPvB:** Not applicable

12.6. Endocrine disrupting properties

No further relevant information is available.

12.7. Other adverse effects

No further relevant information is available.

SECTION 13 Disposal considerations

There are no special requirements. The product can be recycled or the material can be incinerated in accordance with local legislation.

13.1. Waste treatment methods

Uncontaminated or cleanable packaging can be sent for recycling. Packaging that cannot be cleaned should be disposed of in the same way as the product it contains.

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SECTION 14 Transport information

14.1. UN number or ID number

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.2. UN proper shipping name

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.3. Transport hazard class(es)

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.4. Packing group (ADR, IMDG, IATA)

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.5. Environmental hazards

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.6. Special precautions for user

Not applicable, the product is not considered hazardous according to applicable transport regulations.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, the product is not considered hazardous according to applicable transport regulations.

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations/legislation specific to the substance or mixture

Other regulations, limitations and prohibitions: The product is a medical device according to Regulation (EU) 2017/745.

15.2. Chemical Safety Assessment

A chemical safety assessment has not been carried out for the product.

SECTION 16 Other information

The information in this data sheet is based on current knowledge and current EU and national laws. The product must not be used for purposes other than those specified. It is always the responsibility of the user to take appropriate measures in order to comply with the requirements of current legislation. The information contained in this safety data sheet is only a description of the safety requirements of the product and is not to be considered as a guarantee of its properties. For further details on the use and shelf life of the product, please refer to the packaging, catalogues and/or instructions for use.

*Changes from the previous version

This fact sheet contains changes from the previous version in section(s): 4, 6 and 7.

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Abbreviations and acronyms

PBT: Persistent, Bioaccumulative and Toxic Substance

vPvB: very Persistent and very Bioaccumulative

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

IMDG: International Maritime Dangerous Goods Code

IATA: International Air Transport Association

IMO: International Maritime Organisation

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