

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 12.06.2026

Majesthetik-Gingiimplant

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

1.1. Product identifier

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

1.3. Details of the supplier of the safety data sheet

Company name: picodent Dental Produktions- und Vertriebs-GmbH
Street: Lüdenscheider Str. 24-26
City: D-51688 Wipperfürth
Telephone: +49 2267 6580-0
E-Mail: picodent@picodent.de
Internet: www.picodent.de
Department for information: picodent Dental Produktions- und Vertriebs-GmbH
 Telephone-No. +49 2267 6580-0

1.4. Emergency contact number:

Medical Emergency information in case of poisoning:
 Poison Information Center Mainz

-24 h – Phone: +49 6131 19240
 advisory service in German or English language

2. Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

2.3. Other hazards

No information available.

3. Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS-Nr.	Chemical name	Index-No	REACH-No	Quantity
	EG-No			
	Classification (Regulation (EC) No 1272/2008)			
14464-46-1	cristobalite flour			20 - < 40 %
	238-455-4			
	STOT RE 1; H372			

Full text of H and EUH statements: see section 16.

4. First aid measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

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After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect).

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

No information available.

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

Treat symptomatically.

5. Firefighting measures

5.1. Extinguishing media Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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Advice on protection against fire and explosion Advice on general occupational hygiene

No special fire protection measures are necessary.
Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary.
When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

7.3. Specific end use(s)

For use by trained specialist personnel.

8. Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. NBR (Nitrile rubber)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Paste

Colour:

Odour:

neutral

Test method

Melting point/freezing point:

not determined

Boiling point or initial boiling point and boiling range:

not determined

Flammability:

not applicable

Lower explosion limits:

not determined

Upper explosion limits:

not determined

Flash point:

>100 °C DIN 51755

Auto-ignition temperature:

>400 °C DIN 51794

Decomposition temperature:

>180 °C

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pH-Value: not determined
Water solubility: The study does not need to be conducted because the substance is known to be insoluble in water.

Solubility in other solvents
 not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure:

Vapour pressure: <10 hPa

(at 20 °C)

Density (at 20 °C): 1,34 g/cm³ DIN 51757

Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid: not applicable

Gas: not applicable

Oxidizing properties

Not oxidizing.

Other safety characteristics

Evaporation rate: not determined

Solid content: not determined

Viscosity / dynamic: (at 23 °C) 22000 mPa·s Rheometer

10. Stability and reactivity

10.1. Reactivity No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability The product is stable under storage at normal ambient temperatures.

10.5. Incompatible materials No information available.

11. Toxicological information *

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

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

ATEmix calculated ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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

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

Carcinogenic/mutagenic/toxic effects for reproduction Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met. Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

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

Revisions-Nr.: 1.4

GB

Überarbeitet am 12.06.2026

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12. Ecological information *

12.1. Toxicity	The product is not: Ecotoxic.
12.2. Persistence and degradability	The product has not been tested.
12.3. Bioaccumulative potential	The product has not been tested.
12.4. Mobility in soil	The product has not been tested.
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	This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.
12.7. Other adverse effects	No information available.
Further information	Avoid release to the environment.

13. Disposal considerations

13.1. Waste treatment methods	
Disposal recommendations	Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.
Contaminated packaging und empfohlene Reinigungsmittel	This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

14. Transport information

Land transport (ADR/RID)	
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Inland waterways transport (ADN)	
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Marine transport (IMDG)	
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Air transport (ICAO-TI/IATA-DGR)	
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.

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- 14.4. Packing group:** No dangerous good in sense of this transport regulation.
14.6. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.7. Maritime transport in bulk according to IMO instruments No dangerous good in sense of this transport regulation.

15. Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII): Entry 75

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment Chemical safety assessments for substances in this mixture were not carried out.

16. Other information *

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
STOT RE: Specific target organ toxicity - repeated exposure

Relevant H and EUH statements (number and full text)

H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

* Data compared to the previous version Rev.-No. 1.3 altered.