Safety Data Sheet

according to regulation (EU) No. 1907/2006

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

1.1 Information on the product
Trade name: Majesthetik Gingiimplant

1.2 Relevant identified uses of the substance/preparation and uses that are inadvisable

Use of the substance/mixture Silicone material for use in dental technology.

1.3 Details about the supplier of the safety data sheet
Manufacturer/Supplier:
Company name: picodent 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 GmbH
Fax-No. +49 2267 6580-31
Telephone-No. +49 2267 6580-0

1.4 Emergency contact number: Telephone-No. +49 2267 6580-0
(07.30 am - 4.45 pm) Telephone-No. +49 171 6126850

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
Chemical characterization Contains polydimethylsiloxane with functional groups. + fillers and pigment catalyst: additionally platinum complex compound.

Hazardous components

CAS No	Chemical name	Quantity
	EC No Index No REACH No Classification according to Regulation (EC) No. 1272/2008 [CLP]	
14464-46-1	cristobalite flour	35 - < 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

After inhalation
Provide fresh air. Medical treatment necessary.

After contact with skin
Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

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).
Do not induce vomiting. If you feel unwell, seek medical advice.

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. Fire-fighting 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
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 objects and areas thoroughly observing environmental regulations.

6.3. Methods and material for containment and cleaning up
Absorb with liquid-binding material (e.g. 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

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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.

Advice on protection against fire and explosion
No special fire protection measures are necessary.

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 exhaustion at critical locations.

Advice on storage compatibility
Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

Further information on storage conditions
Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Putty for use in dental laboratories.
For use by trained specialist staff.

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.

Protective and hygiene measures
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.

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.
Suitable are gloves of the following material: 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:	base: pink, catalyst: orange brown
Odour:	neutral

		Test method
pH-Value:	not determined	
Changes in the physical state		
Melting point:	not determined	
Initial boiling point and boiling range:	not determined	
Flash point:	not determined	
Flammability		
Solid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Ignition temperature:	>400 °C	DIN 51794
Auto-ignition temperature		
Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	>180 °C	
Oxidizing properties		
Not oxidizing.		
Vapour pressure: (at 20 °C)	<10 hPa	
Density (at 20 °C):	1,33 g/cm³	DIN 51757
Water solubility:	insoluble	
Solubility in other solvents		
not determined		
Partition coefficient:	not determined	
Viscosity / dynamic: (at 23 °C)	22000 mPa·s	Rheometer
Vapour density:	not determined	
Evaporation rate:	not determined	

9.2. Other information

Solid content:	not determined

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.

10.3. Possibility of hazardous reactions — Reacts with :

10.4. Conditions to avoid — Temperatures > 150°C/ 302 °F.

10.5. Incompatible materials — No information available.

10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.
At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.
For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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.
Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.
EC regulation 1272/2008 annex 1, section 1.1.1.5: „For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.“

STOT-repeated exposure

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

Aspiration hazard

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

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

Not identivied as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment.

13. Disposal considerations

13.1. Waste treatment methods

Advice on disposal Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging 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: 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: 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: 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: 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.

14.6. Special precautions for user No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code 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

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils 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 contaminating class (D): - - not water contaminating

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%

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 above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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