

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Rev. 2014-10

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

Information on the product

Trade name: Majesthetik-Gingiva

Company/undertaking identification:

picodent GmbH
Lüdenscheider Str. 24-26
D-51688 Wipperfürth

www.picodent.de
Telephone-No. +49 2267 6580-0
Fax-No. +49 2267 6580-30

Responsible Department:

picodent GmbH
Lüdenscheider Str. 24-26
D-51688 Wipperfürth

www.picodent.de
Telephone-No. +49 2267 6580-0
Fax-No. +49 2267 6580-30

Emergency telephone:

picodent GmbH, Wipperfürth

Telephone-No. +49 2267 6580-0

2. Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Not applicable.

Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the „General Classification guideline for preparations of the EU“ in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Label elements

Hazard-determining components of labelling:

Void

Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

Other hazards

Results of PBT and vPvB assessment

PBT:

Not applicable.

vPvB:

Not applicable.

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3. Composition/information on ingredients

Description: Addition-vulcanising 2-component silicone

Dangerous components:

27306-78-1 Heptamethyltrisiloxan, Polyalkylenoxid modifiziert ≤ 2.5%
 Xn R20-48/20;  Xi R36;  N R51/53
 STOT RE 2, H373;  Aquatic Chronic 2, H411;  Acute Tox. 4, H332; Eye Irrit. 2, H319

Additional information: For the wording of the listed risk phrases refer to section 16.

4. First aid measures

Description of first aid measures

General information: No special measures required.
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Generally the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: If symptoms persist consult doctor.
Information for doctor:
Most important symptoms and effects, both acute and delayed No further relevant information available.
Indication of any immediate medical attention and special treatment needed No further relevant information available.

5. Fire-fighting measures

Extinguishing media
Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
Special hazards arising from the substance or mixture No further relevant information available.
Advice for firefighters
Protective equipment: No special measures required.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Avoid contact with skin and eyes.
Environmental precautions: Do not allow to enter sewers/ surface or ground water.
Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Reference to other sections No dangerous substances are released.
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

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7. Handling and storage

Handling:

Precautions for safe handling

When using do not eat, drink or smoke.

Information about fire - and explosion protection:

No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms

Keep container tightly sealed.

and receptacles:

Information about storage in one common

Not required.

storage facility:

Further information about storage conditions:

None.

Specific end use(s)

No further relevant information available.

8. Exposure controls/personal protection

Additional information about design of technical facilities:

No further data; see item 7.

Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. The lists valid during the making were used as basis.

Additional information:

Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection:

Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Goggles recommended during refilling

Body protection:

Protective work clothing

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9. Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Viscous

Colour: Natural gingiva

Odour: Characteristic

Odour threshold: Not determined.

pH-value: Not determined.

Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 301 °C

Flash point: 131 °C

Ignition temperature: 470 °C

Decomposition temperature: Not determined.

Self-igniting: Product is not selfigniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapour pressure at 20 °C: 100 hPa

Density at 20 °C: 1.4 g/cm³

Relative density: Not determined.

Vapour density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with water: Not miscible or difficult to mix.

Segregation coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

Solvent content:

Organic solvents: 0.0 %

Other information

No further relevant information available.

10. Stability and reactivity

Reactivity

Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No further relevant information available.

Incompatible materials:

No further relevant information available.

Hazardous decomposition products:

No dangerous decomposition products known.

11. Toxicological information

Information on toxicological effects

Acute toxicity:

Primary irritant effect:

on the skin: No irritant effect.

on the eye: No irritant effect.

Sensitization: No sensitizing effects known.

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Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. Ecological information

Toxicity

Acquatic toxicity:

No further relevant information available.

Persistence and degradability

No further relevant information available.

Behaviour in environmental systems:

Bioaccumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment

PBT:

Not applicable.

vPvB:

Not applicable.

Other adverse effects

No further relevant information available.

13. Disposal considerations

Waste treatment methods

Recommendation:

Disposal must be made according to official regulations.

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

14. Transport information

Land transport ADR/RID (cross-border)

ADR/RID class:

-

Maritime transport IMDG:

IMDG Class:

-

Marine pollutant:

No

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class:

-

UN „Model Regulation“:

-

Special precautions for user

Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

15. Regulatory information

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

National regulations:

Waterhazard class:

Water hazard class 1 (Self-assessment): slightly hazardous for water.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

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16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H411 Toxic to aquatic life with long lasting effects.
- R20 Harmful by inhalation.
- R36 Irritating to eyes.
- R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
- R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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)
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- IATA-DGR: Dangerous Goods Regulations by the „International Air Transport Association“ (IATA)
- ICAO: International Civil Aviation Organization
- ICAO-TI: Technical Instructions by the „International Civil Aviation Organization“ (ICAO)
- GHS: Globally Harmonized System of Classification and Labelling of Chemicals