

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Comp. A

Page 1 of 10

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

- 1.1. Product identifier** Majesthetik-Gingiva Comp. A
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Use of the substance/preparation Gingiva mask material
- 1.3. Details of the supplier of the safety data sheet**
Address/Manufacturer picodent Dental Produktions- und Vertriebs-GmbH
 Lüdenscheider Str. 24-26
 D-51688 Wipperfürth
 +49 2267 6580-0
 picodent@picodent.de
 www.picodent.de
 picodent Dental Produktions- und Vertriebs-GmbH
 Telefon-Nr. +49 2267 6580-0
- 1.4. Emergency contact number:**
Medical Emergency information in case of poisoning: -24 h – Phone: +49 6131 19240
 advisory service in German or English language
 Poison Information Center Mainz

2. Hazards identification

- 2.1. Classification of the substance or mixture** This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.
- 2.2. Label elements**
Labelling according to regulation (EC) No 1272/2008
Supplemental information EUH210
 Safety data sheet available on request.
- 2.3. Other hazards** No special hazards have to be mentioned.
- The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

3. Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization Addition-vulcanising 2-component silicone
Hazardous ingredients
- Cristobalit**
 CAS-Nr. 14464-46-1
 EINECS-Nr. 238-455-4
 Concentration >= 25 < 50 %
 Classification (Regulation (EC) No. 1272/2008)
 STOT RE 1 H372

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 2 of 10

White mineral oil

CAS-Nr. 8042-47-5
EINECS-Nr. 232-455-8
Registration no. 01-2119487078-27
Concentration ≥ 1 < 10 %
Classification (Regulation (EC) No.1272/2008)
Asp. Tox. 1 H304

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

CAS-Nr. 68909-20-6
EINECS-Nr. 272-697-1
Registration no. 01-2119379499-16
Concentration ≥ 1 < 10 %
Classification (Regulation (EC) No.1272/2008)
STOT RE 2 H373

Name of set of nanoform Nanoagglomerate
Particle size distribution d50 2,5-50 nm
Method Transmission Electron Microscopy (TEM)

Shape and aspect ratio of particles Spheroidal

4. First aid measures

4.1. Description of first aid measures

General information

After inhalation

No special measures required

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Do not induce vomiting - aspiration hazard. Summon a doctor immediately.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 3 of 10

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting Other information

In case of combustion use a suitable breathing apparatus.
Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Clean contaminated floors and objects thoroughly, observing environmental regulations.

6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals. For personal protection see Section 8.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Further information on storage conditions

Keep container tightly closed and dry.

8. Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

White mineral oil

List

TRGS 900

Typ

AGW

A

Value

5 mg/m³

Short term exposure limit

20 mg/m³

Maximum limit value:

4(II) Pregnancy group: Y; Status: Sept 2015; Remarks: DGF

Other information

Contains no substances with occupational exposure limit values.

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 4 of 10

Derived No/Minimal Effect Levels (DNEL/DMEL)

White mineral oil

Type of value	Derived No Effect Level (DNEL)
Reference group	Worker
Duration of exposure	Repeated exposure
Route of exposure	inhalative
Mode of action	Systemic effects
Concentration	164,6 mg/m ³

Type of value	Derived No Effect Level (DNEL)
Reference group	Worker
Duration of exposure	Repeated exposure
Route of exposure	dermal
Mode of action	Systemic effects
Concentration	217,1 mg/kg/d

Type of value	Derived No Effect Level (DNEL)
Reference group	Consumer
Duration of exposure	Repeated exposure
Route of exposure	inhalative
Mode of action	Systemic effects
Concentration	34,78 mg/m ³

Type of value	Derived No Effect Level (DNEL)
Reference group	Consumer
Duration of exposure	Repeated exposure
Route of exposure	dermal
Mode of action	Systemic effects
Concentration	93,02 mg/kg/d

Type of value	Derived No Effect Level (DNEL)
Reference group	Consumer
Duration of exposure	Repeated exposure
Route of exposure	oral
Mode of action	Systemic effects
Concentration	25 mg/kg/d

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals. Do not eat, drink or smoke during work time. Wash hands before breaks and after work. Avoid contact with eyes.

Respiratory protection

Not necessary.

Hand protection

Not necessary.

Eye protection

Not necessary.

Body protection

Clothing as usual in the chemical industry.

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 5 of 10

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid, viscous
Colour	white
Odour	characteristic
Melting point	
Remarks	not determined
Freezing point	
Remarks	not determined
Boiling point or initial boiling point and boiling range	
Value	> 300 °C
Flammability	
evaluation	not determined
Upper and lower explosive limits	
Remarks	not determined
Flash point	
Value	> 160 °C
Method	closed cup
Ignition temperature	
Remarks	not determined
Decomposition temperature	
Remarks	not determined
pH value	
Remarks	not determined
Viscosity	
Remarks	not determined
Solubility(ies)	
Remarks	not determined
Partition coefficient n-octanol/water (log value)	
Remarks	not determined
Vapour pressure	
Remarks	not determined
Density and/or relative density	
Value	1,25 g/cm ³
Temperature	20 °C
Relative vapour density	
Remarks	not determined

9.2. Other information

Odour threshold	
Remarks	not determined
Evaporation rate (ether = 1) :	
Remarks	not determined
Solubility in water	
Remarks	virtually insoluble
Explosive properties	
evaluation	not determined
Oxidising properties	
Remarks	not determined
Other information	None known

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 6 of 10

10. Stability and reactivity

10.1. Reactivity	No hazardous reactions when stored and handled according to prescribed instructions.
10.2. Chemical stability	No hazardous reactions known.
10.3. Possibility of hazardous reactions	No hazardous reactions known.
10.4. Conditions to avoid	No hazardous reactions known.
10.5. Incompatible materials	None known
10.6. Hazardous decomposition products	No hazardous decomposition products known.

11. Toxicological information

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

Acute oral toxicity

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

Acute oral toxicity (Components)

White mineral oil

Species rat
LD50 > 5000 mg/kg
Method OECD 401

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species rat
LD50 > 5000 mg/kg
Method OECD 401
Remarks Test conducted with a similar formulation.

Acute dermal toxicity

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

Acute dermal toxicity (Components)

White mineral oil

Species rabbit
LD50 > 2000 mg/kg
Method OECD 402

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species rabbit
LD50 > 5000 mg/kg
Source Analogous

Acute inhalational toxicity

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

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 7 of 10

Acute inhalative toxicity (Components)

White mineral oil

Species	rat
LC50	> 5 mg/l
Duration of exposure	4 h
Administration/Form	Dust/Mist
Method	OECD 403

Silanamine, 1,1,1-Trimethyl-N-(trimethylsilyl)

Species	rat
LC50	> 5,01 mg/l
Duration of exposure	4 h
Administration/Form	Dust/Mist
Source	Analogous

Skin corrosion/irritation

Remarks

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

Serious eye damage/irritation

Remarks

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

Sensitization

Remarks

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

Subacute, subchronic, chronic toxicity

Remarks

not determined

Mutagenicity

Remarks

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

Reproductive toxicity

Remarks

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

Carcinogenicity

Bemerkung

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

Specific Target Organ Toxicity (STOT)

Single exposure

Remarks

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

Repeated exposure

Bemerkung

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

Specific Target Organ Toxicity (STOT) (Components)

Cristobalite

Repeated exposure

evaluation

Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

Aspiration hazard

Aspiration hazard (Components)

White mineral oil

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

Harmful: may cause lung damage if swallowed.

11.2. Information on other hazards

Endocrine disrupting properties with respect to humans

The product does not contain a substance that has endocrine disrupting properties with respect to humans.
endokrine Eigenschaften aufweist.

Other information

No toxicological data are available.

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 8 of 10

12. Ecological information

12.1. Toxicity

General information

not determined

Fish toxicity (Components)

White mineral oil

Species	golden orfe (<i>Leuciscus idus</i>)
LC50	> 10000 mg/l
Duration of exposure	96 h
Method	OECD 203

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	zebra fish (<i>Brachydanio rerio</i>)
LC50	> 10000 mg/l
Expositionsdauer	96 h
Source	Analogous

Daphnia toxicity (Components)

White mineral oil

Species	Daphnia magna
LL50	> 100 mg/l
Duration of exposure	48 h
Method	OECD 202

White mineral oil

Species	Daphnia magna
NOEC	10 mg/l
Duration of exposure	21 d
Method	OECD 211

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	Daphnia magna
EC50	> 1000 mg/l
Duration of exposure	48 h
Source	Analogous

Algae toxicity (Components)

White mineral oil

Species	Pseudokirchneriella subcapitata
LOEC	>= 100 mg/l
Duration of exposure	72 h
Method	OECD 201

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	Desmodesmus subspicatus
EC50	> 173 mg/l
Duration of exposure	72 h
Source	Analogous

Bacteria toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	activated sludge
EC50	> 2500 mg/l
Duration of exposure	3 h
Method	OECD 209
Source	Analogous

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 9 of 10

12.2. Persistence and degradability

General information

not determined

Biodegradability (Components)

White mineral oil

Value

31 %

Duration of test

28 d

evaluation

Moderately/partially biodegradable

Method

OECD 301 F

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Remarks

Inorganic product, cannot be eliminated from the water by biological purification processes

12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks

not determined

Octanol/water partition coefficient (log Pow) (Components)

White mineral oil

log Pow

<= 4,3 to 18.2

Temperature

20 °C

Source

ECHA

12.4. Mobility in soil

General information

not determined

12.5. Results of PBT and vPvB assessment

General information

not determined

Results of PBT and vPvB assessment

The product contains no PBT substances

The product contains no vPvB substances

12.6. Endocrine disrupting properties

Endocrine disrupting properties with respect to the environment

The product does not contain a substance that has endocrine disrupting properties with respect to nontarget organisms.

12.7. Other adverse effects

General information

not determined

General information / ecology

Do not allow to enter soil, waterways or waste water canal. Avoid release into the atmosphere.

13. Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Must not be disposed together with household garbage.

Dispose of waste according to applicable legislation.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

Safety Data Sheet

according to regulation (EU) No. 1907/2006

Printing date: 07.12.2023

Majesthetik-Gingiva Komp. A

Page 10 of 10

14. Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN-number or ID-number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	Other information
	All components are contained in the TSCA inventory or exempted.
15.2. Chemical safety assessment	For this preparation a chemical safety assessment has not been carried out.

16. Other information

Hazard statements listed in Chapter 2/3

H304	May be fatal if swallowed and enters airways.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 2/3

Asp. Tox. 1	Aspiration hazard, Category 1
STOT RE 1	Specific target organ toxicity - repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, Category 2

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.