

SAFETY DATA SHEET
according to 1907/2006/EC, Article 31

Issue Date: 02/01/2016

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

1.1 Product identifier

Trade name: SILILIGHT

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

No further relevant information available.

Application of the substance / the mixture: Condensation curing polysiloxane dental impression materials.

1.1 Details of the supplier of the safety data sheet

BMS DENTAL S.R.L.

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1.2 Emergency telephone number

+39 0587 606089 (09.00 – 18.30, European time, GMT+2)

SECTION 2: Hazards Identifications

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

This product is regulated as a medical device or an in vitro diagnostic medical device [Directive 93/42/EEC]

– Exempt from requirements according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5).

The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to regulation (EC) No 1272/2008

Exempt from requirements – product regulated as a medical device or an in vitro diagnostic medical device.

Hazard pictograms: Void

Signal word: Void

Hazard statements: Void

2.3 Other hazards

Results of PBT and vPvB assessment.

PBT: not applicable

vPvB: not applicable

SECTION 3: Composition/Information on ingredients

3.2 Chemical characterization

Mixtures

Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed.

Description: Void

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SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact

Instantly wash with water and soap and rinse thoroughly.

After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing

Rinse mouth. If you feel unwell get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Protective equipment: Wear self-contained respiratory system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area. Avoid contact with eyes and skin. Wear protective clothing.

6.2 Environmental precautions

Avoid release to the environment. Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Collect mechanically. The product may be absorbed by liquid-binding material (sand, diatomite, acid binders). Wash spill area with alcohol or water and soap.

6.4 Reference to other sections

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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SECTION 7: Handling and storage

7.1 Precautions for safe handling

No special precautions are necessary if used correctly.

Information about fire – and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store only in original receptacles.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Protect from heat and direct sunlight.

Keep container tightly sealed.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

This product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the making were used as a basis.

8.2 Exposure control

Personal protective equipment (PPE):

General protective and hygiene measures:

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

Avoid contact with eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

Keep away from foodstuffs, beverages and feed.

Respiratory protection: Not required

Protection of hands:

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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.

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Eye protection: Safety glasses

SECTION 9: Physical and chemical properties

9.1 <u>Information on basic physical and chemical properties</u>	
General information	
Appearance:	
Form:	Pasty to fluid
Colour:	According to product specification
Odour:	Odourless
Odour threshold:	Not determined.
pH value:	Not applicable.
Change in condition:	
Melting point/Melting range:	Undetermined
Boiling point/Boiling range:	Undetermined
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Self-igniting:	Product is not self igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not determined.
Evaporation rate:	Not determined.
Solubility in / Miscibility with:	
Water:	Insoluble.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
9.2 <u>Other information</u>	No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity: No further relevant information available.

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10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: Not known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

LD/LC50 values relevant for classification: No further relevant information available.

Primary irritant effect:

on the skin: No irritant effect.

on the eye: Irritating effect.

Sensitization: No sensitizing effects known.

Additional toxicological information: No further relevant information available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil

Additional ecological information:

General notes:

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water, even if small quantities leak into soil.

12.5 Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendations

Must not be disposed together with household garbage. Do not allow to reach sewage system.

Uncleaned packaging

Recommendations

Disposal must be carried out in accordance to the local and national regulations currently in force.

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SECTION 14: Transport information

14.1 UN-Number ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class	Void
14.4 Packing group ADR, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant	No
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and IBC Code	Not applicable
Transport/Additional information	-
UN "Model Regulation":	-

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

The information provided above is based on our present knowledge and experience. This safety data sheet refers explicitly to the product indicated and comprises no guarantee of particular quality. Any use of this product in any way not indicated on this safety data sheet will be exclusively under the user's responsibility.

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 Harmonised 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 (division of the American Chemical Society)