

SAFETY DATA SHEET

According to Regulation (EC) No.1907/2006, Art.31

Issue date: 21.05.2015

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

Product details :

1.1. Trade name

MONO

1.2. Application of the substance / the preparation Filler/ Extender

Impression material

1.3. Manufacturer/Supplier

DEI ITALIA S.r.l.

Via Torino 765 – 21020 Mercallo (Varese)

Tel.+39 0331 969270 Fax +39 0331 969271

Sito web : www.deiitalia.it

E-mail: info@deiitalia.it

1.4. Information in case of emergency

Ospedale Niguarda di Milano-Centro antiveneni numero di emergenza +39 02 66101029

2. Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: void

Information concerning particular hazards for human and environment:

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

Label elements:

Labeling according to Regulation (EC) 1272/2008: void

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards :

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. Composition/information on ingredients

Chemical characterization:

Description: mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: none

4. First aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after eye contact: rinse with plenty of water and consult a doctor

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after swallowing: If symptoms persist consult a doctor

5. Fire-fighting measures

Extinguishing media: CO₂, water

Protective equipment: no special measures required

6. Accidental release measures

Personal precautions: not required

Environmental precautions: no special measures required

Methods for cleaning up: pick up mechanically

Additional information: none

7. Handling and storage

Information for safe handling:

For dental use only. No special measures required.

Recommendation for fire and explosion protection:

No special measures required

Storage:

Requirements at storerooms and containers:

No special measures required

Requirements for storage with other products: not required

Further information on storage conditions: none

8. Exposure controls and personal protection

Components with limits of values to be supervised at the workplace:

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

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

Personal protective equipment:

General measures of protection and hygiene: normal hygienic measures

Respiratory protection: not required

Protection of hands: not required

Eye protection: not absolute required

9. Physical and chemical properties

Appearance:

Form: paste

Color: different

Odor: odorless

Information on change in the physical state

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.a.

Autoignition temperature: n.a.

Danger of explosion: none

Density: 1,41 (20°C) g/cm³

Vapor pressure: n.a.

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Viscosity: paste
pH: neutral
Solubility in/miscibility with: Partially soluble in toluene, petrol ether
Water: insoluble
Content of solvents: none
Organic solvents: ---
Water: ----
Content of solids: n.a.

10.Stability and reactivity

Conditions to avoid:

No decomposition if used according to specification

Hazardous decomposition products:

none under normal conditions of storage and use

11.Toxicological information

Acute toxicity:

Primary irritation:

skin: no irritating effect

eye: no irritating effect

Additional toxicological information:

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

General information: Avoid transfer into environment

Classification of water endangerment: WGK 1 (EU regulation) slightly hazardous for water

13. Disposal considerations

Product:

Recommendation:

Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

14. Transport information

Land transport ADR, RID: no subject to transport regulations

Maritime transport: IMDG-Code: no subject to transport regulations

Air transport ICAO-TI/IATA-DGR: no subject to transport regulations

15.Regulations

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16.Other informations

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Changes compared with the previous version:

Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.