

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

Issue date: 15.07.2015

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

Product details :

1.1. Trade name

POKER CEM

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

Dental product

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) No 1272/2008:

Skin Irrit. 2, H315 Causes skin irritation

Eye Irrit. 2, H319 Causes serious eye irritation

Skin Sens. 1; H317 May cause allergic skin reaction

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms

Signal word

Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause allergic skin reaction

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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.

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Other hazards :

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. Composition/information on ingredients

Chemical characterization:

Description:

Mixture of resin based on Bis-GMA, catalyst, stabilizer, pigments

Hazardous components:

Methacrylates GHS07, H315, H319, H317, H335

4. First aid measures

General information:

Seek medical advice, if symptoms occur, which can be caused by the product

after skin contact: wash with plenty of water and soap

after inhalation: fresh air

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

after swallowing: If symptoms persist consult a doctor

5. Fire-fighting measures

Extinguishing media:

CO₂, powder, water spray. Use extinguishing method and media suitable to surrounding fire.

Special hazards arising from the substance or mixture:

No further relevant information available

Protective equipment :

Wear self-contained respiratory protective equipment

6. Accidental release measures

Personal precautions: not required

Environmental precautions: Do not allow to enter drains/surface water/ ground-water.

Methods for cleaning up: Pick up mechanically. Clean up affected area.

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

7. Handling and storage

Handling:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information for safe handling: Observe normal care for working with chemicals.

Information about fire and explosion protection: No special measures required

Storage:

Store at a dry place. Store tightly closed. Storage temperature <25°C.

Requirements at storerooms and containers: Store only in the original containers

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Further information on storage conditions: Store away from food stuffs.

Specific end uses:

No further relevant information available

8. Exposure controls and personal protection

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

The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

Additional information:

The lists valid during the making were used as basis Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

Hand protection: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form: flowable paste

Color: tooth colored

Odor: odorless

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.d.

Ignition temperature: n.d.

Danger of explosion: none

Density: 1.72 g/cm³ (20°C)

Vapor pressure: n.a.

pH: neutral

Solubility in/miscibility with: Partially soluble in toluene, silicone oil

Water: insoluble

Content of solvents: none

Organic solvents: none

10. Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: no information available

Conditions to avoid:

Heat, direct sunlight and radical starters.

The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.

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11.Toxicological information

Acute toxicity: no data available

Primary irritation:

skin: irritant

eye: irritant

Sensitization: sensitization by skin contact possible

Additional toxicological information:

Allergic reactions to the product after long-term exposure are possible. 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 (slightly polluting substance).

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 and GGVSt/GGVE (EU): no subject to transport regulations

Sea transport IMDG: no subject to transport regulations

Air transport ICAO-TI and 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

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.