

SAFETY DATA SHEET

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

Date of issue: 29.05.2015

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

Product details :

1.1. Trade name

COMPO CAPS – POWDER

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

Dental product

1.3. Manufacturer/Supplier

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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: void

Information concerning particular hazards for human and environment: The product does not have 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: 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: Mixture

Description of the mixture: barium-fluoro-aluminosilicate glass powder, nano-fillers and pigments

Hazardous components: none

4. First aid measures

General information: no special measures required

after skin contact: wash with plenty of water and soap

after inhalation: supply with fresh air

after eye contact: rinse opened eye for several minutes under running water and consult a doctor

after swallowing: seek medical advice if problems persist

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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, protective equipment and emergency procedures

Avoid formation of dust.

Environmental precautions:

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

Methods for cleaning up:

Take 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.

Precautions for safe handling: Observe normal care for working with chemicals

Information about fire and explosion protection: No special measures required

Storage:

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

Further information on storage conditions: Store at dry place, at room temperature (< 25°C, 78°F).

Store away from food stuffs. Always store with lid on

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 limit 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.

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

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9. Physical and chemical properties

9.1. General Information

Form: fine powder

Colour: white

Odour: odourless

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. (non combustible)

Danger of explosion: none

Density: n.a.

Vapour pressure: n.a. (non volatile)

Viscosity: n.a. (powder)

pH: n.a.

Solubility in/miscibility with:

Water: slightly

Content of solvents: none

Organic solvents: none

10. Thermal decomposition / conditions to be avoided

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications. Avoid heat and direct sunlight.

Possibility of hazardous reactions: No dangerous reaction 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

Acute toxicity:

Primary irritation:

skin: may cause skin irritation (aerosols)

eye: irritating effect (aerosols)

Sensitization: no sensitizing effect known

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

Toxicity:

Aquatic toxicity: No further relevant information available

Persistence and degradability: No further relevant information available

Behavior in environmental systems:

Bioaccumulative potential : No further relevant information available

Mobility in soil : No further relevant information available

General information: Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system .

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13. Disposal considerations

Product:

Recommendation: 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 GGVS/GGVE (EU)

Not classified as dangerous goods in the meaning of transport regulations

Sea transport IMDG

Not classified as dangerous goods in the meaning of transport regulations

Air transport ICAO-TI and IATA-DGR

Not classified as dangerous goods in the meaning of 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 information

Changes compared with the previous version:

Adaptation according to REACH-regulation (EC) No. 1907/2006, 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.