

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

date: 20.05.2015

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

Product details :

1.1. Trade name

SEAL COAT FAST1.2. 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.itE-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:**

Flam. Liq. 2, H225 Highly flammable liquid and vapour

Skin Irrit. 2, H315 Causes skin irritation

Skin Sens1, H317 May cause allergic skin reaction

STOT SE 3, H335 May cause respiratory irritation.

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**

Danger

Hazard statements

H225 Highly flammable liquid and vapour

H315 Causes skin irritation

H317 May cause allergic skin reaction

H335 May cause respiratory irritation

Precautionary statements

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

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.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. Composition/information on ingredients**Chemical characterization:****Description:**

Light cure varnish based on multifunctional methacrylates and methylmethacrylate

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Hazardous components:

CAS-No.	Name	
80-62-6	Methyl methacrylate	GHS02, GHS07, H225, H315, 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 off with plenty of water. In case of skin irritation, consult a doctor.

after inhalation: Fresh air. Consult a doctor if feeling unwell.

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

after swallowing: Rinse mouth immediately and drink plenty of water. Seek medical advice if necessary.

5. Fire-fighting measures

Extinguishing media:

CO₂, powder, water, foam.

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:

Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms

Environmental precautions:

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

Methods for cleaning up:

Absorb with liquid binding material. Forward for disposal. 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:

Keep away from sources of ignition. Take measure to prevent electrostatic charge

Storage:

Store at a dry place, protected from light. Store tightly closed. Storage temperature <25°C.

Requirements at storerooms and containers:

Store only in the original containers

Further information on storage conditions:

Store away from food stuffs.

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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:

CAS-No.	name	art	value unit
[80-62-6]	Methyl methacrylate	TRGS 900 (EU)	210 mg/m ³ resp. 50 ml/m ³

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 vapors/aerosols are generated.

9.Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form: liquid

Color: slightly yellow

Odor: characteristic

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: 100 °C

Flash point: 10 °C DIN 51794

Ignition temperature: no information available

Danger of explosion: Lower 2.1 - Upper 12.5

Density: ca. 1 g/cm³

Vapor pressure: n.d.

pH: n.a.

Solubility in/miscibility with:

Water: slightly soluble

Content of solvents:

Organic solvents: none

10.Thermal decomposition / conditions to be avoided

Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions:

no information available

Conditions to avoid:

Warming > 50°C. Exposure to light. Polymerization possible in presence of heat, light, radical starters as peroxides, reducing agents, etc. Do not use various plastics or rubber as working materials.

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Hazardous decomposition products:

No information available.

11.Toxicological information

Acute toxicity:

(methyl methacrylate) LD50 (oral, rat) 7872 mg/kg

Primary irritation:

skin: irritant

eye: irritant

Sensitization: Sensitizing in case of skin contact possible

Additional toxicological information:

Allergic reactions to methacrylates 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:

Do not allow to enter drains/canalisation/ground-water

Classification of water endangerment:

WGK=1 (slightly polluting substance).

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):

UN 1247 METHYLMETHACRYLAT, MONOMER, STABILIZED, 3,II

Sea transport IMDG:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II

EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II

The transport regulations are cited according to international regulations and in the form applicable in EU. Possible national deviations in other countries are not considered.

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 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.