

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 FAST LED

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:

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

Eye Irrit. 2, H319 Causes serious eye irritation

STOT SE 3, H336 May cause drowsiness or dizziness

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

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

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

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

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PBT: not applicable
vPvB: not applicable

3. Composition/information on ingredients

Chemical characterization:

Description:

Light cure varnish based on multifunctional methacrylates and ethylacetate

Hazardous components:

CAS-No.	EC- No.	
[141-78-6],	2005-500-4	Ethylacetate GHS02, GHS07

4. First aid measures

General information:

no special measures required

after skin contact: Wash off with plenty of water and soap

after inhalation: Fresh air.

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

after swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free.

Consult a physician. Subsequently administer: activated charcoal (20 – 40 g in 10% slurry).

Laxative: Sodium sulfate (1 tablespoon/ 1/4 l water)

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:

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. Clean up affected area.

Reference to other sections:

See Section 7 for information on safe handling

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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 in well ventilated place at 15 °C to 25 °C, protected from light. Store away from food stuffs.

Store tightly closed. Keep away from heat and sources of ignition.

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
[141-78-6]	Ethylacetate	TRGS 900 (EU)	1500 mg/m ³ or 400 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 aerosols are generated.

9. Physical and chemical properties

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Information on basic physical and chemical properties

Appearance

Form: liquid

Color: slightly yellow

Odor: sweetish

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: approx 77 °C

Flash point: - 4°C DIN 51755

Ignition temperature: no information available

Danger of explosion: Lower 2.1 - Upper 11.5

Density: ca. 1,03 g/cm³

Vapor pressure: n.d.

pH: n.a.

Solubility in/miscibility with:

Water: soluble

Content of solvents:

Organic solvents: ethylacetate

10. Thermal decomposition / conditions to be avoided

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.

11. Toxicological information

Acute toxicity:

LD50 (oral, rat) 5600 mg/kg

LD50 (dermal, rabbit) >18000 mg/kg

LD50 (inhal., rat) 5,86 mg/l (8h)

Primary irritation:

skin: repeated exposure may cause skin dryness or cracking

eye: strong irritating effect

Inhalation and swallowing: irritation of mucous membranes, loss of appetite, headache, drowsiness

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

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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 flush into surface water or sanitary sewer system

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 1173 ETHYLACETATE, 3, II

Sea transport IMDG:

UN 1173 ETHYLACETAT, 3, II

Air transport ICAO-TI and IATA-DGR:

UN 1173 ETHYLACETATE, 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.