

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

Printing date: 21.03.2016

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

Product details :

1.1. Trade name

EASYFILL OPAQUE

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

Dental filling material

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

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms :

GHS07

Signal word Warning

Hazard-determining components of labelling:

tetramethylene dimethacrylate

Hazard statements :

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P321 Specific treatment (see on this label). P363 Wash contaminated clothing before reuse. P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms :

GHS07

Signal word :Warning

Hazard-determining components of labelling:

tetramethylene dimethacrylate

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Hazard statements

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P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3. Composition/information on ingredients

3.2 Chemical characterisation:

Mixtures

Description:

Urethandimethacrylate

1,4-Butandioldimethacrylate

Dangerous components:			
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate	Skin Sens. 1B, H317	2,5-10%

Additional information For the wording of the listed risk phrases refer to section 16.

4.First aid measures

4.1 Description of first aid measures

General information :No special measures required.

After inhalation :Supply fresh air; consult doctor in case of complaints.

After skin contact : Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing : Rinse out mouth and then drink plenty of water. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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

Printing date: 21.03.2016

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents : CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents Water with full jet.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: Adapt to environment.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid eye and skin contact with the substance.

6.2 Environmental precautions

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4 Reference to other sections

No dangerous substances are released.

7. Handling and storage

7.1 Precautions for safe handling

Keep away from heat and direct sunlight. No special measures required.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage :

Requirements to be met by storerooms and receptacles:

Close container immediately after use and protect product from light incidence. Storage between 10 °C and 25 °C.

Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions: None.

7.3 Specific end use(s)

No further relevant information available.

8. Exposure controls and personal protection gear

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

Printing date: 21.03.2016

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

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures : The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not necessary if room is well-ventilated.

Protection of hands: Protective gloves.

Material of gloves Butyl rubber, BR

Penetration time of glove material 0,1 - 0,2 mm - Penetration time: 5 min.

Eye protection: Goggles recommended during refilling.

Body protection: Protective work clothing.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Viscous

Colour: According to product specification

Odour: Weak, characteristic

Odour threshold: Not determined.

pH-value: Not determined.

Change in condition

Melting point/Melting range: < - 20 °C

Boiling point/Boiling range: 251 °C

Flash point: 113 °C

Flammability (solid, gaseous) Not applicable.

Ignition temperature: 400 °C

Decomposition temperature: Not determined.

Self-igniting: Product is not selfigniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined. Upper: Not determined.

Vapour pressure: 1,3 mbar (110 °C)

Density: Not determined

Relative density Not determined.

Vapour density Not determined.

Evaporation rate Not determined.

Solubility in / Miscibility with

Water: Not miscible or difficult to mix

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

dynamic: Not determined.

kinematic: Not determined.

Solvent content:

Organic solvents: 0.0 %

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Printing date: 21.03.2016

9.2 Other information

No further relevant information available.

10. Thermal decomposition / conditions to be avoided

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Exothermic polymerization

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11. Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity

Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity Based on available data, the classification criteria are not met.

· Carcinogenicity Based on available data, the classification criteria are not met.

· Reproductive toxicity Based on available data, the classification criteria are not met.

· STOT-single exposure Based on available data, the classification criteria are not met.

· STOT-repeated exposure Based on available data, the classification criteria are not met.

· Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

SAFETY DATA SHEET

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

Printing date: 21.03.2016

12.1 Toxicity

Aquatic toxicity:

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

Additional ecological information:

General notes: Water hazard class 2 (EU Regulation) (Self-assessment): hazardous for water. Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects

No further relevant information available.

13. Disposal considerations

13.1 Waste treatment methods

Recommendation

Must be specially treated adhering to official regulations.

Uncleaned packaging:

Recommendation:

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning. Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agents: Ethyl acetate

European waste catalogue 08 04 10 waste adhesives and sealants other than those mentioned in 08 04 09

14. Transport information

14.1. UN Number --

14.2. Chemical Name --

14.3. Class --

14.4. Packing group--

14.5. Hazard--

SAFETY DATA SHEET

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

Printing date: 21.03.2016

14.6.Special precautions for the transporter--

14.7. Transport/Additional information--

15.Regulations

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

National regulations

Technical instructions (air):

Class III

Share in % 2,5-10

Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16.Other informations

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship

Relevant phrases H317 May cause an allergic skin reaction.