

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Enigma Gingival Composite
Product Code: 0924-1, 0924-2, 0924-3, 0924-4, 0924-5, 0924-6, 0924-7, 0924-8
0924-9, 0924-10, 0924-11, 0924-K
Application: Dental Restorations

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Date: 01.08.2017 V1.0

2. HAZARD 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 labelled due to calculation procedure for the "General Classification Guideline for preparations of the EU" in the latest version.

Label elements:

Labelling 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.

Labelling 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:**

mixture of poly- and difunctional methacrylates, barium glass filler, fumed silica, photoinitiator, accelerator, stabilizer

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

Further information on storage conditions:

Store away from food stuffs.

Specific end uses:

No further relevant information available

8. EXPOSURE CONTROLS / 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: | Paste |
| Color: | Different |
| Odor: | Odourless |

| | Value | Unit | Method |
|--|-------|------|--------|
|--|-------|------|--------|

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: | 1.90 (20°C) g/cm ³ |
| 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. STABILITY AND REACTIVITY

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. TOXICOLOGY 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 GGVS/GGVE (Germany):

Not subject to transport regulations.

Sea transport IMDG:

Not subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:

Not subject to transport regulations.

15. REGULATORY INFORMATION

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. FURTHER INFORMATION

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.