

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Enigma Flowable Gingival Composite Stains

Product Code: 0350-R and 0350-B

Application: Dental Restorations

Distributed by: Davis Schottlander & Davis Ltd
Fifth Avenue, Letchworth Garden City,
Herts SG6 2WD UK
Tel: +44 (0)1462 480848 Fax: +44 (0)1462 482802
msds@schottlander.co.uk www.schottlander.com

Manufactured by: GDF GmbH
Dieselstrasse 5-6,
D-61191 Rosbach v.d.H,
Germany
info@gdfmbh.com

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2. HAZARD IDENTIFICATION**Classification of the substance or mixture:**

Classification according to Regulation (EC) No 1272/2008:

Skin Sens. 1; H317 May cause allergic skin reaction

Label elements:

Labelling according to Regulation (EC) 1272/2008:

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

Hazard pictograms:

GHS07

Signal word: Warning**Hazard determining components of labelling:** tetramethylene dimethacrylate diphenyl (2, 4, 6- trimethylbenzoyl) phosphine oxide**Hazard statements:**

H317 May cause 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 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: Mixtures





Description:

Preparation of methacryl acid ester.

Urethandimethacrylate

1,4-Butandioldimethacrylate

Dangerous components:

CAS: 2082-81-7 EINECS: 218-218-1	Tetramethylene dimethacrylate  Skin Sens. 1B, H317	10-25%
CAS: 75980-60-8 EINECS: 278-355-8	Diphenyl (2,4,6- trimethylbenzoyl) phosphine oxide  Repr. 2, H361f;  Aquatic Chronic 2, H411;  Skin Sens. 1B, H317	<2.5%

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

4. FIRST AID MEASURES

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

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Do not induce vomiting; call for medical help immediately.

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

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing media:

Foam, Fire-extinguishing powder, water haze, carbon dioxide

Special hazards arising from the substance or mixture:

No further relevant information available.

Advice for firefighters:**Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Not required.

Environmental precautions: Do not allow to enter sewers/surface or ground-water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Reference to other sections:

No dangerous substances are released.

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

Precautions for safe handling Keep receptacles tightly sealed.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

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: Protect from heat and direct sunlight.

Specific end use(s): No further relevant information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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.

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

Exposure controls**Personal protective equipment**

SAFETY DATA SHEET

General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Respiratory protection: Not required.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Appearance

Form:	Viscous.
Color:	According to product specification.
Odour:	Weak, characteristic.
Odour threshold:	Not determined.
pH value:	Not determined.
Change in condition:	
Melting point/melting range:	Undetermined.
Boiling point/boiling range:	251°C
Flash point:	101°C
Flammability (solid, gaseous)	Not applicable.
Ignition temperature:	370°C
Decomposition temperature	Not determined.
Self-igniting	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
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:	None
Other information:	No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No further relevant information available.

Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: Photoreactive, Danger of polymerization

Conditions to avoid: No further relevant information available.

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

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGY INFORMATION

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

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability: No further relevant information available.

Bioaccumulative potential: No further relevant information available.

Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 2 (German 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.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects: No further relevant information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation

Must be specially treated adhering to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

08 04 10 - Waste adhesives and sealants other than those mentioned in 08 04 09

Uncleaned packaging:

Recommendation:

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agents: Alcohol

14. TRANSPORT INFORMATION

UN-Number	
ADR, ADN, IMDG, IATA	Void
UN proper shipping name	
ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADR, ADN, IMDG, IATA	Void
Class	
Packing group	
ADR, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of Marpol and the IBC Code:	Not applicable.
UN "Model Regulation":	Void

15. REGULATORY INFORMATION

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	Share in %
III	2.5 - 10

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

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.