

Safety Data Sheet
According to 1907/2006/EC, Article 31

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Solafil M90

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture Dental Filling Material

1.3 Details of the supplier of the safety data sheet

Manufacturer /supplier:

Unit 3C, 88 Peterborough Road, London SW6 3HH, United Kingdom

Tel: 0044 (0) 20 3689 9046

www.trentdent.co.uk

E-mail: info@trentdent.co.uk

1.4 Emergency telephone number:

Tel: +44 20 3091 6068 (office hours)

SECTION 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

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Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms



GHS07

Signal word Warning

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tetramethylene dimethacrylate

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Precautionary statements

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

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

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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.

vyPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterisation: Mixtures

Description:

1, 4-Butandioldimethacrylate

Urethandimethacrylate

Bis-GMA

Dangerous components:		
CAS: 2082-81-7	Tetramethylene dimethacrylate	Skin Sens. 1B, H317 2.5-10%
EINECS: 218-218-1		

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

SECTION 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

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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. Then consult a doctor.

After swallowing

Do not induce vomiting; call for medical help 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.

SECTION 5: Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing agents

Foam

Fire-extinguishing powder

Water haze

Carbon dioxide

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 fire-fighters

Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

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

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.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 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.

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: Protect from heat and direct sunlight.

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

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SECTION 8: Exposure controls/Personal protection

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.

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

8.2 Exposure controls

Personal protective equipment

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: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties	
General Information	
Appearance	
Form	viscous
Colour	Different according to colouring
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
Self-igniting	Product is not self-igniting
Danger of explosion	Product does not present an explosion hazard.

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SECTION 10: Stability and reactivity

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 Photo reactive

Danger of polymerisation

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, polymerisation with heat release is possible.

SECTION 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.

SECTION 12: Ecological information

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 (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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable. vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 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 cleaning agents: Alcohol

SECTION 14: Transport information

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

SECTION 15: Regulatory information

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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

- REGULATION (EU) 2019/114

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- Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

- Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

- Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878. 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. H411 Toxic to aquatic life with long lasting effects

- Department issuing SDS: R&D, TRENT DENT PRODUCTS LTD
- Contact: S.Filsouf
- Date of previous version: Apr 2023
- Abbreviations and acronyms: ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.

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