

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 N50 Nano Hybrid Universal Light Curing Composite

Article number:30050[17...33], 30150[17...33].

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

Dental material intended for professional use in restorative dental procedures.

Application of the substance / the mixture Dental filling material.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Trent Dent Products Limited, Unit 3C, 88 Peterborough Road, London SW6 3HH, United Kingdom

Tel: 0044 20 3689 9046

www.trentdent.co.uk

E-mail: info@trentdent.co.uk

Further information from: R&D, Trent Dent Products Limited, [Tel:+44 20 3689 9046](tel:+442036899046)

1.4 Emergency telephone number:

Tel: +44 20 3689 9046, Trent Dent Products Limited (9:00- 17:00)

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.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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:

di-urethane dimethacrylate

tetramethylene dimethacrylate

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Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

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

P273 Avoid release to the environment.

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

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

P321 Specific treatment (see on this label).

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:

di-urethane dimethacrylate

tetramethylene dimethacrylate

Hazard statements

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

P321 Specific treatment (see on this label).

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description:

Resin-based dental composite material containing methacrylate-based resins, inorganic fillers and photoinitiators, intended for restorative dental applications.

Dangerous components:		
CAS:41137-60-4	di-urethane dimethacrylate	2.5-10%
	 Aquatic Chronic 2, H411;  Skin Sens. 1B, H317.	
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate	2.5-10%
	 Skin Sens. 1B, H317	

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Additional information For the wording of the listed hazard 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

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 Remove contact lenses if present and easy to do If symptoms persist, 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: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

Foam

Fire-extinguishing powder

Water haze

Carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

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)

Dispose contaminated material as waste according to section 13. **6.4 Reference to other sections**

See Section 7 for information on handling and storage

See Section 8 for information on

See Section 13 for disposal considerations.

SECTION 7: Handling and storage

7.1 Handling

- Avoid contact with eyes and skin.

- Use appropriate PPE (gloves, eye protection) when handling.

- Ensure good ventilation in the work area.

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--Keep receptacles tightly sealed.

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:

Storage between 10 °C and 25 °C.

Close container immediately after use and protect product from light incidence.

- Store in a cool, dry place.

- Keep container tightly closed.

- Incompatible materials: Strong acids, oxidizers.

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

Further information about storage conditions: Store in cool, dry conditions in well-sealed receptacles.

7.3 Specific end use(s) Professional dental use only.

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

Appropriate engineering controls No further; see section 7.

Individual protection measures, such as **personal protective equipment**

General protective and hygienic measures.

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not required.

Hand protection Protective gloves.

Material of gloves

Butyl rubber, BR

Nitrile rubber, NBR

Penetration time of glove material

0,3 mm

Penetration time 60 min.

0,11 mm

Penetration time 10 min.

Eye/face protection Goggles recommended during refilling.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Fluid
Colour:	According to product specification
Odour:	Weak, characteristic
Odour threshold:	Not determined.

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Melting point/freezing point:	Undetermined
Boiling point or initial boiling point and boiling range	251 °C
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	151 °C
Auto-ignition temperature:	400 °C
Decomposition temperature:	Not determined.
pH	Mixture is non-soluble (in water). Not determined.
Viscosity:	
Kinematic viscosity:	Not determined.
Dynamic:	Not determined.
Solubility:	
Water:	Not miscible or difficult to mix
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.

9.2 Other information	
Appearance:	
Form:	Pasty
Important information on protection of health and environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
Organic solvents:	0.0 %
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classes	
Explosives	Void
Flammable gases	Void
Aerosols	Void

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Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

SECTION 10: Stability and reactivity

10.1 Reactivity

Light-sensitive material. Polymerization may occur upon exposure to intense light.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Photoreactive

Danger of polymerization

10.4 Conditions to avoid

- Exposure to light (light-sensitive material).
- High temperatures or open flame.
- Direct contact with incompatible materials (strong acids, strong bases).
- Moisture or humidity during the curing process.

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:

- Carbon monoxide (CO) and carbon dioxide (CO₂) may form during combustion.
- Incomplete combustion may produce harmful fumes such as aldehydes, ketones, and other toxic gases.
- Polymerization products: May release toxic compounds under heat or light exposure.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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)

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

- Skin Sens. 1; H317 (May cause an allergic skin reaction).

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

- Eye Irrit. 2; H319 (Causes serious eye irritation).

Respiratory or skin sensitisation May cause an allergic skin reaction.

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.

11.2 Information on other hazards

Endocrine disrupting properties		
128-37-0	Butylated hydroxytoluene	List II

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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties: For information on endocrine disrupting properties see section 11.

12.7 Other adverse effects

Remark: Harmful to fish

Additional ecological information:

General notes:

Water hazard class 2(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.

Harmful to aquatic organisms

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 12	Adhesive and sealant sludges other than those mentioned in 08 04 11

Uncleaned packaging:

Recommendation:

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

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Recommended cleansing agents: Acetone

SECTION 14: Transport information

14.1 UN number or ID number ADR, ADN, IMDG, IATA	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 Maritime transport in bulk according to IMO Instruments	Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.
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) 2019/1148

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.

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National regulations

Technical instructions (air):

Class	Share in %
III	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.

SECTION 16: Other information

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 Limited

Date of previous version: Dec 2024

Version number of previous version: 02

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (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.**