

Safety Data Sheet according to WHS Regulations

Printing date 16.08.2024

Version number 3

Revision: 16.08.2024



Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name:** **TEMPSMART DC Paste B**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.
Specific target organ toxicity (repeated exposure) – Category 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms**

GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Urethane Dimethacrylate (UDMA) (50-<75 %)
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (25-<50 %)
2,2'-ethylenedioxydiethyl dimethacrylate (10-<25 %)
- **Hazard statements**
May cause an allergic skin reaction.
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

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- **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.

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

Specific treatment (see on this label).

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

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

- **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

- **Dangerous components:**

72869-86-4	Urethane Dimethacrylate (UDMA) Skin sensitisation – Category 1B, H317	50-<75%
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica Specific target organ toxicity (repeated exposure) – Category 2, H373	25-<50%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin sensitisation – Category 1B, H317	10-<25%
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) Reproductive toxicity – Category 1B, H360D; Specific target organ toxicity (repeated exposure) – Category 2, H373; Acute toxicity - inhalation – Category 4, H332; Eye damage/irritation – Category 2A, H319	0.2-<0.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

- **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

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.

If symptoms persist consult doctor.

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** Allergic reactions
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid formation of dust.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Prevent formation of dust.
Dispose of the material collected according to regulations.
- **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:**
- **Precautions for safe handling**
Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.

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

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Do not inhale dust / smoke / mist.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Immediately remove all soiled and contaminated clothing
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Protection of hands:**



Protective gloves

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Pasty
- **Colour:** White
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** 283 °C (541.4 °F)
- **Flash point:** 101 °C (213.8 °F)
- **Flammability (solid, gas):** Not determined.

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· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 °C (68 °F):	1.3 g/cm ³ (10.8485 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic:	Not applicable.
· Kinematic:	Not applicable.
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
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67-43-6 N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

Inhalative	LC50/4 h	1.5 mg/l (ATE)
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- **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.
- **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**
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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- **Additional toxicological information:**
- **Repeated dose toxicity** May cause damage to organs through prolonged or repeated exposure.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**

- **Aquatic toxicity:**

72869-86-4 Urethane Dimethacrylate (UDMA)	
<i>EC50/48h (static)</i>	>1.2 mg/l (<i>daphnia magna</i>) (OECD 202)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Harmful to aquatic organisms
- **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 not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|----------------------------------|---|
| · UN-Number | |
| · ADG, IMDG, IATA | UN3077 |
| · UN proper shipping name | |
| · ADG | 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA)) |
| · IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA), Butylated hydroxytoluene), MARINE POLLUTANT |
| · IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA)) |

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· **Transport hazard class(es)**· **ADG**

· **Class** 9 (M7) Miscellaneous dangerous substances and articles.
 · **Label** 9

· **IMDG, IATA**

· **Class** 9 Miscellaneous dangerous substances and articles.
 · **Label** 9

· **Packing group**

· **ADG, IMDG, IATA** III

· **Environmental hazards:**

· **Marine pollutant:** No
 Symbol (fish and tree)

· **Special marking (ADG):** Symbol (fish and tree)

· **Special marking (IATA):** Symbol (fish and tree)

· **Special precautions for user** Warning: Miscellaneous dangerous substances and articles.

· **Hazard identification number (Kemler code):** 90

· **EMS Number:** F-A,S-F

· **Stowage Category** A

· **Stowage Code** SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

· **Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**· **ADG**

· **Limited quantities (LQ)** 5 kg

· **Excepted quantities (EQ)** Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **Transport category** 3

· **Tunnel restriction code** (-)

· **IMDG**

· **Limited quantities (LQ)** 5 kg

· **Excepted quantities (EQ)** Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

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· **UN "Model Regulation":** *UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (URETHANE DIMETHACRYLATE (UDMA)), 9, III*

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

72869-86-4	Urethane Dimethacrylate (UDMA)
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
112945-52-5	Silicon dioxide
13122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate (not more than 42%, and inert solid not less than 58%)
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)
128-37-0	Butylated hydroxytoluene

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**

Urethane Dimethacrylate (UDMA) (50-<75 %)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (25-<50 %)

2,2'-ethylenedioxydiethyl dimethacrylate (10-<25 %)

· **Hazard statements**

May cause an allergic skin reaction.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.

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

Specific treatment (see on this label).

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

· **Directive 2012/18/EU**

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

· **Seveso category E2** Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

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- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

- **Relevant phrases**

- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H360D May damage the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gc.dental

- **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
- 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
- Acute toxicity - inhalation – Category 4: Acute toxicity – Category 4
- Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
- Skin sensitisation – Category 1: Skin sensitisation – Category 1
- Skin sensitisation – Category 1B: Skin sensitisation – Category 1B
- Reproductive toxicity – Category 1B: Reproductive toxicity – Category 1B
- Specific target organ toxicity (repeated exposure) – Category 2: Specific target organ toxicity (repeated exposure) – Category 2

- **Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

- *** Data compared to the previous version altered.**

This version replaces all previous versions.

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