



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_A
- 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.

- · 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



- · Signal word Warning
- · Hazard-determining components of labelling:

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

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

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing 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.

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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) | 50-<75% |
| | Skin sensitisation – Category 1B, H317 | |
| 109-16-0 | 2,2'-ethylenedioxydiethyl dimethacrylate | 10-<25% |
| | Skin sensitisation – Category 1B, H317 | |
| 1985-51-9 | 2,2-dimethyl-1,3-propanediyl bismethacrylate | 5-<10% |
| | Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319 | |
| 68909-20-6 | Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica | 2.5-<5% |
| | Specific target organ toxicity (repeated exposure) – Category 2, H373 | |
| 1309-37-1 | Iron(III)oxide | 0.5-<1% |
| 13463-67-7 | titanium dioxide | 0.5-<1% |
| | Carcinogenicity – Category 2, H351 | |
| 150-76-5 | mequinol | 0.2-<0.59 |
| | Acute toxicity - oral — Category 4, H302; Eye damage/irritation — Category 2A, H319; Skin sensitisation — Category 1, H317 | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | 0.2-<0.59 |
| | Reproductive toxicity – Category 2, H361; Skin sensitisation – Category 1B, H317 | 1 |

·SVHC

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

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.

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[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

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· 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.

- · 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 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:

Absorb liquid components with liquid-binding material.

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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

- · Information about fire and explosion protection: No special measures required.
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.

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- · Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- · 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:

1309-37-1 Iron(III)oxide

WES Long-term value: 5 mg/m³

13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m³

inhalable dust

150-76-5 mequinol

WES Long-term value: 5 mg/m³

Sen

· DNELs

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m3 (man)

- · 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.

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

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9 Physical and Chemical Properties

· General Information

· Appearance:

Form: Pasty
Colour: Yellow
Odour: Odourless
Odour threshold: Not determined.
pH-value: Not determined.

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Undetermined.
 Flash point:
 Flammability (solid, gas):
 Auto-ignition temperature:
 Decomposition temperature:
 Not determined.
 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 determined.

• **Density at 20 °C (68 °F):** 1.2 g/cm³ (10.014 lbs/gal)

Relative density
 Vapour density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

• water: Insoluble. • Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.Kinematic: Not determined.

· Solvent content:

 \cdot VOC (EC) 0.0 g/l

• 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.

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Safety Data Sheet according to WHS Regulations

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| | | (Contd. of page 5) | | | | | | |
|----------|---|--------------------------------------|--|--|--|--|--|--|
| · LD/LC | · LD/LC50 values relevant for classification: | | | | | | | |
| 72869-8 | 72869-86-4 Urethane Dimethacrylate (UDMA) | | | | | | | |
| Oral | LD50 | >5,000 mg/kg (rat female) (OECD 401) | | | | | | |
| 1309-37 | 1309-37-1 Iron(III)oxide | | | | | | | |
| Oral | LD50 | >5,000 mg/kg (rat (f+m)) | | | | | | |
| 13463-6 | 13463-67-7 titanium dioxide | | | | | | | |
| Oral | LD50 | >5,000 mg/kg (mouse) (OECD 420) | | | | | | |
| Inhalati | ive $LC50/4 h$ | >6.82 mg/l (rat male) | | | | | | |

- · 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 Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 No further relevant information available.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity:

72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 mg/l (daphnia magna) (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.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 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.

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- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

| UN-Number | |
|---|---|
| ADG, IMDG, IATA | UN3082 |
| UN proper shipping name | |
| ADG | 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANG |
| | LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA)) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANC |
| | LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA MARINE POLLUTANT |
| IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANC |
| | LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA)) |
| Transport hazard class(es) | |
| ADG | |
| | |
| Class | 9 (M6) Miscellaneous dangerous substances and articles. |
| Label | 9 |
| IMDG, IATA | |
| | |
| | 9 Miscellaneous dangerous substances and articles. |
| Label | 9 Miscellaneous dangerous substances and articles. 9 |
| Label Packing group | 9 |
| Label Packing group ADG, IMDG, IATA | |
| Label Packing group ADG, IMDG, IATA Environmental hazards: | 9 III |
| Label Packing group ADG, IMDG, IATA Environmental hazards: | 9 |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: | 9 III No Symbol (fish and tree) Symbol (fish and tree) |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): | 9 III No Symbol (fish and tree) |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA): Special precautions for user | III No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree) Warning: Miscellaneous dangerous substances and article |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA): Special precautions for user Hazard identification number (Kemler code): | III No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree) Warning: Miscellaneous dangerous substances and articles |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA): Special precautions for user Hazard identification number (Kemler code): EMS Number: | III No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree) Warning: Miscellaneous dangerous substances and article 90 F-A,S-F |
| Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA): Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category | III No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree) Warning: Miscellaneous dangerous substances and article 90 F-A,S-F A |
| Class Label Packing group ADG, IMDG, IATA Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA): Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category Transport in bulk according to Annex II of Mar | III No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree) Warning: Miscellaneous dangerous substances and art 90 F-A,S-F A |

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|-----------------------------------|---|
| Transport/Additional information: | |
| · ADG | |
| · Limited quantities (LQ) | 5L |
| Excepted quantities (EQ) | Code: E1 |
| | Maximum net quantity per inner packaging: 30 ml |
| | Maximum net quantity per outer packaging: 1000 ml |
| Transport category | 3 |
| Tunnel restriction code | (-) |
| · IMDG | |
| · Limited quantities (LQ) | 5L |
| Excepted quantities (EQ) | Code: E1 |
| | Maximum net quantity per inner packaging: 30 ml |
| | Maximum net quantity per outer packaging: 1000 ml |
| · UN "Model Regulation": | UN 3082 ENVIRONMENTALLY HAZARDOU |
| <u> </u> | SUBSTANCE, LIQUID, N.O.S. (URETHAN |
| | DIMETHACRYLATE (UDMA)), 9, III |

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· 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

- · Signal word Warning
- Hazard-determining components of labelling:

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

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

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing 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).

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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
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- · Other regulations, limitations and prohibitive regulations
- · Substances of very high concern (SVHC) according to REACH, Article 57

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

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

16 Other information

· Relevant phrases

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H361 Suspected of damaging fertility or 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)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute toxicity - oral - Category 4: Acute toxicity - Category 4

Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2

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

Carcinogenicity – Category 2: Carcinogenicity – Category 2

Reproductive toxicity – Category 2: Reproductive toxicity – Category 2

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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