



*Date of issue: 05.08.2025 Version number 4 Revision: 05.08.2025* 

Hazardous according to criteria of Australian Safety and Compensation Council.

# 1 Identification

- · Other means of identification
- · Trade name: REVOTEK\_LC
- 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

Acute toxicity - inhalation – Category 4

Skin corrosion/irritation – Category 2

Eye damage/irritation – Category 2A

Respiratory sensitisation – Category 1

Skin sensitisation – Category 1 Specific target organ toxicity (single exposure) – Category 3 H332 Harmful if inhaled.

H315 Causes skin irritation.

H319 Causes serious eve irritation.

H334 May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

- · 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

- · **Signal word** Danger
- · Hazard-determining components of labelling: hexamethylene-di-isocyanate (25-<50 %)

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2-hydroxyethyl metacrylate (25-<50 %)

*Urethane Dimethacrylate (UDMA) (10-<25 %)* 

#### · Hazard statements

Harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

#### Precautionary statements

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

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

Wear respiratory protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

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.

822-06-0	hexamethylene-di-isocyanate	25-<50%
	Acute toxicity - inhalation - Category 3, H331; Respiratory sensitisation - Category 1, H334; Skin corrosion/irritation - Category 2, H315; Eye damage/irritation - Category 2A, H319; Skin sensitisation - Category 1, H317; Specific target organ toxicity (single exposure) - Category 3, H335	
868-77-9	2-hydroxyethyl metacrylate Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	25-<50%
72869-86-4	Urethane Dimethacrylate (UDMA) Skin sensitisation – Category 1B, H317	10-<25%
7631-86-9	silicon dioxide	10-<25%
13463-67-7	7 titanium dioxide Carcinogenicity – Category 2, H351	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Reproductive toxicity – Category 2, H361; Skin sensitisation – Category 1B, H317	0.5-<1%

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

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# 4 First Aid Measures

#### General information:

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

*In case of irregular breathing or respiratory arrest provide artificial respiration.* 

*If symptoms persist consult doctor.* 

#### · After inhalation:

Supply fresh air or oxygen; call for doctor.

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

Do not use mouth to mouth or mouth to nose resuscitation.

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:

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then 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:

Mouth respiratory protective device.

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.

Inform respective authorities in case of seepage into water course or sewage system.

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Do not allow to penetrate the ground/soil.

*In case of seepage into the ground inform responsible authorities.* 

· Methods and material for containment and cleaning up:

Ensure adequate ventilation.

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.

Do not inhale dust / smoke / mist.

Prevent formation of aerosols.

Avoid contact with the eves and skin.

Open and handle receptacle with care.

- Information about fire and explosion protection: Keep respiratory protective device available.
- 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: Keep container tightly sealed.
- · Specific end use(s) No further relevant information available.

## 8 Exposure controls and personal protection

· Appropriate engineering controls No further data; see section 7.

· Ingredients with	limit values that	require mon	iitoring at t	he workplace:

## 822-06-0 hexamethylene-di-isocyanate

WES Short-term value: 0.07 mg/m³ Long-term value: 0.02 mg/m³ Sen, as -NCO

7631-86-9 silicon dioxide

TWA Long-term value: 2 mg/m³

13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m<sup>3</sup>

inhalable dust

#### · 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.

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Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Store protective clothing separately.

- · 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:

Pasty · Form: · Colour: Light yellow **Odourless** · Odour: Not determined. · Odour threshold: Not determined. · pH-value:

· Change in condition

· Melting point/freezing point: Undetermined. · Initial boiling point and boiling range: Undetermined. Not applicable. · Flash point: · Flammability Not applicable. Undetermined. · Auto-ignition temperature: Not determined. · Decomposition temperature:

Product is not selfigniting. · Ignition temperature:

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Not determined. · Lower: · Upper: Not determined. · Vapour pressure: Not determined. Not determined. · Density: · Relative density Not determined. Not determined. · Vapour density Not determined. · Evaporation rate

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· Solubility in / Miscibility with

water: Fully miscible.
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

Particle characteristics SiO2: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-

based)

Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d50,

volume based)

7631-86-9 silicon dioxide:

set including amorphous nanoforms; non-surface-treated nanoforms;

Spheroidal; amorphous forms; amorphous nanoform

· Physical state Liquid

# 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 Harmful if inhaled.

· LD/LC50	· LD/LC50 values relevant for classification:						
72869-86-	72869-86-4 Urethane Dimethacrylate (UDMA)						
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)					
7631-86-9	7631-86-9 silicon dioxide						
Oral	LD50	10,000 mg/kg (rat (f+m))					
13463-67-	13463-67-7 titanium dioxide						
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)					
Inhalative		>6.82 mg/l (rat male)					

- · Primary irritant effect:
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.

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- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure May cause respiratory irritation.
- · 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.
- · Interactive effects
- · 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.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

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.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

# 14 Transport information

- · UN-Number
- · ADG, IMDG, IATA

UN3082

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· UN proper shipping name · ADG	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE
· IMDG	LIQUID, N.O.S. (Propylidynetrimethyl trimethacrylate Urethane Dimethacrylate (UDMA)) ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (Propylidynetrimethyl trimethacrylate Urethane Dimethacrylate (UDMA)), MARINE POLLUTAN
·IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (Propylidynetrimethyl trimethacrylate Urethane Dimethacrylate (UDMA))
· Transport hazard class(es)	
· ADG	
· Class · Label	9 (M6) Miscellaneous dangerous substances and articles. 9
· IMDG, IATA	
· Class · Label	<ul><li>9 Miscellaneous dangerous substances and articles.</li><li>9</li></ul>
· 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 · Hazard identification number (Kemler code):	Warning: Miscellaneous dangerous substances and articles 90
· EMS Number:	F-A,S-F
Stowage Category	A
Transport in bulk according to Annex II of Marp and the IBC Code	pol Not applicable.
· Transport/Additional information:	
· ADG	
· Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml

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Tunnel restriction code	(Contd. of page
· IMDG	
11.12 0	\$ I
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
o de la companya de	SUBSTANCE, LIQUID, N.O.S
	(PROPYLIDYNETRIMETHYL TRIMETHACRYLAT
	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

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

868-77-9 2-hydroxyethyl metacrylate

*S*5

· 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 Danger
- · Hazard-determining components of labelling:

hexamethylene-di-isocyanate (25-<50 %)

2-hydroxyethyl metacrylate (25-<50 %)

*Urethane Dimethacrylate (UDMA) (10-<25 %)* 

· Hazard statements

Harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

#### · Precautionary statements

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

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

Wear respiratory protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

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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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H361 Suspected of damaging fertility or the unborn child.

- · 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 - inhalation - Category 3: Acute toxicity - Category 3

Acute toxicity - inhalation - 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 Respiratory sensitisation – Category 1: Respiratory sensitisation – Category 1

Skin sensitisation – Category 1: Skin sensitisation – Category 1

Skin sensitisation – Category 11: 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 (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3

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

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#### \* \* Data compared to the previous version altered.

This version replaces all previous versions.

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