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Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Other means of identification
- · Trade name: G-aenial A'CHORD
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxiliary 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:

2,2'-ethylenedioxydiethyl dimethacrylate (2.5-<5 %)

Urethane Dimethacrylate (UDMA) (2.5-<5 %)

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate (1-<2.5 %)

· 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.

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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.

	components:	2.550/
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
	Skin sensitisation – Category 1B, H317	
72869-86-4	Urethane Dimethacrylate (UDMA)	2.5-<5%
	Skin sensitisation – Category 1B, H317	
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	1-<2.5%
	Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate	1-<2.5%
	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	
1309-37-1	Iron(III)oxide	0.5-<1%
13463-67-7	titanium dioxide	0.5-<1%
	Carcinogenicity – Category 2, H351	
60676-86-0	Silica, vitreous	1-<2.5%
1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
	Acute toxicity - dermal – Category 2, H310; Specific target organ toxicity (repeated exposure) – Category 2, H373; Acute toxicity - oral – Category 4, H302; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	

[·] 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.

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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, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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

Ensure good ventilation/exhaustion at the workplace.

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:

Protect against electrostatic charges.

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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.
- · 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 i	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

60676-86-0 Silica, vitreous

WES Long-term value: 0.05 mg/m³

· DNELs

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m3 (man)

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 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.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

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.

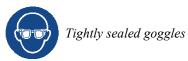
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· Eye protection:



9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Pasty

• Colour: According to product specification

Odour:
Odour less
Not determined.
pH-value:
Not applicable.

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Flash point:
 Flammability
 Auto-ignition temperature:
 Decomposition temperature:
 Undetermined.
 Undetermined.
 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 applicable.

• Density at 20 °C (68 °F): 1.9 g/cm³ (15.8555 lbs/gal)

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

· Solubility in / Miscibility with

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

· Viscosity:

Dynamic: Not applicable.Kinematic: Not applicable.

· Other information

• Particle characteristics Not determined.

Physical state Solid

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.

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· 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	· LD/LC50 values relevant for classification:					
72869-86-	4 Urethane	e Dimethacrylate (UDMA)				
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)				
1309-37-1	Iron(III)o	xide				
Oral	LD50	>5,000 mg/kg (rat (f+m))				
13463-67-	7 titanium	dioxide				
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)				
Inhalative	LC50/4 h	>6.82 mg/l (rat male)				
1879-09-0	6-tert-buty	yl-2,4-xylenol				
Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)				
Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)				

- · 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.
- · 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.
- · 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:

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

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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.

UN-Number		
ADG, IMDG, IATA	not regulated	
UN proper shipping name ADG, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA Class	not regulated	
Packing group		
ADG, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex I		
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

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).

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· Hazard pictograms



· Signal word Warning

· Hazard-determining components of labelling:

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· 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).

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

16 Other information

· Relevant phrases

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

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)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

Acute toxicity - dermal - Category 2: Acute toxicity - Category 2

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

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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

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