

Page 1/9

Safety Data Sheet according to WHS Regulations

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- Trade name: GC Essentia Light, Dark and Medium Dentin
- *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 Tox. 4 H302 Harmful if swallowed.

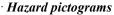
Acute Tox. 3 H331 Toxic if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· Label elements

· GHS label elements

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labelled according to the Globally Harmonised System (GHS).





· Signal word Danger

• Hazard-determining components of labelling: Ytterbium trifluoride Urethane Dimethacrylate (UDMA) 2-(2H-benzotriazol-2-yl)-p-cresol

• Hazard statements Harmful if swallowed. Toxic if inhaled. May cause an allergic skin reaction.

(Contd. on page 2)

AU

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

Trade name: GC Essentia Light, Dark and Medium Dentin

(Contd. of page 1)

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

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

Wear protective gloves.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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.

· Dangerous components:		
72869-86-4	Urethane Dimethacrylate (UDMA)	10-<25%
	Skin Sens. 1, H317	
13760-80-0	Ytterbium trifluoride	5-<10%
	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	-
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	2.5-<5%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.1-<0.2%
	Acute Tox. 3, H311; Skin Sens. 1, H317	
Additional	information. For the wording of the listed har and physics refer to section 16	

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

4 First Aid Measures

· Description of first aid measures

• General information:

Immediately remove any clothing soiled by the product. 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:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

• After swallowing:

Do not induce vomiting; call for medical help immediately. Rinse out mouth and then drink plenty of water.

(Contd. on page 3)

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

Trade name: GC Essentia Light, Dark and Medium Dentin

(Contd. of page 2)

- 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

- Extinguishing media
- 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.
- Advice for firefighters
- · 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.
 Inform respective authorities in case of seepage into water course or sewage system.
 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 eyes and skin.

• Information about fire - and explosion protection: No special measures required.

(Contd. on page 4)

AU

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

Trade name: GC Essentia Light, Dark and Medium Dentin

(Contd. of page 3)

- · Conditions for safe storage, including any incompatibilities
- · 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

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.

· Exposure controls

- · 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

9 Physical and Chemical Properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
 - Form: Colour:

Pasty According to product specification

(Contd. on page 5)

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

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		(Contd. of page
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	2: Undetermined.	
Flash point:	>150 °C (>302 °F)	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto-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:	Not determined.	
	$2,56 \text{ g/cm}^3$	
	1,18g/ml	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
VOC (EC)	0.0 g/l	
Other information	No further relevant information available.	

10 Stability and Reactivity

· Reactivity No further relevant information available.

· Chemical stability

- 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.

(Contd. on page 6)

Printing date 20.05.2020

Version number 5

Revision: 17.03.2020

Trade name: GC Essentia Light, Dark and Medium Dentin

(Contd. of page 5)

11 Toxicological Information

· Information on toxicological effects

• Acute toxicity

· LD/LC50 values relevant for classification:

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 >5,000 mg/kg (rat female) (OECD 401)

2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

Oral LD50 10,000 mg/kg (rat (f+m))

Inhalative LC50/4 h = 0.59 mg/l (rat (f+m))

· Primary irritant effect:

• Skin corrosion/irritation No irritant effect.

• Serious eye damage/irritation No irritating effect.

• Respiratory or skin sensitisation Sensitisation possible through skin contact.

• *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) $\geq 1.2 \text{ mg/l}$ (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:

Water hazard class 2 (German Regulation) (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.
- · 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.

(Contd. on page 7)

AU

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Version number 5

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Trade name: GC Essentia Light, Dark and Medium Dentin

(Contd. of page 6)

• Uncleaned packaging:

• *Recommendation: Disposal must be made according to official regulations.*

not regulated		
not regulated		
not regulated		
not regulated		
No		
Not applicable.		
· Transport in bulk according to Annex II of Marpol		
Not applicable.		
	not regulated not regulated not regulated No Not applicable. of Marpol	

15 Regulatory information

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

· Australian In	· Australian Inventory of Chemical Substances				
65997-17-3	Glass, oxide, chemicals				
72869-86-4	-4 Urethane Dimethacrylate (UDMA)				
112945-52-5	Silicon dioxide				
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate				
2530-85-0	3-trimethoxysilylpropyl methacrylate				
1309-37-1	Iron(III)oxide				
465-29-2	Bornane-2,3-dione				
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol				
21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate				
1317-61-9	triiron tetraoxide				
5870-38-2	Diethyl 2,5-dihydroxyterephthalate				
13463-67-7	titanium dioxide				
1879-09-0	6-tert-butyl-2,4-xylenol				
· Standard for	· Standard for the Uniform Scheduling of Medicines and Poisons				
None of the in	None of the ingredients is listed.				
	(Contd. on page 8)				

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Trade name: GC Essentia Light, Dark and Medium Dentin

	(Contd. of page 8)
CAS: Chemical Abstracts Service (division of the American Chemical Society)	
VOC: Volatile Organic Compounds (USA, EU)	
LC50: Lethal concentration, 50 percent	
LD50: Lethal dose, 50 percent	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
Acute Tox. 3: Acute toxicity - oral – Category 3	
Acute Tox. 4: Acute toxicity - oral – Category 4	
Skin Irrit. 2: Skin corrosion/irritation – Category 2	
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A	
Skin Sens. 1: Skin sensitisation – Category 1	
· 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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