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Safety Data Sheet according to WHS Regulations

Printing date 09.12.2020

Version number 3

Revision: 09.12.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· Product identifier

- Trade name: G-Premio Bond
- *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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

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

STOT SE 3 H336 May cause drowsiness or dizziness.

· 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).

· 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



GHS02 GHS05 GHS07

· Signal word Danger

- · Hazard-determining components of labelling:
- 2,2'-ethylenedioxydiethyl dimethacrylate
- · Hazard statements
- Highly flammable liquid and vapour.

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Causes severe skin burns and eye damage.
May cause an allergic skin reaction.
May cause drowsiness or dizziness.
Precautionary statements
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not breathe dusts or mists.
Wear protective gloves / eye protection / face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
Immediately call a POISON CENTER/doctor.
Specific treatment (see on this label).
Take off contaminated clothing and wash it before reuse.
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:		
67-64-1	acetone	25-<50%
	Flam. Liq. 2, H225; Eye Irrit. 2A, H319; STOT SE 3, H336	
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
	Skin Sens. 1, H317	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%
	Repr. 2, H361	
· 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. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

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• 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. Call a doctor immediately.

• *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

- · Extinguishing media
- 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.
- · 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

Rem	ove persons from danger area.
Кеер	away from ignition sources.
Avoi	d contact with the eyes and skin.
Wea	r protective clothing.
Envi	ironmental precautions:
Do n	not allow product to reach sewage system or any water course.
Do n	not allow to penetrate the ground/soil.
Metl	hods and material for containment and cleaning up:
Ensi	ire adequate ventilation.
Use	neutralising agent.
Absc	orb liquid components with liquid-binding material.
Disp	ose of the material collected according to regulations.
Refe	rence to other sections
	Section 7 for information on safe handling.
See 2	Section 8 for information on personal protection equipment.
	Section 13 for disposal information.

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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: Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

\cdot Conditions for safe storage, including any incompatibilities

- Storage:
- **Requirements to be met by storerooms and receptacles:** Store in a cool location. 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. Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

- Store in a cool place.
- 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:

cetone

WES Short-term value: 2375 mg/m³, 1000 ppm Long-term value: 1185 mg/m³, 500 ppm

· DNELs

128-37-0 Butylated hydroxytoluene

DermalDNEL dermal0.5 mg/kg bw/day (man)InhalativeDNEL inhalation3.5 mg/m3 (man)

• 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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· Respiratory protection: Suitable respiratory protective device recommended.

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• 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

Information on basic physical and ch General Information	emical properties	
Appearance:		
Form:	Liquid	
Colour:	Yellow	
Odour:	Acetone-like	
Odour threshold:	Not determined.	
<i>pH-value at 20 °C (68 °F):</i>	1.8	
Change in condition		
Melting point/freezing point:	-95 °C (-139 °F)	
Initial boiling point and boiling ran	ge: 55 °C (131 °F)	
Flash point:	-17 °C (1.4 °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:	2.6 Vol %	
Upper:	13 Vol %	
Vapour pressure:	Not determined.	
Density at 20 °C (68 °F):	0.94 g/cm ³ (7.8443 lbs/gal)	
Relative density	Not determined.	
Vapour density	Not determined.	

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· 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:	
Organic solvents:	31.1 %
Water:	24.0 %
VOC (EC)	377.9 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.

11 Toxicological Information

· Information on toxicological effects

· Acute toxicity

· LD/LC50 values relevant for classification:

67-64-1 acetone

Oral LD50 5,800 mg/kg (rat (f+m))

Dermal LD50 20,000 mg/kg (rabbit)

128-37-0 Butylated hydroxytoluene

Oral LD50 >6,000 mg/kg (rat (f+m)) (OECD 401)

- · Primary irritant effect:
- · Skin corrosion/irritation Strong caustic effect on skin and mucous membranes.
- · Serious eye damage/irritation

Strong caustic effect.

Strong irritant with the danger of severe eye injury.

• Respiratory or skin sensitisation Sensitisation possible through skin contact.

• Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Irritant Corrosive

• *Repeated dose toxicity No further relevant information available.*

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· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

12 Ecological Information

· Toxicity

· Aquatic toxicity:

128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 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:

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Harmful to aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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.

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

· UN-Number		
· ADG, IMDG, IATA	UN1090	
· UN proper shipping name		
ADG	1090 ACETONE mixture	
· IMDG, IATA	ACETONE	

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[·] Uncleaned packaging:

Printing date 09.12.2020 Version number 3 Revision: 09.12.2020 Trade name: G-Premio Bond (Contd. of page 7) • Transport hazard class(es) · ADG · Class 3 (F1) Flammable liquids. · Label 3 · IMDG, IATA · Class 3 Flammable liquids. · Label 3 · Packing group · ADG, IMDG, IATA Ш • Environmental hazards: · Marine pollutant: No Warning: Flammable liquids. · Special precautions for user · Hazard identification number (Kemler code): 33 · EMS Number: F-E, S-D· Stowage Category Ε · Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. • Transport/Additional information: · ADG · Limited quantities (LQ) lL• Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · Transport category 2 D/E• Tunnel restriction code ·IMDG · Limited quantities (LQ) lL· Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml • UN "Model Regulation": UN 1090 ACETONE MIXTURE, 3, II ΑI

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15 Regulatory information

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

· Australian Inventory of Chemical Substances			
67-64-1	acetone		
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate		
	Silane, dichlorodimethyl-, reaction products with silica		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
465-29-2	Bornane-2,3-dione		
10287-53-3	ethyl 4-dimethylaminobenzoate		
128-37-0	Butylated hydroxytoluene		
1344-28-1	aluminium oxide		
7732-18-5	Water		
• Standard fo	• Standard for the Uniform Scheduling of Medicines and Poisons		

67-64-1 acetone

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



· Signal word Danger

· Hazard-determining components of labelling:

2,2'-ethylenedioxydiethyl dimethacrylate

· Hazard statements

Highly flammable liquid and vapour.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause drowsiness or dizziness.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Do not breathe dusts or mists.

Wear protective gloves / eye protection / face protection.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

Store locked up.

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 P5c FLAMMABLE LIQUIDS

- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- \cdot Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

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

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16 Other information

· Relevant phrases

H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H361 Suspected of damaging fertility or the unborn child. · Department issuing SDS: Regulatory affairs · Contact: msds@gc.dental · Abbreviations and acronyms: ADR: Accord européen sur le transport 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 vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids - Category 2 Skin Corr. 1A: Skin corrosion/irritation – Category 1A Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A Skin Sens. 1: Skin sensitisation – Category 1 Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 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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