

Printing date 30.09.2019 Version number 5 Revision: 30.09.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: Solare Universal 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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

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

STOT SE 3 H336 May cause drowsiness or dizziness.

- · 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





GHS02

GHS07

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

2,2'-ethylenedioxydiethyl dimethacrylate

· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

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May cause an allergic skin reaction.

May cause drowsiness or dizziness.

· Precautionary statements

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

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.

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.

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.

· 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.

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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

- · 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.

Keep away from ignition sources.

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.

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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.

- · 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

ingredicing with times values that require monitoring at the wormplace.	· Ingredients with	h limit values that	require monitorin	g at the workplace:
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67-64-1 acetone

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

· DNELs

128-37-0 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 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.
- · Protection of hands:



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· 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	Chei	mical	Pro	perties

· Inform	atio	n on	basic p	hysical	and	chemica	l properties
		_	_				

- · General Information
- · Appearance: Form:

Colour:

· Odour:

• Odour threshold:
• pH-value:

• Change in condition
• Of SC (202.85)

Melting point/freezing point: -95 °C (-203 °F) Initial boiling point and boiling range: 56 °C (132.8 °F)

• Flash point: -17 °C (-62.6 °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.

Liquid

Light yellow

Ester-like

· Explosion limits:

 Lower:
 2.6 Vol %

 Upper:
 13 Vol %

· Vapour pressure: Not determined.

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

· Solubility in / Miscibility with

water: Fully miscible.

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

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· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

· Solvent content:

 Organic solvents:
 37.9 %

 Water:
 19.4 %

 VOC (EC)
 470.0 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.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity

· LD/LC50 values relevant for classification:				
67-64-1	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 Irritant to skin and mucous membranes.
- · Serious eve damage/irritation Irritating effect.
- · 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

- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

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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:

Harmful to aquatic organisms

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.

- · 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

UN1090

- · UN proper shipping name
- \cdot ADG

1090 ACETONE mixture

· IMDG, IATA

ACETONE mixture

- · Transport hazard class(es)
- $\cdot ADG$



· Class 3 (F1) Flammable liquids.

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Label	3
IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group	
ADG, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
EMS Number:	F-E,S-D
Stowage Category	E
Transport in bulk according to Annex II o and the IBC Code	f Marpol Not applicable.
Transport/Additional information:	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
· · · · · · · ·	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN1090, ACETONE mixture, 3, II

15 Regulatory information

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

· Australian	· 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			
1344-28-1	aluminium oxide			
465-29-2	Bornane-2,3-dione			
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10287-53-3	ethyl 4-dimethylaminobenzoate
128-37-0	Butylated hydroxytoluene
7732-18-5	Water

· Standard for the Uniform Scheduling of Medicines and Poisons

67-64-1 acetone S5

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





GHS02 GHS0

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

2,2'-ethylenedioxydiethyl dimethacrylate

· Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause drowsiness or dizziness.

· Precautionary statements

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

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.

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.
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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

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· 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 Irrit. 2: Skin corrosion/irritation – Category 2

Skin Irrii. 2. Skin corrosion/irritation – Category 2

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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