

Printing date 09.12.2020 Version number 3 Revision: 09.12.2020

1 Identification of the substance or mixture and of the supplier

- · 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

Henry Schein Dental 23 William Pickering Drive, Albany Auckland 0632, NEW ZEALAND

PO Box 101140, NSMC Auckland 0745, NEW ZEALAND

Free Phone: 0800 808 855

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards 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.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 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

02 GHS05

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- · Signal word Danger
- · Hazard-determining components of labelling:
- 2,2'-ethylenedioxydiethyl dimethacrylate

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· 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.

Harmful to aquatic life with long lasting effects.

· 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/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:		
CAS: 67-64-1	acetone	25-<50%
EINECS: 200-662-2	Flam. Liq. 2, H225; Eye Irrit. 2A, H319; STOT SE 3, H336	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	1
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%
EINECS: 278-355-8	Repr. 2, H361	
CAS: 128-37-0	Butylated hydroxytoluene	0.5-<1%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

[•] 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.

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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.

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

· 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.

Do not allow to penetrate the ground/soil.

· Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Use neutralising agent.

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.

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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 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/personal protection

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

· Control parameters · Ingredients with limit vali	· Ingredients with limit values that require monitoring at the workplace:	
67-64-1 acetone	7 Y	
WES (New Zealand)	Short-term value: 2375 mg/m³, 1000 ppm Long-term value: 1185 mg/m³, 500 ppm bio	
IOELV (European Union)	Long-term value: 1210 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.

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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.

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties	
· Information on basic physical and o · General Information · Appearance:	chemical properties
Form:	Liquid
Colour:	Yellow
· Odour:	Acetone-like
· Odour threshold:	Not determined.
· pH-value at 20 °C:	1.8
· Change in condition Melting point/freezing point: Initial boiling point and boiling re	-95 °C ange: 55 °C
· Flash point:	-17 °C
· 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.

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Density at 20 °C:	0.94 g/cm³	
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:		
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

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	· LD/LC50 values relevant for classification:			
Γ	67-64-1 acetone			
ſ	Oral	LD50	5,800 mg/kg (rat (f+m))	
	Dermal	LD50	20,000 mg/kg (rabbit)	
	128-37-	128-37-0 Butylated hydroxytoluene		
ľ	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

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Corrosive

- · 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:

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.

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

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

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Transport hazard class(es)	
ADR	
3	
Class	3 (F1) Flammable liquids.
Label	3
IMDG, IATA	
A	
3	
V	
Class	3 Flammable liquids.
Label	3
Packing group	77
ADR, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	33
EMS Number:	F-E,S-D
Stowage Category	E
Transport in bulk according to Annex II of Mary	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
T	Maximum net quantity per outer packaging: 500 ml
Transport category Tunnel restriction code	2 D/E
Tunnei restriction code	<i>D/E</i>
IMDG	
Limited quantities (LQ)	IL G. 1. E2
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

NZ

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15 Regulatory information

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

· New Zealan	· New Zealand Inventory of Chemicals		
67-64-1	acetone		
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane		
70293-55-9	2-[(2-methyl-1-oxoallyl)oxy]ethyl 1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate		
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate		
	Silane, dichlorodimethyl-, reaction products with silica		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
10287-53-3	ethyl 4-dimethylaminobenzoate		
128-37-0	Butylated hydroxytoluene		
1344-28-1	aluminium oxide		
7732-18-5	Water		

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







GHS02

GHS05 GHS0

- · 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.

Harmful to aquatic life with long lasting effects.

· 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
- 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

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· 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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· 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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard - Category 3

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - 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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