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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 02.08.2018

Version number 3

Revision: 08.02.2017

SECTION 1: Identification

- · 1.1 Product identifier
- · Trade name: G-Premio Bond
- 1.2 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
- \cdot 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00 Fax +32/(0)16/40.26.84 msds@gc.dental

· Information department: Regulatory affairs

· 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

SECTION 2: Hazard(s) identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

- *Flam. Liq.* 2 *H225 Highly flammable liquid and vapour.*
- Skin Irrit. 2 H315 Causes skin irritation.
- *Eye Irrit.* 2 *H319 Causes serious eye irritation.*
- Skin Sens. 1 H317 May cause an allergic skin reaction.
- STOT SE 3 H336 May cause drowsiness or dizziness.

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

· 2.2 Label elements

• Labelling according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labeled according to the CLP regulation.

• Hazard pictograms



· Signal word Danger

- Hazard-determining components of labeling: acetone
- $2,2'-ethylenedioxydiethyl\ dimethacrylate$
- · Hazard statements

H225 Highly flammable liquid and vapour.

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H315 Causes	s skin irritation.
H319 Causes	s serious eye irritation.
H317 May ca	use an allergic skin reaction.
	ause drowsiness or dizziness.
	ul to aquatic life with long lasting effects.
· Precautional	
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves / eye protection / face protection.
P303+P361-	+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351-	+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
· 2.3 Other ha	zards
· Results of Pl	BT and vPvB assessment
. PRT. Not an	

• *PBT*: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: 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. 2, H319; STOT SE 3, H336	
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	10-<25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, 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, H361f	
128-37-0	Butylated hydroxytoluene	0.5-<1%
	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1
· Additional i	<i>nformation:</i> For the wording of the listed hazard phrases refer to section 16.	•

SECTION 4: First-aid measures

• 4.1 Description of first aid measures

• General information:

Immediately remove any clothing soiled by the product. If symptoms persist consult doctor.

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• After inhalation:

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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. Then consult a doctor. • After swallowing:

Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

• 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Fire-fighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 5.2 Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- 5.3 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.

SECTION 6: Accidental release measures

6.1 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.
6.2 Environmental precautions: Do not allow product to reach sewage system or any water course. Do not allow to penetrate the ground/soil.
6.3 Methods and material for containment and cleaning up: Ensure adequate ventilation. Absorb liquid components with liquid-binding material. Dispose of the collected material according to regulations.
6.4 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.

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SECTION 7: Handling and storage

• 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Avoid contact with the eyes and skin.

• Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray on a naked flame or any incandescent material.

- 7.2 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 receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight. Store in a cool place.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

- · 8.1 Control parameters
- · Components with limit values that require monitoring at the workplace:
- 67-64-1 acetone

IOELV 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 that were valid during the creation were used as basis.

· 8.2 Exposure controls

· Personal protective equipment:

• General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

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.

· Breathing equipment: 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

SECTION 9: Physical and chemical properties		
• 9.1 Information on basic physical ar • General Information	nd chemical properties	
· Appearance:		
Form: Color:	Liquid Yellow	
· Odor:	Acetone-like	
· Odor threshold:	Not determined.	
· pH-value at 20 °C:	2.1	
· Change in condition		
Melting point/Melting range:	-95 °C	
Boiling point/Boiling range:	55 °C	
· Flash point:	-17 °C	
· Flammability (solid, gaseous):	Not applicable.	
· Ignition temperature:	Undetermined.	
• Decomposition temperature:	Not determined.	
· Auto igniting:	Product is not selfigniting.	
• Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	2.6 Vol %	
Upper:	13.0 Vol %	
· Vapor pressure:	Not determined.	
· Density at 20 °C:	0.94 g/cm ³	
· Relative density	Not determined.	
· Vapor density	Not determined.	

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Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octano	l/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	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- \cdot 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity: Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:

67-64-1 acetone

Oral LD50 5800 mg/kg (*rat* (*f*+*m*))

Dermal LD50 20000 mg/kg (rabbit)

128-37-0 Butylated hydroxytoluene

Oral LD50 > 6000 mg/kg (rat (f+m)) (OECD 401)

• Primary irritant effect:

• on the skin:

Causes skin irritation.

- on the eye:
- Causes serious eye irritation.
- · Sensitization:
- May cause an allergic skin reaction.
- Additional toxicological information:
- · OSHA-Ca (Occupational Safety & Health Administration)
- None of the ingredients is listed.

• *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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- · 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
- May cause drowsiness or dizziness.
- · 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.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Ecotoxical effects:
- · Remark: Harmful to fish
- \cdot Additional ecological information:
- · General notes:
- Harmful to aquatic organisms
- Water hazard class 1 (Self-assessment): slightly hazardous for water

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans

18 01 06* chemicals consisting of or containing hazardous substances

· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport inj	formation	
· 14.1 UN-Number · ADR, IMDG, IATA	UN1090	
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14.2 UN proper shipping name	
DOT, IATA	Acetone mixture
ADR	1090 ACETONE mixture
IMDG	ACETONE mixture
14.3 Transport hazard class(es)	
ADR	
- Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
3	
Class	3 Flammable liquids
Label	3
14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	33
EMS Number:	F- E , S - D
Stowage Category	E
14.7 Transport in bulk according to Anne	
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
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
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	1L
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

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SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture \cdot Sara

• Section 355 (extremely hazardous substances):

None of the ingredient is listed.

• Section 313 (Specific toxic chemical listings):

1344-28-1 aluminium oxide

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

67-64-1 acetone

· TLV (Threshold Limit Value established by ACGIH)

67-64-1 acetone

1344-28-1 aluminium oxide

128-37-0 Butylated hydroxytoluene

· MAK (German Maximum Workplace Concentration)

1344-28-1 aluminium oxide

128-37-0 Butylated hydroxytoluene

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· 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

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

SECTION 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.

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 H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H361 Suspected of damaging fertility. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life. H410 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. Classification according to Regulation (EC) No 1272/2008 Calculation method Department issuing SDS: Regulatory affairs Contact: msds@gc.dental Abbreviations and acronyms: AbR: Accord europhen 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 DOT: US Degariment of Transportation IATA: International Maritime Code for Dangerous Goods DOT: US Degariment of Transportation IATA: International Maritime Code for Dangerous Goods DOT: US Degariment of Transportation IATA: International Maritime Code for Dangerous Goods DOT: US Deupoen Inventory of Existing Commercial Chemical Substances ELINCS: European Instant or Substant of Constitution and Labelling of Chemicals ACCIH: American Conference of Governmental Industrial Hygienists ELINCS: European Inventory of Existing Commercial Chemical Substances ELINCS: European Inventory Responder (IREACI) LCS: Elabel concentration, 50 percent DYBE: Derived No-Effect Level (IREACI) LCS: Head Concentuative and Toxic WPB: versistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSH: Accordonional Safety Sub Headth Fiam, Li, 2: Flammable liquids - Caregory 2 Stis Instra: Sist nestisticand everyonment - Long-term aquatic hazard - Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - Long-term aquatic hazard - Category 1 Aquatic Chro	(Co	ontd. of page 9)
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