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

Printing date 09.12.2020 *Version number 3* *Revision: 09.12.2020*

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **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

· **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.)

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SECTION 2: Hazards 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 Corr. 1	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 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.

· **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 labeling:**
acetone

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2,2'-ethylenedioxydiethyl dimethacrylate

· **Hazard statements**
H225 Highly flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H336 May cause drowsiness or dizziness.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dusts or mists.
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.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **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 Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25-<50%
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5-<5%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	1-<2.5%
128-37-0	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.5-<1%

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

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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.
· **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.
· **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: Firefighting 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.
No further relevant information available.
· **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.
Use neutralizing agent.
Absorb liquid components with liquid-binding material.

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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.

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.

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Immediately remove all soiled and contaminated clothing.

· ***Breathing equipment:*** *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

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Appearance:***	
Form:	*Liquid*
Color:	*Yellow*
· ***Odor:***	*Acetone-like*
· ***Odor threshold:***	*Not determined.*
· ***pH-value at 20 °C:***	*1.8*
· ***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 Vol %*
· ***Vapor pressure:***	*Not determined.*
· ***Density at 20 °C:***	*0.94 g/cm³*

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· **Relative density**	Not determined.
· **Vapor 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
· **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.
· **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	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:**
· **on the skin:**
Causes severe skin burns and eye damage.
· **on the eye:**
Causes serious eye damage.
· **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.

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· ***CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)***
No further relevant information available.
· ***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
· ***Additional ecological information:***
· ***General notes:***
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
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.
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***	
18 00 00	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

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

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1090
· **14.2 UN proper shipping name**	
· **DOT**	Acetone mixture
· **ADR**	1090 ACETONE mixture
· **IMDG, IATA**	ACETONE
· **14.3 Transport hazard class(es)**	
· **ADR**	

· **Class**	3 (F1) Flammable liquids
· **Label**	3
· **IMDG, IATA**	

· **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
· **Hazard identification number (Kemler code):**	33
· **EMS Number:**	F-E,S-D
· **Stowage Category**	E
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **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
· **Transport category**	2
· **Tunnel restriction code**	D/E

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· **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

SECTION 15: Regulatory information

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

· **TLV (Threshold Limit Value established by ACGIH)**

67-64-1	acetone	A4
1344-28-1	aluminium oxide	A4
128-37-0	Butylated hydroxytoluene	A4

· **MAK (German Maximum Workplace Concentration)**

1344-28-1	aluminium oxide	2
128-37-0	Butylated hydroxytoluene	4

· **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

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· **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.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H361f Suspected of damaging fertility.
H400 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:**
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
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Flam. Liq. 2: Flammable liquids – Category 2
Skin Corr. 1: Skin corrosion/irritation – Category 1
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
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 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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