

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

Printing date 12.11.2020

Version number 1

Revision: 12.11.2020

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

· **1.1 Product identifier**

· **Trade name:** *GC G2-BOND Universal Primer*

· **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

· **Further information obtainable from:** *Regulatory affairs*

· **1.4 Emergency telephone number:**

National poison center for United Kingdom of Great Britain and Northern Ireland:

Belfast: +44 28 90 63 2032

Birmingham: +44 121 507 4123

Edinburgh: +44 131 242 1383

Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180

Penarth: +44 292 071 55 54

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.

Unst. Expl. H200 Unstable explosives.

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**

The product is classified and labelled 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).

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· **Hazard pictograms**

GHS01 GHS05 GHS07

· **Signal word** *Danger*· **Hazard-determining components of labelling:***acetone**2,2'-ethylenedioxydiethyl dimethacrylate*· **Hazard statements***H200 Unstable explosives.**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/protective clothing/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.**P373 DO NOT fight fire when fire reaches explosives.**P380 Evacuate area.**P401 Store in accordance with local/regional/national/international regulations.**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 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. 2, H319; STOT SE 3, H336	
Index number: 606-001-00-8		

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CAS: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5-<5%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	1-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1-<2.5%

· **Additional information:** 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.

· **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, 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

· 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.

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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 neutralising agent.

Absorb liquid components with liquid-binding material.

Dispose of the material collected 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.

Open and handle receptacle with care.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Prevent impact and friction.

Do not spray onto 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 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.

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 facilities: No further data; see item 7.

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· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:****67-64-1 acetone**

WEL	Short-term value: 3620 mg/m ³ , 1500 ppm
	Long-term value: 1210 mg/m ³ , 500 ppm

· **DNELs****128-37-0 Butylated hydroxytoluene**

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m ³ (man)

· **Additional information:** The lists valid during the making were used as basis.

· 8.2 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:**

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
Colour:	Light yellow
Odour:	Acetone-like
Odour threshold:	Not determined.

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· pH-value at 20 °C:	1.8
· Change in condition	
Melting point/freezing point:	-95 °C
Initial boiling point and boiling range:	55.8-56.6 °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. Risk of explosion by shock, friction, fire or other sources of ignition.
· Explosion limits:	
Lower:	2.6 Vol %
Upper:	13 Vol %
· Vapour pressure:	Not determined.
· Density at 20 °C:	0.94 g/cm ³
· 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.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	33.0 %
Water:	24.0 %
VOC (EC)	400.6 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.

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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 relevant for classification:

67-64-1 acetone

Oral	LD50	5,800 mg/kg (rat (f+m))
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Dermal	LD50	20,000 mg/kg (rabbit)
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128-37-0 Butylated hydroxytoluene

Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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)
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- **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.
- **Ecotoxicological 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.
Water hazard class 1 (German Regulation) (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.

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- **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 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.

SECTION 14: Transport information

- | | |
|---|---|
| · 14.1 UN-Number
· ADR, IMDG, IATA | UN1993 |
| · 14.2 UN proper shipping name
· ADR
· IMDG, IATA | 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE), special provision 640D
FLAMMABLE LIQUID, N.O.S. (ACETONE) |
| · 14.3 Transport hazard class(es)
· ADR | |
|  | |
| · Class
· Label | 3 (F1) Flammable liquids.
3 |
| · IMDG, IATA | |
|  | |
| · Class
· Label | 3 Flammable liquids.
3 |
| · 14.4 Packing group
· ADR, IMDG, IATA | II |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user
· Hazard identification number (Kemler code):
· EMS Number:
· Stowage Category | Warning: Flammable liquids.
33
F-E, S-E
B |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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· **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

· **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 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ACETONE), 3, II

SECTION 15: Regulatory information· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Seveso category P1a** EXPLOSIVES· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 10 t· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50 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.

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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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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
 Unst. Expl.: Explosives – Unstable explosive
 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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