

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

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

- **1.1 Product identifier**
- **Trade name: GC CERAMIC PRIMER II**
- **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.  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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 labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
2,2'-ethylenedioxydiethyl dimethacrylate  
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

(Contd. on page 2)

GB

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

Trade name: GC CERAMIC PRIMER II

(Contd. of page 1)

- **Hazard statements**

H225 Highly flammable liquid and vapour.

H317 May cause an allergic skin reaction.

- **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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].

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: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	ethyl alcohol Flam. Liq. 2, H225	90-<100%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-<2.5%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	1-<2.5%
CAS: 1565-94-2 EINECS: 216-367-7	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Eye Dam. 1, H318; Skin Sens. 1, H317	0.5-<1%

- **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:**

Generally the product does not irritate the skin.

Immediately wash with water and soap and rinse thoroughly.

(Contd. on page 3)

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

**Trade name: GC CERAMIC PRIMER II**

(Contd. of page 2)

Seek medical treatment.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, 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: Firefighting measures**

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

CO<sub>2</sub>, 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.

· **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.

Wear protective equipment. Keep unprotected persons away.

Use respiratory protective device against the effects of fumes/dust/aerosol.

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.

Do not allow to enter sewers/ surface or ground water.

Prevent seepage into sewage system, workpits and cellars.

Dilute with plenty of water.

· **6.3 Methods and material for containment and cleaning up:**

Ensure adequate ventilation.

Allow to evaporate.

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.

GB

(Contd. on page 4)

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

Trade name: GC CERAMIC PRIMER II

(Contd. of page 3)

### 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 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.
- **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 container 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 facilities:** No further data; see item 7.

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

<b>64-17-5 ethyl alcohol</b>
------------------------------

WEL   Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm
--

- **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.

Immediately remove all soiled and contaminated clothing

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Suitable respiratory protective device recommended.

- **Protection of hands:**

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



Protective gloves

(Contd. on page 5)

GB

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

**Trade name: GC CERAMIC PRIMER II**

(Contd. of page 4)

- **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:**

· <b>Form:</b>	Liquid
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Alcohol-like
· <b>Odour threshold:</b>	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

· <b>Melting point/freezing point:</b>	-114.5 °C
· <b>Initial boiling point and boiling range:</b>	78 °C

- **Flash point:** 13 °C

- **Flammability (solid, gas):** Not applicable.

- **Ignition temperature:** 425 °C

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

· <b>Lower:</b>	3.5 Vol %
· <b>Upper:</b>	15.0 Vol %

- **Vapour pressure at 20 °C:** 59 hPa

· <b>Density at 20 °C:</b>	0.8 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

- **Solubility in / Miscibility with water at 20 °C:**

1.000 g/l  
Fully miscible.

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

(Contd. on page 6)

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

Trade name: GC CERAMIC PRIMER II

(Contd. of page 5)

- |                                |  |
|--------------------------------|--|
| · <b>Viscosity:</b>            |  |
| <b>Dynamic:</b>                | Not determined.                            |
| <b>Kinematic:</b>              | Not determined.                            |
| · <b>Solvent content:</b>      |  |
| <b>Organic solvents:</b>       | 92.5 %                                     |
| <b>VOC (EC)</b>                | 740.1 g/l                                  |
| · <b>9.2 Other information</b> | 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 relevant for classification:**

**64-17-5 ethyl alcohol**

Oral	LD50	7060 mg/kg (rat (f+m))
Inhalative	LC50/4 h	20000 mg/l (rat (f+m))

- **Primary irritant effect:**
- **Skin corrosion/irritation** No further relevant information available
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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)**  
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** Based on available data, the classification criteria are not met.
- **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:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.

(Contd. on page 7)

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

Trade name: GC CERAMIC PRIMER II



(Contd. of page 6)

- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
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.
- **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** UN1170
- **14.2 UN proper shipping name**  
· **ADR** 1170 ETHANOL SOLUTION mixture  
· **IMDG, IATA** ETHANOL SOLUTION mixture
- **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

(Contd. on page 8)

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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

**Trade name: GC CERAMIC PRIMER II**

(Contd. of page 7)

· <b>14.6 Special precautions for user</b>	Warning: Flammable liquids.
· <b>Danger code (Kemler):</b>	33
· <b>EMS Number:</b>	F-E,S-D
· <b>Stowage Category</b>	A
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1170 ETHANOL SOLUTION MIXTURE, 3, II

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **Department issuing SDS:** Regulatory affairs
- **Contact:** msds@gc.dental
- **Abbreviations and acronyms:**
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
- ICAO: International Civil Aviation Organisation

(Contd. on page 9)



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

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

**Trade name: GC CERAMIC PRIMER II**

(Contd. of page 8)

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)  
 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  
 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)  
 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  
 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  
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

• **Sources**

- ECHA (<http://echa.europa.eu/>)
  - EnviChem ([www.echemportal.org](http://www.echemportal.org))
- \* **Data compared to the previous version altered.**

This version replaces all previous versions.

**Disclaimer:**

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.