

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

Printing date 22.08.2023

Version number 4 (replaces version 3)

Revision: 22.08.2023

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

- **1.1 Product identifier**
- **Trade name: COMPOSITE 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** Auxillary 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**  
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            H335 May cause respiratory irritation.  
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 GB 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**



GHS07

- **Signal word** Warning

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- **Hazard-determining components of labelling:**

2-hydroxyethyl metacrylate  
Tetrahydrofurfuryl methacrylate  
Urethane Dimethacrylate (UDMA)

- **Hazard statements**

H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.  
H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

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.  
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 hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 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: 868-77-9 EINECS: 212-782-2 Index number: 607-124-00-X	2-hydroxyethyl metacrylate ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	50-<75%
CAS: 2455-24-5 EINECS: 219-529-5	Tetrahydrofurfuryl methacrylate ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	≥20-<25%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) ----- Aquatic Chronic 2, H411; Skin Sens. 1B, H317	10-<25%

- **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.

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*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: Firefighting measures**

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:** CO<sub>2</sub>, 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.*

*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:**

*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.*

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- *Avoid contact with the eyes and skin.*
- **Information about fire - and explosion protection:** *Protect against electrostatic charges.*
- **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.*
- **7.3 Specific end use(s)** *No further relevant information available.*

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
*The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.*
- **Additional information:** *The lists valid during the making were used as basis.*
- **8.2 Exposure controls**
- **Appropriate engineering controls** *No further data; see section 7.*
- **Individual protection measures, such as 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.*
- **Hand protection**



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/face protection**



Tightly sealed goggles

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

· Physical state	Fluid
· Colour:	Light yellow
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.

#### · 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0.0 g/l
· Change in condition	
· Evaporation rate	Not determined.

#### · Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

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- |   |      |
|---|------|
| · Self-heating substances and mixtures                                      | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids   | Void |
| · Oxidising solids  | Void |
| · Organic peroxides   | Void |
| · Corrosive to metals   | Void |
| · Desensitised explosives   | Void |

### 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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
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- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **STOT-single exposure** May cause respiratory irritation.

- **Additional toxicological information:**

- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)** No further relevant information available.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

128-37-0	Butylated hydroxytoluene
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List II

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

2455-24-5 Tetrahydrofurfuryl methacrylate

LC50/96h	34.7 mg/L (fish)
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72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static)	>1.2 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **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.

### 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.

### SECTION 14: Transport information

· <b>14.1 UN number or ID number</b> · <b>ADR, ADN, IMDG, IATA</b>	not regulated
· <b>14.2 UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	not regulated
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	not regulated
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	not regulated
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 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.

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

### SECTION 16: Other information

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H411 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 relatif au transport international 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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

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