

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

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

- **1.1 Product identifier**
- **Trade name: GC Acrylic 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**
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	H335-H336	May cause respiratory irritation. 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 labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

(Contd. on page 2)

GB

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 1)

· **Signal word** *Danger*· **Hazard-determining components of labelling:***Methyl methacrylate*
*acetone**Urethane Dimethacrylate (UDMA)*· **Hazard statements***H225 Highly flammable liquid and vapour.**H315 Causes skin irritation.**H319 Causes serious eye irritation.**H317 May cause an allergic skin reaction.**H335-H336 May cause respiratory irritation. 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.**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 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 EINECS: 200-662-2 Index number: 606-001-00-8	<i>acetone</i> Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25-<50%
CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6	<i>Methyl methacrylate</i> Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-<50%
CAS: 72869-86-4 EINECS: 276-957-5	<i>Urethane Dimethacrylate (UDMA)</i> Skin Sens. 1, H317	10-<25%
CAS: 128-37-0 EINECS: 204-881-4	<i>Butylated hydroxytoluene</i> Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.25-<0.5%

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

GB

(Contd. on page 3)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 2)

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. 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:** 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 material collected according to regulations.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.

(Contd. on page 4)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 3)

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 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:**

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm

Long-term value: 1210 mg/m³, 500 ppm

80-62-6 Methyl methacrylate

WEL Short-term value: 416 mg/m³, 100 ppm

Long-term value: 208 mg/m³, 50 ppm

· **DNELs**

80-62-6 Methyl methacrylate

Dermal DNEL dermal 13.67 mg/kg bw/day (man) (worker, l. te., syst.)

Inhalative DNEL inhalation 208 mg/m³ (air) (worker, l. te., syst.)

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 valid during the making were used as basis.

(Contd. on page 5)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 4)

- **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:	Clear
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· Change in condition

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	55 °C

· **Flash point:** -17 °C

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

· **Ignition temperature:** Undetermined.

· **Decomposition temperature:** Not determined.

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

(Contd. on page 6)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 5)

· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	13 Vol %
· Vapour pressure:	Not determined.
· Density at 20 °C:	0.9 g/cm ³
· Relative density	Not determined.
· Vapour 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:	48.5 %
VOC (EC)	436.7 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 relevant for classification:		
67-64-1 acetone		
Oral	LD50	5,800 mg/kg (rat (f+m))
Dermal	LD50	20,000 mg/kg (rabbit)
80-62-6 Methyl methacrylate		
Oral	LD50	6,000 mg/kg (rabbit)
Dermal	LD50	>5,000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat (f+m))

(Contd. on page 7)

GB

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 6)

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 >5,000 mg/kg (rat female) (OECD 401)

128-37-0 Butylated hydroxytoluene

Oral LD50 >6,000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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**
May cause respiratory irritation. 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:****72869-86-4 Urethane Dimethacrylate (UDMA)**

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Harmful to aquatic organisms
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.

GB

(Contd. on page 8)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 7)

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.

- **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

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1993

- **14.2 UN proper shipping name**
- **ADR** 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE, METHYL METHACRYLATE MONOMER, STABILIZED), special provision 640D
- **IMDG, IATA** FLAMMABLE LIQUID, N.O.S. (ACETONE, METHYL METHACRYLATE MONOMER, STABILIZED)

- **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.
- **Danger code (Kemler):** 33

(Contd. on page 9)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 8)

· EMS Number:	<u>F-E,S-E</u>
· Stowage Category	B
· 14.7 Transport in bulk according to Annex II of Marpol 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
· 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, METHYL METHACRYLATE MONOMER, STABILIZED), 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 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.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- 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

(Contd. on page 10)

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

Printing date 03.08.2018

Version number 2

Revision: 08.02.2018

Trade name: GC Acrylic Primer

(Contd. of page 9)

· **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

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

Flam. Liq. 2: Flammable liquids – Category 2

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

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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