Safety data sheet
according to UK REACH

Printing date 25.06.2025 Version number 5 (replaces version 4) Revision: 25.06.2025

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

· **1.1 Product identifier**

· **Trade name: 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**
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**
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**

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)

Safety data sheet
according to UK REACH

(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/protective clothing/eye protection/face protection/hearing 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 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 substance with a Community workplace exposure limit	90-<100%
CAS: 109-16-0 EINECS: 203-652-6 Index number: 607-768-00-1	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1B, H317	1-<2.5%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	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	0.2-<0.5%

· **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:**
Generally the product does not irritate the skin.

(Contd. on page 3)

Safety data sheet
according to UK REACH

(Contd. of page 2)

Immediately wash with water and soap and rinse thoroughly.
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:**
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.
· **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.

(Contd. on page 4)

Safety data sheet
according to UK REACH

(Contd. of page 3)

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

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
64-17-5 ethyl alcohol	
WEL	Long-term value: 1920 mg/m³, 1000 ppm

· **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.
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.

(Contd. on page 5)

Safety data sheet
according to UK REACH

(Contd. of page 4)

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

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

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	*Fluid*
· **Colour:**	*Colourless*
· **Odour:**	*Alcohol-like*
· **Odour threshold:**	*Not determined.*
· **Melting point/freezing point:**	*-114.5 °C*
· **Boiling point or initial boiling point and boiling range**	*78 °C*
· **Flammability**	*Highly flammable.*
· **Lower and upper explosion limit**	
· **Lower:**	*3.5 Vol %*
· **Upper:**	*15 Vol %*
· **Flash point:**	*13 °C*
· **Auto-ignition temperature:**	*425 °C*
· **Decomposition temperature:**	*Not determined.*
· **pH**	*Not determined.*
· **Viscosity:**	
· **Kinematic viscosity**	*Not determined.*
· **Dynamic:**	*Not determined.*
· **Solubility**	
· **water at 20 °C:**	*1.000 g/l* *Fully miscible.*
· **Partition coefficient n-octanol/water (log value)**	*Not determined.*
· **Vapour pressure at 20 °C:**	*59 hPa*
· **Density and/or relative density**	
· **Density at 20 °C:**	*0.8 g/cm³*
· **Relative density**	*Not determined.*
· **Vapour density**	*Not determined.*

(Contd. on page 6)

Safety data sheet
according to UK REACH

(Contd. of page 5)

· **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:**	
· **Organic solvents:**	93.5 %
· **VOC (EC)**	748.0 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**	Highly flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **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.

(Contd. on page 7)

Safety data sheet
according to UK REACH

(Contd. of page 6)

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

64-17-5 ethyl alcohol

Oral	LD50	7,060 mg/kg (rat (f+m))
Inhalative	LC50/4 h	20,000 mg/l (rat (f+m))

· **Primary irritant effect:**
· **Skin corrosion/irritation** No further relevant information available
· **Respiratory or skin sensitisation** May cause an allergic skin reaction.
· **Additional toxicological information:**
· **Repeated dose toxicity** No further relevant information available.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

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.
· **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**
The product does not contain substances with endocrine disrupting properties.
· **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.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN1170

(Contd. on page 8)

Safety data sheet
according to UK REACH

Trade name: CERAMIC_PRIMER_II

(Contd. of page 7)

· **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
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Hazard identification number (Kemler code):**	33
· **EMS Number:**	F-E,S-D
· **Stowage Category**	A
· **14.7 Maritime transport in bulk according to IMO instruments**	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 1170 ETHANOL SOLUTION MIXTURE, 3, II

(Contd. on page 9)

Safety data sheet
according to UK REACH

(Contd. of page 8)

SECTION 15: Regulatory information

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

· **Regulated explosives precursors**
None of the ingredients is listed.

· **Regulated poisons**
None of the ingredients is listed.

· **Reportable explosives precursors**
None of the ingredients is listed.

· **Reportable poisons**
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
· **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
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
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
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

(Contd. on page 10)

Safety data sheet
according to UK REACH

(Contd. of page 9)

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

· ***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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