

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

Printing date 05.07.2023

Version number 4 (replaces version 3)

Revision: 05.07.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**· 1.1 Product identifier****· Trade name: GC Initial Opaque Liquid MC****· 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**

The product is not classified, according to the GB CLP regulation.

· 2.2 Label elements**· Labelling according to Regulation (EC) No 1272/2008** Void**· 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 Void**· Signal word** Void**· Hazard statements** Void**· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.

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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:** Void

· **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:**

No special measures required.

If symptoms persist consult doctor.

· **After inhalation:** Take affected persons into fresh air and keep quiet.

· **After skin contact:** Immediately rinse with water.

· **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** No further relevant information available.

· **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.

· **6.2 Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

Dilute with plenty of water.

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- **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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **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.
Wash hands before breaks and at the end of work.
- **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** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid

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· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	100 °C
· 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:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· 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:	
· Water:	98.4 %
· 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
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void

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· 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:** No further relevant information available.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.
- **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**

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.

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- **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.

Contact waste processors for recycling information.

- **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, ADN, IMDG, IATA** not regulated

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** not regulated

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** not regulated

- **14.4 Packing group**

- **ADR, IMDG, IATA** not regulated

- **14.5 Environmental hazards:**

- **Marine pollutant:** No

- **14.6 Special precautions for user**

Not applicable.

- **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

- **UN "Model Regulation":**

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.

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

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SECTION 16: Other information

- **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
- **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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