

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

Printing date 07.08.2018

Version number 2

Revision: 28.04.2016

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

- **1.1 Product identifier**
- **Trade name: GC Initial LiSi Dentine, Dentine Modifier, Enamel, Transparent material**
- **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.  
The product is not classified, according to the CLP regulation.

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- **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.
- **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 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: 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:**

Generally the product does not irritate the skin.

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:**

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.

**· 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.

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

*Pick up mechanically.*

*Dispose of the material collected according to regulations.*

*Dispose contaminated material as waste according to item 13.*

· **6.4 Reference to other sections**

*No dangerous substances are released.*

*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**

*Prevent formation of dust.*

*Any unavoidable deposit of dust must be regularly removed.*

· **Information about fire - and explosion protection:** *Dust can combine with air to form an explosive mixture.*

· **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**

· **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:**

*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**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

*The usual precautionary measures are to be adhered to when handling chemicals.*

*Do not inhale dust / smoke / mist.*

*Wash hands before breaks and at the end of work.*

· **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:**

*Protective gloves*

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

· **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.*

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· **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:** Safety glasses

**SECTION 9: Physical and chemical properties**

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Solid
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

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

· **Ignition temperature:** Undetermined.

· **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>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not applicable.

· <b>Density at 20 °C:</b>	2.4 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

· **Solubility in / Miscibility with water:** Insoluble.

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

· **Viscosity:**

· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	Not applicable.

· **9.2 Other information** No further relevant information available.

**SECTION 10: Stability and reactivity**

· **10.1 Reactivity** No further relevant information available.

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- **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:** No further relevant information available.
- **Primary irritant effect:**
- **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.
- **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.
- **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.  
Contact waste processors for recycling information.

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

**SECTION 14: Transport information**

- **14.1 UN-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 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.
- **UN "Model Regulation":** not regulated

**SECTION 15: Regulatory information**

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

**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:**  
*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 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)*  
*LC50: Lethal concentration, 50 percent*  
*LD50: Lethal dose, 50 percent*  
*PBT: Persistent, Bioaccumulative and Toxic*

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vPvB: very Persistent and very Bioaccumulative

· **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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