

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

Printing date 10.07.2023

Version number 3 (replaces version 2)

Revision: 10.07.2023

**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** 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
- **Information department:** Regulatory affairs
- **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

**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 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.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterization: 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.

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### 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>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **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.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the collected material according to regulations.  
Dispose contaminated material as waste according to section 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.

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See Section 13 for disposal information.

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### SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Prevent formation of dust.

Any deposit of dust which cannot be avoided must be regularly removed.

· **Information about protection against explosions and fires:**

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

· **8.1 Control parameters**

· **Components 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 that were valid during the creation were used as basis.

· **8.2 Exposure controls**

· **Additional information about design of technical systems:** No further data; see section 7.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

Do not inhale dust / smoke / mist.

Wash hands before breaks and at the end of work.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

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.

· **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

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**SECTION 9: Physical and chemical properties**

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

**· General Information**

|   |                                    |
|---|------------------------------------|
| · <b>Physical state</b>                           | Solid                              |
| · <b>Color:</b>                                   | According to product specification |
| · <b>Odor:</b>                                    | Characteristic                     |
| · <b>Odor threshold:</b>                          | Not determined.                    |
| · <b>Melting point/Melting range:</b>             | Undetermined.                      |
| · <b>Boiling point/Boiling range:</b>             | Undetermined.                      |
| · <b>Flammability (solid, gaseous):</b>           | Not determined.                    |
| · <b>Explosion limits:</b>                        |                                    |
| · <b>Lower:</b>                                   | Not determined.                    |
| · <b>Upper:</b>                                   | Not determined.                    |
| · <b>Flash point:</b>                             | Not applicable.                    |
| · <b>Auto igniting:</b>                           | Undetermined.                      |
| · <b>Decomposition temperature:</b>               | Not determined.                    |
| · <b>pH-value:</b>                                | Not applicable.                    |
| · <b>Viscosity:</b>                               |                                    |
| · <b>Kinematic:</b>                               | Not applicable.                    |
| · <b>Dynamic:</b>                                 | Not applicable.                    |
| · <b>Solubility in / Miscibility with</b>         |                                    |
| · <b>Water:</b>                                   | Insoluble.                         |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                    |
| · <b>Vapor pressure:</b>                          | Not applicable.                    |
| · <b>Density and/or relative density</b>          |                                    |
| · <b>Density at 20 °C:</b>                        | 2.4 g/cm <sup>3</sup>              |
| · <b>Relative density</b>                         | Not determined.                    |
| · <b>Vapor density</b>                            | Not applicable.                    |
| · <b>Particle characteristics</b>                 | See section 3.                     |

**· 9.2 Other information**

|  |   |
|--|---|
| · <b>Appearance:</b>   |   |
| · <b>Form:</b>   | Solid   |
| · <b>Important information on protection of health and environment, and on safety.</b> |   |
| · <b>Ignition temperature:</b>   | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>  | Product does not present an explosion hazard. |
| · <b>Change in condition</b>   |   |
| · <b>Evaporation rate</b>  | Not applicable.                               |

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

|  |      |
|--|------|
| · <b>Explosives</b>                            | Void |
| · <b>Flammable gases</b>                       | Void |
| · <b>Aerosols</b>                              | Void |
| · <b>Oxidising gases</b>                       | Void |
| · <b>Gases under pressure</b>                  | Void |
| · <b>Flammable liquids</b>                     | Void |
| · <b>Flammable solids</b>                      | Void |
| · <b>Self-reactive substances and mixtures</b> | Void |
| · <b>Pyrophoric liquids</b>                    | Void |
| · <b>Pyrophoric solids</b>                     | Void |
| · <b>Self-heating substances and mixtures</b>  | Void |

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- |  |      |
|--|------|
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | Void |
| · <b>Oxidising liquids</b>   | Void |
| · <b>Oxidising solids</b>  | Void |
| · <b>Organic peroxides</b>   | Void |
| · <b>Corrosive to metals</b>   | Void |
| · <b>Desensitised explosives</b>   | 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 toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **LD/LC50 values that are relevant for classification:** No further relevant information available.
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** 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.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - 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:**

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.

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- **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 (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 of together with household garbage. Do not allow product to reach sewage system.  
Contact waste processors for recycling information.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| · <b>14.1 UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | not regulated   |
| · <b>14.2 UN proper shipping name</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b>                 | not regulated   |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | not regulated   |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | not regulated   |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No              |
| · <b>14.6 Special precautions for user</b>  | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>      | Not applicable. |
| · <b>UN "Model Regulation":</b>   | not regulated   |

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### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

- **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

None of the ingredients is listed.

- **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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

· **Classification according to Regulation (EC) No 1272/2008** Calculation method

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **Date of previous version** 10.07.2023

· **Version number of previous version:** 2

· **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*

*DOT: US Department of Transportation*

*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*

*vPvB: very Persistent and very Bioaccumulative*

*NIOSH: National Institute for Occupational Safety*

*OSHA: Occupational Safety & Health*

· **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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