

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.05.2024

Version number 1

Revision: 23.05.2024

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

- **1.1 Product identifier**
- **Trade name:** GC Initial Zirconia Coloring Liquid (Body, Cervical)
- **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**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labeled according to the 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**



GHS07

- **Signal word** Warning
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.
- **Precautionary statements**  
P264 Wash thoroughly after handling.  
P280 Wear protective gloves / eye protection / face protection.  
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P362+P364 Take off contaminated clothing and wash it before reuse.

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P337+P313 If eye irritation persists: Get medical advice/attention.

- **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:**

10025-77-1	Ironchloride Hexahydrate	≥2.5-<3%
	Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315	

- **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:**  
Immediately wash with water and soap and rinse thoroughly.  
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** 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>, 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.  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

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**· 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.*

*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:**

*Absorb liquid components with liquid-binding material.*

*Dispose of the collected material 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**

*Ensure good ventilation/exhaustion at the workplace.*

*Prevent formation of aerosols.*

*Avoid contact with the eyes and skin.*

**· Information about protection against explosions and fires: Protect against electrostatic charges.**

**· 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:** *Keep receptacle tightly sealed.*

**· 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.*

*Avoid contact with the eyes and skin.*

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

*Keep away from foodstuffs, beverages and feed.*

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Immediately remove all soiled and contaminated clothing.

- **Breathing equipment:** 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**

· <b>Physical state</b>	Fluid
· <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>	100 °C (7732-18-5 Water)
· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	279 °C (25322-68-3 Polyethylene Glycol)
· <b>Auto igniting:</b>	Undetermined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Kinematic:</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.

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- **9.2 Other information**
  - **Appearance:**
  - **Form:** Liquid
  - **Important information on protection of health and environment, and on safety.**
  - **Ignition temperature:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Solvent content:**
  - **Water:** 81.1 %
  - **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
  - **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 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:** Causes skin irritation.
- **on the eye:** Causes serious eye irritation.

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- **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.
- **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.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, IMDG, IATA</b>	not regulated
· <b>14.2 UN proper shipping name</b> · <b>DOT, ADR, IMDG, IATA</b>	not regulated
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	not regulated
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	not regulated
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### SECTION 15: Regulatory information

· <b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b> · <b>Sara</b>		
· <b>Section 355 (extremely hazardous substances):</b>		
7647-01-0	hydrochloric acid	
· <b>Section 313 (Specific toxic chemical listings):</b>		
7647-01-0	hydrochloric acid	
· <b>Proposition 65</b>		
· <b>Chemicals known to cause cancer:</b>		
None of the ingredients is listed.		
· <b>Chemicals known to cause reproductive toxicity for females:</b>		
None of the ingredients is listed.		
· <b>Chemicals known to cause reproductive toxicity for males:</b>		
None of the ingredients is listed.		
· <b>Chemicals known to cause developmental toxicity:</b>		
None of the ingredients is listed.		
· <b>Carcinogenic categories</b>		
· <b>EPA (Environmental Protection Agency)</b>		
10034-96-5	Manganesesulfate Monohydrate	D
· <b>TLV (Threshold Limit Value)</b>		
7647-01-0	hydrochloric acid	A4
· <b>MAK (German Maximum Workplace Concentration)</b>		
None of the ingredients is listed.		

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· **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.· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3· **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**

7647-01-0 hydrochloric acid

3

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

7647-01-0 hydrochloric acid

3

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**· **Relevant phrases**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing SDS:** Regulatory affairs· **Contact:** msds@gc.dental· **Date of previous version** 23.05.2024· **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

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety &amp; Health

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

**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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