

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

Printing date 03.08.2018

Version number 3

Revision: 26.04.2018

**SECTION 1: Identification**

- **1.1 Product identifier**
- **Trade name: GC Fuji IX GP Fast Powder**
- **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: Hazard(s) 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.

**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: Fire-fighting 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.
- **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.
- **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.

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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

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

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**  
**Form:** Powder

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<b>Color:</b>	According to product specification
· <b>Odor:</b>	Odorless
· <b>Odor threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Ignition temperature:</b>	Undetermined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>9.2 Other information</b>	No further relevant information available.

### 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.

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- **LD/LC50 values that are relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **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.
- **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.
- **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 (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 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

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated

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|---|-----------------|
| · 14.2 UN proper shipping name<br>· ADR, ADN, IMDG, IATA                          | not regulated   |
| · 14.3 Transport hazard class(es)<br>· ADR, ADN, IMDG, IATA<br>· Class            | not regulated   |
| · 14.4 Packing group<br>· ADR, IMDG, IATA   | not regulated   |
| · 14.5 Environmental hazards:<br>· Marine pollutant:                              | No              |
| · 14.6 Special precautions for user   | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of<br>MARPOL73/78 and the IBC Code | 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  
· 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 established by ACGIH)

1309-37-1 Iron(III)oxide

A4

- 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.

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- **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.

### 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)
    - ICAO: International Civil Aviation Organisation
    - 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
    - ACGIH: American Conference of Governmental Industrial Hygienists
    - 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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