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

Printing date 25.01.2024

Version number 4 (replaces version 3)

Revision: 25.01.2024

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

· 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: 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
- · Additional information:
- Safety data sheet available on request.
- · 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:

9003-01-4 Polyacrylic acid	<i>Eye Irrit. 2, H319</i> 5-<10	0%
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• 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: 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:

Generally the product does not irritate the skin.

If skin irritation continues, consult a doctor.

• 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, 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. Avoid formation of dust. 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. Do not allow to enter sewers/ surface or ground water.
6.3 Methods and material for containment and cleaning up: Pick up mechanically. Prevent formation of dust. Dispose of the collected material according to regulations.

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· 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 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: 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 pro	operties
9.1 Information on basic physical and chemical	
General Information on busic physical and chemical General Information	i properues
Physical state	Solid
Color:	According to product specification
Odor:	Odorless
Odor threshold:	Not determined.
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flammability (solid, gaseous):	Not determined.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto igniting:	Undetermined.
Decomposition temperature:	Not determined.
pH-value:	Not applicable.
Viscosity:	Not applicable.
Kinematic:	Not applicable.
Dynamic:	Not applicable.
Solubility in / Miscibility with	Not applicable.
Water:	Insoluble.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure:	Not applicable.
Density and/or relative density	Not applicable.
Density and of relative density Density:	Not determined.
Relative density	Not determined.
Vapor density	Not applicable.
Particle characteristics	Not applicable.
See section 3.	
9.2 Other information	
Appearance:	
Form:	Powder
I orm. Important information on protection of heal	
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Change in condition	2. Suner uses not present un explosion nuzuru.
Evaporation rate	Not applicable.
•	
Information with regard to physical hazard clas	
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

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Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammal	ble 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.

 \cdot on the skin: Based on available data, the classification criteria are not met.

 \cdot 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 (carcinogenity, 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.

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• 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.*

14.1 UN-Number ADR, ADN, IMDG, IATA	not regulated	
14.2 UN proper shipping name DOT, 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 Ann MARPOL73/78 and the IBC Code	nex II of Not applicable.	
UN "Model Regulation":	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)

1309-37-1 Iron(III)oxide

· 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

· Relevant phrases

- H319 Causes serious eye irritation.
- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- Date of previous version 25.01.2024
- Version number of previous version: 3
- 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 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

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

- 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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