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

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Version number 5 (replaces version 4)

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SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: GC Initial Powders · 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)16/40.26.84msds@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 The product is not classified, according to the GB CLP regulation.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Exemptions

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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.

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SECTION 3: Composition/information on ingredients

· 3.2 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: 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:
- *CO2, 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. 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.
- **6.3** Methods and material for containment and cleaning up: Pick up mechanically.

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Dispose of the material collected 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

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

- 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

• Appropriate engineering controls No further data; see item 7.

· Individual protection measures, such as 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:* Suitable respiratory protective device recommended.
- · Hand protection 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.

 \cdot 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/face protection** Safety glasses

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^{· 8.1} Control parameters

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9.1 Information on basic physical and chemical prop	perties
General Information	
Physical state	Solid
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling rang	ge 2,980 °C Not determined.
Flammability	Not determinea.
Lower and upper explosion limit Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
pH	Not applicable.
Viscosity:	uppnouoro.
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
9.2 Other information	
Appearance:	
Form:	Solid
Important information on protection of health ar	nd
environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Change in condition	
Evaporation rate	Not applicable.
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 gas in contact with water	es Void

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· 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 hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity
- · LD/LC50 values relevant for classification: No further relevant information available.
- · Additional toxicological information:
- · 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.
- 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 (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.

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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.

· Uncleaned packaging:

• *Recommendation: Disposal must be made according to official regulations.*

SECTION 14: Transport information	ion	
· 14.1 UN number or ID 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 Maritime transport in bulk according instruments	g to IMO 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

· 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:

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

IATA: International Air Transport Association

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 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 PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Sources ECHA (http://echa.europa.eu/) EnviChem (www.echemportal.org) * Data compared to the previous version altered. This version replaces all previous versions. Disclaimer: The information contained herein is believed to be true and accurate. However, all statements, recommendator or suggestions are made without any guarantee, representation or warranty, express or implied, on our performed to the and without any guarantee, representation or warranty, express or implied, on our performed to herein. All such risks are assumed by the purchaser/user. The information contained herein is accurate to be implied that the information set out in this document is accurate. complete, and we accordingly exclude all liability in connection with the use of this information or the procuration or performation contained herein is accurate.

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