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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_(blue,_grey,_pink,_neutral,_red,_yellow,_green))

• 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



• Signal word Warn	ing	
• Hazard statements		
H315 Causes skin	irritation.	
H319 Causes serio	us eye irritation.	
· Precautionary stat	tements	
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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≥10-<20%

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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:

10024-93-8 Neodymiumchloride Hydrate

Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335

• 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 eve.*

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: CO2, 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

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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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(Contd. of page 3) 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 · Physical state Fluid · Color: According to product specification · Odor: Characteristic Not determined. · Odor threshold: • Melting point/Melting range: Undetermined. 100 °C (7732-18-5 Water) • Boiling point/Boiling range: Not applicable. · Flammability (solid, gaseous): · Explosion limits: · Lower: Not determined. · Upper: Not determined. 279 °C (25322-68-3 Polyethylene Glycol) • Flash point: Undetermined. · Auto igniting: • Decomposition temperature: Not determined. · pH-value: Not determined. · Viscosity: Not determined. · Kinematic: Not determined. · Dvnamic: · Solubility in / Miscibility with Fully miscible. • Water: · Partition coefficient (n-octanol/water): Not determined. · Vapor pressure: Not determined. · Density and/or relative density · Density: Not determined. · Relative density Not determined. · Vapor density Not determined. (Contd. on page 5)

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9.2 Other information	
Appearance:	
Form:	Liquid
Important information on protection of hea	ulth and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Solvent content:	· ·
Water:	51.6 %
VOC (EC)	$0.0 \ g/l$
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard cla	isses
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 flammab	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.
- 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 (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 (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 informa	ition	
· 14.1 UN-Number · ADR, IMDG, IATA	not regulated	
14.2 UN proper shipping name DOT, ADR, 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:	Not applicable.	
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	

SECTION 15: Regulatory information

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

• Section 355 (extremely hazardous substances):

7647-01-0 hydrochloric acid

• Section 313 (Specific toxic chemical listings):

7647-01-0 hydrochloric acid

10034-96-5 Manganesesulfate Monohydrate

· 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)

10034-96-5 Manganesesulfate Monohydrate

• TLV (Threshold Limit Value)

7647-01-0 hydrochloric acid

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(Contd. of page 7) · 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. · 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

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

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- Date of previous version 23.05.2024

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 & Health

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

[•] Abbreviations and acronyms:

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(Contd. of page 8) Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 • 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, recommendations

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