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

Printing date 09.10.2023

Version number 3 (replaces version 2)

Revision: 09.10.2023

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

· 1.1 Product identifier

· Trade name: GC_Fuji_PLUS_CONDITIONER

• 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)16/40.26.84msds@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

Eye Dam. 1 H318 Causes serious eye damage.

· 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 Danger

• Hazard-dete	rmining components of labeling:
Ironchloride	Hexahydrate
• Hazard state	ements
H318 Cause	s serious eye damage.
· Precautiona	ry statements
P280	Wear 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.
P310	Immediately call a poison center/doctor.
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· 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:		
5949-29-1	citric acid mono hydrate	10-<25%
	<i>Eye Irrit. 2, H319</i>	
10025-77-1	Ironchloride Hexahydrate	≥3-<5%
	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:* Seek medical treatment. If skin irritation continues, consult a doctor.
- *After eye contact: Protect unharmed eye. Rinse opened eye for several minutes under running water.*
- Call a doctor immediately.
- · 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

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• 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.

· 6.1 Personal precautions, protective equipment and emergency procedures

• Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

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. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil. In case of seepage into the ground inform responsible authorities.
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: No special measures required.

- 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.

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9.2 E	(Contd. or	i page
8.2 Exposure controls		
	hnical systems: No further data; see section 7.	
Personal protective equipment:		
General protective and hygienic measures:		
The usual precautionary measures for handle	ing chemicais should be jollowed.	
Avoid contact with the eyes and skin.	work	
Wash hands before breaks and at the end of Keep away from foodstuffs, beverages and fe		
Immediately remove all soiled and contamin		
Breathing equipment: Suitable respiratory		
Protection of hands:		
Protective gloves		
Material of gloves		
	only depend on the material, but also on further marks of qual	'itv ar
	As the product is a preparation of several substances, the resist	
	idvance and has therefore to be checked prior to the application	
Penetration time of glove material	5 1 11	
	und out by the manufacturer of the protective gloves and ha	s to l
observed.		
Eye protection:		
Tightly sealed goggles		
Tightly sealed goggles		
Tightly sealed goggles SECTION 9: Physical and chemical	l properties	
SECTION 9: Physical and chemical 9.1 Information on basic physical and chem	• •	
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Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	1.1 g/cm^3
Relative density	Not determined.
Vapor density	Not determined.
9.2 Other information	
Appearance:	
Form:	Liquid
Important information on protection of heat	lth and
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Solvent content:	
Water:	87.0 %
VOC (EC)	0.0 g/l
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard cla	sses
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	le 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.

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• 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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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: Based on available data, the classification criteria are not met.
- on the eye: Causes serious eye damage.
- 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 3 (Self-assessment): extremely hazardous for water*

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

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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.

· European waste catalogue

18 00 00 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)

18 01 00 wastes from natal care, diagnosis, treatment or prevention of disease in humans

18 01 06* chemicals consisting of or containing hazardous substances

· Uncleaned packagings:

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

• *Recommended cleansing agent: Water, if necessary with cleansing agents.*

SECTION 14: Transport information

· 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 Annex II of 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.

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· 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)

None of the ingredients is listed.

· 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

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.

• 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. H319 Causes serious eye irritation.

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Classification according to Regulation (EC) No 1272/2008 Calculation method	(Contd. of page 8
Department issuing SDS: Regulatory affairs	
Contact: msds@gc.dental	
Date of previous version 09.10.2023	
Version number of previous version: 2	
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 & 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	
<i>Eye Irrit. 2: Serious eye damage/eye irritation – Category 2</i> 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 statem	nents, recommendation
or suggestions are made without any guarantee, representation or warranty, express o	or implied, on our par
Therefore, no warranty is made or to be implied that the information set out in this de	
complete, and we accordingly exclude all liability in connection with the use of this infor	
referred to herein. All such risks are assumed by the purchaser/user. The information c	
subject to change without notice. For the avoidance of doubt, however, nothing in this	
subject to change without notice. For the avoidance of doubt, nowever, nothing in this	accument excludes o

limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.