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

Printing date 06.07.2023

Version number 3 (replaces version 2)

Revision: 06.07.2023

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

- · 1.1 Product identifier
- · Trade name: GC Initial LRF Diluting Liquid
- 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
- · 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: 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, 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.

• 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 No special precautions are necessary if used correctly.

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· Information about protection against explosions and fires: No special measures required.

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· 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. Wash hands before breaks and at the end of work.
- 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: Safety glasses

SECTION 9: Physical and chemical properties

· General Information		
· Physical state	Fluid	
· Color:	According to product specification	
· Odor:	Characteristic	
· Odor threshold:	Not determined.	
• Melting point/Melting range:	Undetermined.	
· Boiling point/Boiling range:	Undetermined.	
· Flammability (solid, gaseous):	Not applicable.	
• Explosion limits:		
· Lower:	2.6 Vol %	
· Upper:	12.6 Vol %	
· Flash point:	Not applicable.	
· Auto igniting:	Undetermined.	
· Decomposition temperature:	Not determined.	

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· pH-value:	Not determined.
· Viscosity:	
· Kinematic:	Not determined.
· Dynamic:	Not determined.
Solubility in / Miscibility with	
· Water:	Fully miscible.
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.
9.2 Other information	
· Appearance:	
Form:	Fluid
Important information on protection of hea	lth and
environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	<i>99.9 %</i>
· Water:	0.1 %
· VOC (EC)	1,000.0 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.

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- · 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: 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.
- · 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.

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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. Contact waste processors for recycling information.

· European waste catalogue

	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 07 chemicals other than those mentioned in 18 01 06

· 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	
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• 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	
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· 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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Trade name: GC Initial LRF Diluting Liquid

· 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)

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.

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.

 \cdot 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

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

· Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

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(Contd. of page 7) • 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 · 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 or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.