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

Printing date 22.11.2022

Version number 3 (replaces version 2)

Revision: 22.11.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: GC Fuji LINING LC 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 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 Skin Corr. 1 H314 Causes severe skin burns and eye damage. Eye Dam. 1 H318 Causes serious eye damage. Skin Sens. 1 H317 May cause an allergic skin reaction. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the GB 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 GHS05 GHS07 · Signal word Danger

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· Hazard-determini	ng components of labelling:
2-hydroxyethyl me	
Tartaric acid	•
Urethane Dimetha	crylate (UDMA)
· Hazard statements	
H314 Causes sever	re skin burns and eye damage.
H317 May cause a	n allergic skin reaction.
H412 Harmful to a	equatic life with long lasting effects.
· Precautionary stat	tements
P260	Do not breathe dusts or mists.
P280	Wear protective gloves / eye protection / face protection.
P303+P361+P353	B IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water
	[or shower].
P305+P351+P338	3 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.
P321	Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
· 2.3 Other hazards	
· Results of PBT an	d vPvB assessment
· PBT: Not applicat	ole.
• vPvB: Not applica	ble.

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.

CAS: 868-77-9	2-hydroxyethyl metacrylate	25-<50%
EINECS: 212-782-2 Index number: 607-124-00-X	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 9003-01-4	Polyacrylic acid	10-<25%
	<i>Eye Irrit. 2, H319</i>	
CAS: 87-69-4	Tartaric acid	5-<10%
EINECS: 201-766-0	Eye Dam. 1, H318	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	5-<10%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	5-<10%
EINECS: 276-957-5	Aquatic Chronic 2, H411; Skin Sens. 1B, H317	
CAS: 128-37-0	Butylated hydroxytoluene	≥0.25-<0.5%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1

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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. 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 Allergic reactions

- 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.
- 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 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: Use neutralising agent. Absorb liquid components with liquid-binding material. Dispose of the material collected according to regulations.

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· 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 fire - and explosion protection: 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 container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· 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.

· DNELs

128-37-0 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m3 (man)

• *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.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

- · 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.

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· 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



Tightly sealed goggles

SECTION 9: Physical and chemical properties

General Information	Eluid
Physical state	Fluid Light wellow
Colour:	Light yellow
Odour:	Odourless
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling rang	
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	97 °C
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
рН at 20 °С	1.9
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Liquid
I orm. Important information on protection of health an	
environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	i rouner uoes not present un exprosion nuzuru.
Water:	25.0 %
VOC (EC)	0.0 g/l
Change in condition	0.0 5/1
Evaporation rate	Not determined.
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Information with regard to physical hazard clo	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 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 hazard classes as defined in Regulation (EC) No 1272/2008

• Acute toxicity

· LD/LC50 values relevant for classification:

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 >5,000 mg/kg (rat female) (*OECD* 401)

128-37-0 Butylated hydroxytoluene

Oral LD50 >6,000 mg/kg (rat (f+m)) (OECD 401)

· Skin corrosion/irritation Causes severe skin burns and eye damage.

• Serious eye damage/irritation Causes serious eye damage.

• Respiratory or skin sensitisation May cause an allergic skin reaction.

· Additional toxicological information:

· Repeated dose toxicity No further relevant information available.

• *CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)* No further relevant information available.

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List II

Trade name: GC_Fuji_LINING_LC_Liquid

· 11.2 Information on other hazards

· Endocrine disrupting properties

128-37-0 Butylated hydroxytoluene

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

- · 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 For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects
- Remark: Harmful to fish
- 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. Must not reach sewage water or drainage ditch undiluted or unneutralised.

Harmful to aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

• 14.1 UN number or ID number

· ADR, ADN, IMDG, IATA

• 14.2 UN proper shipping name • ADR, ADN, IMDG, IATA not regulated

not regulated

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· 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 to IMO instruments 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

· Relevant phrases

H315 Causes skin irritation.

- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- *H411 Toxic to aquatic life with long lasting effects.*
- · 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

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)
- DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent
- LC50: Lethal concentration, 50 LD50: Lethal dose, 50 percent
- *PBT: Persistent, Bioaccumulative and Toxic*
- vPvB: very Persistent and very Bioaccumulative
- Skin Corr. 1: Skin corrosion/irritation Category 1

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Skin Irrit. 2: Skin corrosion/irritation – Category 2	
Eye Dam. 1: Serious eye damage/eye irritation – Category 1	
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2	
Skin Sens. 1: Skin sensitisation – Category 1	
Skin Sens. 1B: Skin sensitisation – Category 1B	
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3	
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1	
Aquatic Chronic 1: Induradus to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2	
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – 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.	
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