

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: GC Fuji LINING LC Paste Pak Paste A
- 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
- Details of the supplier of the safety data sheet

Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · 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



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

2-hydroxyethyl metacrylate

Urethane Dimethacrylate (UDMA)

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

(Contd. on page 2)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 1)

Contaminated work clothing should not be allowed out of the workplace.

Avoid release to the environment.

Wear protective gloves / eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/Information on ingredients

- · Chemical characterisation: 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 compone	ents:	
	2-hydroxyethyl metacrylate	10-<25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
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	
	Urethane Dimethacrylate (UDMA)	5-<10%
EINECS: 276-957-5	Aquatic Chronic 2, H411; Skin Sens. 1, H317	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
EINECS: 217-533-1	Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 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. Then consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

(Contd. on page 3)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 2)

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed Allergic reactions
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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.

- · 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.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid contact with the eyes and skin.

Wear protective clothing.

· 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.

· Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· 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.

7 Handling and storage

- · Handling:
- 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.
- · 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.

(Contd. on page 4)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 3)

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 mg/m3 (man)

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · 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.
- 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.

· Eve protection:



Tightly sealed goggles

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty
Colour: Yellow

(Contd. on page 5)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

		(Contd. of page
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	: Undetermined.	
Flash point:	97 °C	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
VOC (EC)	$0.0 \ g/l$	
Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 5)

11 Toxicological information

- Information on toxicological effects
- · Acute toxicity

· LD/LC5	0 valu	es relevant for classification:
72869-8	86-4 Ur	ethane Dimethacrylate (UDMA)
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
1879-09	0-0 6-te	rt-butyl-2,4-xylenol
Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)

- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eve damage/irritation Irritating effect.
- · Respiratory or skin sensitisation Sensitisation possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Irritant

- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

72869-86-4 Urethane Dimethacrylate (UDMA)

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

- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (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.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

(Contd. on page 7)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 6)

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

TINI NI I		
UN-Number NZS, ADN, IMDG, IATA	not regulated	
NZS, ADN, IMDO, IATA	noi reguiatea	
UN proper shipping name		
NZS, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
NZS, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
NZS, IMDG, IATA	not regulated	
Environmental hazards:		
Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex L	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · New Zealand Inventory of Chemicals

All ingredients are listed.

· HSNO Approval numbers

1879-09-0 6-tert-butyl-2,4-xylenol

HSR003625

- GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

2-hydroxyethyl metacrylate

Urethane Dimethacrylate (UDMA)

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

(Contd. on page 8)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 7)

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Avoid release to the environment.

Wear protective gloves / eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Relevant phrases

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

· 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

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 (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 2: Acute toxicity - Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – 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.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations
(Contd. on page 9)

Printing date 15.12.2022 Version number 3 Revision: 15.12.2022

Trade name: GC_Fuji_LINING_LC_Paste_Pak_Paste_A

(Contd. of page 8)

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.

- NZ