



Revision: 19.02.2024 Printing date 19.02.2024 Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
- · Trade name: SOFT-LINER 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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

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 statements

H225 Highly flammable liquid and vapour.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

(Contd. on page 2)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER_Liquid

(Contd. of page 1)

P233 Keep container tightly closed.

P280 Wear protective gloves / eye protection / face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water

[or shower].

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT**: Not applicable. · **vPvB**: Not applicable.

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.

· Dangerous components:			
	ethyl alcohol	Flam. Liq. 2, H225	10-<25%
EINECS: 200-578-6		substance with a Community workplace exposure limit	
Index number: 603-002-00-5			

[·] 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: 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: If skin irritation continues, consult a doctor.
- · 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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

· For safety reasons unsuitable extinguishing agents: Water with full jet

(Contd. on page 3)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER_Liquid

(Contd. of page 2)

· 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.

Keep away from ignition sources.

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:

Ensure adequate ventilation.

Absorb liquid components with liquid-binding material.

Dispose of the material collected 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.
- · Information about fire and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:

Store in a cool location.

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.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

Store in a cool place.

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

GB ·

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER Liquid

(Contd. of page 3)

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethyl alcohol

WEL Long-term value: 1920 mg/m³, 1000 ppm

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 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.

Wash hands before breaks and at the end of work.

- · 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.

· 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

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Physical state Fluid · Colour: Fluid

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling range 78 °C (64-17-5 ethyl alcohol)

Flammability Highly flammable.

· Lower and upper explosion limit

Lower: 3.5 Vol % (64-17-5 ethyl alcohol)
 Upper: 15 Vol % (64-17-5 ethyl alcohol)
 Flash point: 13 °C (64-17-5 ethyl alcohol)

· Auto-ignition temperature:
 · Decomposition temperature:
 · pH

Undetermined.

Not determined.

Not determined.

· Viscosity:

Kinematic viscosityDynamic:Not determined.Not determined.

(Contd. on page 5)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER_Liquid

	(Contd. of pag
Solubility	
water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	$0.9 \ g/cm^3$
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Liquid
Important information on protection of health a	
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	-
Organic solvents:	15.0 %
VOC (EC)	135.0 g/l
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classes	
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Highly flammable liquid and vapour.
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 ga	ses
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.

(Contd. on page 6)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER_Liquid

(Contd. of page 5)

· 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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

64-17-5 ethyl alcohol

 Oral
 LD50
 7,060 mg/kg (rat (f+m))

 Inhalative
 LC50/4 h
 20,000 mg/l (rat (f+m))

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation 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.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-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:
- · 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 (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.

– GE

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER_Liquid

(Contd. of page 6)

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.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14.1 UN number or ID number ADR, IMDG, IATA	UN1170
14.2 UN proper shipping name ADR IMDG, IATA	1170 ETHANOL SOLUTION mixture ETHANOL SOLUTION mixture
14.3 Transport hazard class(es)	
ADR	
Class Label	3 (F1) Flammable liquids. 3
IMDG, IATA	
Class Label	3 Flammable liquids. 3
14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards: Marine pollutant:	No
<u> </u>	
14.6 Special precautions for user Hazard identification number (Kemler code):	Warning: Flammable liquids. 33
EMS Number:	F-E,S-D
Stowage Category	A 2,0 2

(Contd. on page 8)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER Liquid

	(Contd. of page
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1170 ETHANOL SOLUTION MIXTURE, 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Poisons Act
- · Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H225 Highly flammable liquid and vapour.

- · 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

(Contd. on page 9)

Printing date 19.02.2024 Version number 4 (replaces version 3) Revision: 19.02.2024

Trade name: SOFT-LINER Liquid

(Contd. of page 8)

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

Flam. Liq. 2: Flammable liquids – Category 2

· 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.

GB