

Revision: 24.01.2024



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

Printing date 24.01.2024

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
- · Trade name: GC TISSUE CONDITIONER 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)16/40.26.84

msds@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.

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



- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

H412 Harmful to aquatic life with long lasting effects.

(Contd. on page 2)

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC_TISSUE_CONDITIONER_Liquid

(Contd. of page 1)

· Precautionary statements

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

smoking.

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:			
CAS: 64-17-5	ethyl alcohol	10-<25%	
EINECS: 200-578-6 Index number: 603-002-00-5	Flam. Liq. 2, H225 substance with a Community workplace exposure limit		
CAS: 3290-92-4 EINECS: 221-950-4	Propylidynetrimethyl trimethacrylate Aquatic Chronic 2, H411	2.5-<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.

GB

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC TISSUE CONDITIONER Liquid

(Contd. of page 2)

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.

Keep away from ignition sources.

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:

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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· 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.

(Contd. on page 4)

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC TISSUE CONDITIONER Liquid

(Contd. of page 3)

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.

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

· PNECs

3290-92-4 Propylidynetrimethyl trimethacrylate

PNEC Aqua 2.76 μg/L (freshwater)

20 μg/L (intermittent releases)

0.276 μg/L (marine water)

PNEC STP 10 mg/L (Sewage Treatment Plants)

PNEC Sediment 0.4951 mg/kg sed dw (freshwater)

0.04951 mg/kg sed dw (marine water)

PNEC Air mg/L (air)

PNEC Soil 0.0974 mg/kg soil dw (soil)

PNEC Predator mg/kg (Predator)

- · 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

GB

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC_TISSUE_CONDITIONER_Liquid

(Contd. of page 4)

SECTION 9: Physical and chemical proper	rties
9.1 Information on basic physical and chemical pro	perties
General Information	•
Physical state	Fluid
Colour:	Clear
Odour:	Ester-like
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling ran	ge Undetermined.
Flammability	Highly flammable.
Lower and upper explosion limit	
Lower:	3.5 Vol %
Upper:	15 Vol %
Flash point:	13 °C
Auto-ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
pH	Not determined.
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	Tiol determined.
water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
•	1101 determined.
9.2 Other information	
Appearance:	T
Form:	Liquid
Important information on protection of health a	nd
environment, and on safety.	5 1
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	1.00/
Organic solvents:	15.0 %
VOC (EC)	$150.0 \mathrm{g/l}$
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 Void
Pyrophoric liquids	Void
Pyrophoric aquas Pyrophoric solids	voia Void
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(Contd. on page 6)

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC_TISSUE_CONDITIONER_Liquid

		(Contd. of page 5)
· Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit flammal	ole 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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:				
64-17-5 et	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 eve 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

128-37-0 Butylated hydroxytoluene

List II

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC TISSUE CONDITIONER Liquid

(Contd. of page 6)

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

3290-92-4 Propylidynetrimethyl trimethacrylate

LC50/96h (dynamic) > 1 mg/L (Oncorhynchus mykiss) (OECD Guideline 203 (Fish, Acute Toxicity Test))

- · 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 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Harmful to aquatic organisms

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.

UN1170

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- · 14.1 UN number or ID number
- · ADR, IMDG, IATA

· 14.2 UN proper shipping name

1170 ETHANOL SOLUTION · IMDG, IATA ETHANOL SOLUTION

- · 14.3 Transport hazard class(es)
- $\cdot ADR$



3 (F1) Flammable liquids. · Class

(Contd. on page 8)

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC_TISSUE_CONDITIONER_Liquid

	(Contd. of pa	
Label	3	
IMDG, IATA		
Class	3 Flammable liquids.	
Label	3	
14.4 Packing group		
ADR, IMDG, IATA	II	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Warning: Flammable liquids.	
Hazard identification number (Kemler code):	33 E E C D	
EMS Number: Stowage Category	F-E,S-D A	
14.7 Maritime transport in bulk according to IM		
instruments	Not applicable.	
Transport/Additional information:		
ADR		
Limited quantities (LQ)	1L	
Excepted quantities (EQ)	Code: E2	
	Maximum net quantity per inner packaging: 30 ml	
Towns and and an arm	Maximum net quantity per outer packaging: 500 ml	
Transport category Tunnel restriction code	D/E	
	<i>DIE</i>	
IMDG	IL	
Limited quantities (LQ) Excepted quantities (EQ)	1L Code: E2	
Excepted quantities (LQ)	Maximum net quantity per inner packaging: 30 ml	
	Maximum net quantity per outer packaging: 500 ml	
UN "Model Regulation":	UN 1170 ETHANOL SOLUTION, 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.

(Contd. on page 9)

Printing date 24.01.2024 Version number 4 (replaces version 3) Revision: 24.01.2024

Trade name: GC TISSUE CONDITIONER Liquid

(Contd. of page 8)

· 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.

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)

PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

 $Flam.\ Liq.\ 2: Flammable\ liquids-Category\ 2$

 $\label{lem:aquatic Chronic 2: Hazardous to the aquatic environment - long-term\ aquatic\ hazard-Category\ 2$

 $\label{lem:aquatic chronic 3: Hazardous to the aquatic environment - long-term\ aquatic\ hazard-Category\ 3$

- · 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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