

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

Printing date 24.01.2024

Version number 3 (replaces version 2)

Revision: 24.01.2024

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

- **1.1 Product identifier**
- **Trade name:** GC TISSUE CONDITIONER Coating
- **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

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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.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **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**



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**
ethyl acetate

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Hazard statements

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements

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

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].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

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

Additional information:

20 % of the mixture consists of component(s) of unknown toxicity.

Contains 20 % of components with unknown hazards to the aquatic environment.

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: 141-78-6	ethyl acetate	75-<90%
EINECS: 205-500-4	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	
Index number: 607-022-00-5	substance with a Community workplace exposure limit	

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:

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: 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.

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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, 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.*
 - 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:**
 - 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.*
 - Avoid contact with the eyes and skin.*
- **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.*

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- **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.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

141-78-6 ethyl acetate

WEL	Short-term value: 1468 mg/m ³ , 400 ppm
	Long-term value: 734 mg/m ³ , 200 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.

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.

- **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.

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- 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:

Transparent

· Odour:

Ester-like

· Odour threshold:

Not determined.

· Melting point/freezing point:

Undetermined.

· Boiling point or initial boiling point and boiling range

77 °C

· Flammability

Highly flammable.

· Lower and upper explosion limit

2.1 Vol %

· Lower:

11.5 Vol %

· Upper:

-1 °C

· Flash point:

Undetermined.

· Auto-ignition temperature:

Not determined.

· Decomposition temperature:

Not determined.

· pH

Not determined.

· Viscosity:

Not determined.

· Kinematic viscosity

Not determined.

· Dynamic:

Not determined.

· Solubility

Not determined.

· water:

Insoluble.

· 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.

· 9.2 Other information

· Appearance:

Liquid

· Form:

Liquid

· Important information on protection of health and environment, and on safety.

Product is not selfigniting.

Product does not present an explosion hazard.

· Ignition temperature:

Not determined.

· Explosive properties:

Not determined.

· Solvent content:

Not determined.

· Organic solvents:

80.0 %

· VOC (EC)

800.0 g/l

· Change in condition

Not determined.

· Evaporation rate

Not determined.

· Information with regard to physical hazard classes

Void

· Explosives

Void

· Flammable gases

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· 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 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.

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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:**

141-78-6 ethyl acetate

Oral	LD50	4,935 mg/kg (rabbit)
Inhalative	LC50/4 h	1,600 mg/l (rat (f+m))

- **Serious eye damage/irritation** Causes serious eye irritation.

- **STOT-single exposure** May cause drowsiness or dizziness.

- **Additional toxicological information:**

- **Repeated dose toxicity** No further relevant information available.

- **CMR effects (carcinogenicity, 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.

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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.

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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, IMDG, IATA	UN1173
· 14.2 UN proper shipping name	
· ADR	1173 ETHYL ACETATE mixture
· IMDG, IATA	ETHYL ACETATE mixture
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	3 (F1) Flammable liquids.
· Label	3

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· 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
· EMS Number:	F-E,S-D
· Stowage Category	B

· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
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· Transport/Additional information:

· ADR	
· 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

· 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 1173 ETHYL ACETATE MIXTURE, 3, II
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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.

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· 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.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

· 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)

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

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

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

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Revision: 24.01.2024

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**



GHS02

- **Signal word** Danger
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H412 Harmful to aquatic life with long lasting effects.

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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.

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

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: 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.

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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.

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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.

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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.

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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.

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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/m ³ , 1000 ppm
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· **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

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· 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 range	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	
· water:	Fully miscible.
· 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
· Important information on protection of health and 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)	150.0 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

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· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable 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 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 (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

128-37-0	Butylated hydroxytoluene
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List II

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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.

- **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**

UN1170

- **14.2 UN proper shipping name**

- **ADR**

1170 ETHANOL SOLUTION

- **IMDG, IATA**

ETHANOL SOLUTION

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class**

3 (F+) Flammable liquids.

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· 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
· EMS Number:	F-E,S-D
· Stowage Category	A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	
· 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
· 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, 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.

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· 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

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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according to 1907/2006/EC, Article 31

Printing date 03.08.2018

Version number 3

Revision: 21.06.2017

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

· 1.1 Product identifier

· Trade name: GC Tissue Conditioner, Powder

· 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

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

The product is not classified, according to the CLP regulation.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

· 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.

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SECTION 3: Composition/information on ingredients

· 3.2 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 components: Void

· 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:

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, 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

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

· 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:

Pick up mechanically.

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

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

· Information about fire - and explosion protection: Dust can combine with air to form an explosive mixture.

· 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

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

· 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.

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

· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Do not inhale dust / smoke / mist.

Wash hands before breaks and at the end of work.

· 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.

· Eye protection: Safety glasses

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	<i>Solid</i>
Colour:	<i>According to product specification</i>
· Odour:	<i>Odourless</i>
· Odour threshold:	<i>Not determined.</i>
· pH-value:	<i>Not applicable.</i>
· Change in condition	
Melting point/freezing point:	<i>Undetermined.</i>
Initial boiling point and boiling range:	<i>Undetermined.</i>
· Flash point:	<i>Not applicable.</i>
· Flammability (solid, gas):	<i>Not determined.</i>
· Ignition temperature:	<i>Undetermined.</i>
· Decomposition temperature:	<i>Not determined.</i>
· Auto-ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapour pressure:	<i>Not applicable.</i>
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with water:	<i>Insoluble.</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Organic solvents:	<i>0.0 %</i>
· 9.2 Other information	<i>No further relevant information available.</i>

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.*

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- **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 relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **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.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **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.

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

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.
Contact waste processors for recycling information.

· **European waste catalogue**

18 00 00	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

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18 01 07 | chemicals other than those mentioned in 18 01 06

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

SECTION 14: Transport information

· 14.1 UN-Number	
· ADR, ADN, IMDG, IATA	not regulated
· 14.2 UN proper shipping name	
· ADR, ADN, IMDG, IATA	not regulated
· 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 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

- **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

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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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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