

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

Printing date 03.08.2018



Version number 4

Revision: 21.06.2017

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

- **1.1 Product identifier**
- **Trade name: GC MI Varnish**
- **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.
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Acute Tox. 4 H302 Harmful if swallowed.
- **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.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Sodium fluoride
- **Hazard statements**
H225 Highly flammable liquid and vapour.

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*H302 Harmful if swallowed.***· 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.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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.

· Additional information:

EUH031 Contact with acids liberates toxic gas.

2 % of the mixture consists of component(s) of unknown toxicity.

Contains 2 % 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 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:

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	ethyl alcohol Flam. Liq. 2, H225	25-<50%
CAS: 7681-49-4 EINECS: 231-667-8 Index number: 009-004-00-7	Sodium fluoride Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319	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:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

If symptoms persist consult doctor.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Do not use mouth to mouth or mouth to nose resuscitation.

Take affected persons into fresh air and keep quiet.

· After skin contact:

Generally the product does not irritate the skin.

Immediately wash with water and soap and rinse thoroughly.

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*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:***Do not induce vomiting; call for medical help immediately.**Rinse out mouth and then drink plenty of water.**Call for a doctor immediately.***· 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions****· 4.3 Indication of any immediate medical attention and special treatment needed***No further relevant information available.***SECTION 5: Firefighting measures****· 5.1 Extinguishing media***· Suitable extinguishing agents: CO₂, sand, extinguishing powder. Do not use water.**· For safety reasons unsuitable extinguishing agents: Water***· 5.2 Special hazards arising from the substance or mixture***Formation of toxic gases is possible during heating or in case of fire.***· 5.3 Advice for firefighters****· Protective equipment:***Mouth respiratory protective device.**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 equipment. Keep unprotected persons away.**Mount respiratory protective device.**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.**Prevent seepage into sewage system, workpits and cellars.**Do not allow to enter sewers/ surface or ground water.***· 6.3 Methods and material for containment and cleaning up:***Ensure adequate ventilation.**Allow to evaporate.**Absorb liquid components with liquid-binding material.**Dispose of the material collected according to regulations.**Dispose contaminated material as waste according to item 13.***· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.*

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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.
- **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:**
Do not store together with acids.
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

- **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:**

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**
- **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.

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· Protection of hands:

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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:

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties**· General Information****· Appearance:**

Form:	Pasty
Colour:	White
· Odour:	Product specific
· Odour threshold:	Not determined.

· pH-value at 20 °C:	6.6
	Not determined.

· Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	78 °C
	Undetermined.

· Flash point:	13 °C
	Not applicable.

· Flammability (solid, gas):	Not applicable.
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· Ignition temperature:	Undetermined.
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· Decomposition temperature:	Not determined.
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· Auto-ignition temperature:	Product is not selfigniting.
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· Explosive properties:	Product does not present an explosion hazard.
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· Explosion limits:	
Lower:	3.5 Vol % Not determined.
Upper:	15 Vol % Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.1 g/cm ³ 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 at 20 °C:	5 mPas Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	35.6 %
VOC (EC)	391.6 g/l
· 9.2 Other information	No further relevant information available.

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 toxicological effects**

· **Acute toxicity**
Harmful if swallowed.

- **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))

- **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.

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

SECTION 14: Transport information

- | | |
|---------------------------------------|--|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | UN1993 |
| · 14.2 UN proper shipping name | |
| · ADR | 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION), special provision 640D |
| · IMDG, IATA | FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION) |

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· 14.3 Transport hazard class(es)

· ADR



· Class 3 (F1) Flammable liquids.
· 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.
· Danger code (Kemler): 33
· EMS Number: F-E, S-E
· Stowage Category B

· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ETHANOL SOLUTION), 3, II

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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.
H301 Toxic if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **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)
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
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – 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.

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