

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

Printing date 22.08.2023

Version number 6 (replaces version 5)

Revision: 22.08.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** 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**

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**

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:**

Sodium fluoride

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· Hazard statements*H225 Highly flammable liquid and vapour.**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:***EUH032 Contact with acids liberates very 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 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 | 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, EUH032 | 5-<10% |
| CAS: 68611-44-9 EINECS: 271-893-4 | Silane, dichlorodimethyl-, reaction products with silica Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms | 1-<2.5% |
| CAS: 7631-86-9 EINECS: 231-545-4 | silicon dioxide Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, non-surface-treated nanoforms | 0.2-<0.5% |

· 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:**
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.
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:**
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** 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:**
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.
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.

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- 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 section 13.
 - **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:**
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

- **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 |

- **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.

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Keep away from foodstuffs, beverages and feed.

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Hand protection**

Protective gloves

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

· **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:**

White

· **Odour:**

Product specific

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

78 °C

· **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 at 20 °C**

6.6

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic at 20 °C:**

5 mPas

· **Solubility**

· **water:**

Insoluble.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**

· **Density at 20 °C:**

1.1 g/cm³

· **Relative density**

Not determined.

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| | |
|--|---|
| <ul style="list-style-type: none"> · Vapour density · Particle characteristics | <p>Not determined.</p> <p>SiO₂: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based)</p> <p>Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d50, volume based)</p> <p>68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms</p> <p>7631-86-9 silicon dioxide: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, non-surface-treated nanoforms</p> |
|--|---|

| | |
|---|---|
| <ul style="list-style-type: none"> · 9.2 Other information · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Ignition temperature: · Explosive properties: · Solvent content: · Organic solvents: · VOC (EC) · Change in condition · Evaporation rate | <p>Pasty</p> <p>Product is not selfigniting.</p> <p>Product does not present an explosion hazard.</p> <p>36.0 %</p> <p>396.0 g/l</p> <p>Not determined.</p> |
|---|---|

| | |
|--|--|
| <ul style="list-style-type: none"> · Information with regard to physical hazard classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals · Desensitised explosives | <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Highly flammable liquid and vapour.</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> |
|--|--|

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.

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- **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** 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)) |
|------------|----------|-------------------------|

7631-86-9 silicon dioxide

| | | |
|------|------|--------------------------|
| Oral | LD50 | 10,000 mg/kg (rat (f+m)) |
|------|------|--------------------------|

- **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.

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.

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.

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- **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**

UN1170

- **14.2 UN proper shipping name**
- **ADR**
- **IMDG, IATA**

1170 ETHANOL SOLUTION
ETHANOL SOLUTION

- **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

- **14.6 Special precautions for user**
- **Hazard identification number (Kemler code):**
- **EMS Number:**
- **Stowage Category**

Warning: Flammable liquids.
33
F-E,S-D
A

- **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

- **Transport/Additional information:**

- **ADR**
- **Limited quantities (LQ)**
- **Excepted quantities (EQ)**
- **Transport category**
- **Tunnel restriction code**

1L
Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
2
D/E

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- | | |
|-----------------------------------|--|
| · IMDG | |
| · 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 |
| · 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**
- **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.
 - H301 Toxic if swallowed.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - EUH032 Contact with acids liberates very toxic gas.
- **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
 - 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)

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*** Data compared to the previous version altered.***This version replaces all previous versions.***Disclaimer:**

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