

**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

Nanoform

**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** Auxiliary 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

· **Information department:** Regulatory affairs· **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)**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 labeled according to the 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 labeling:**

Sodium fluoride

**Hazard statements**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

**Precautionary statements**

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

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- P280 *Wear protective gloves/protective clothing/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/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 Chemical characterization: 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:**

64-17-5	ethyl alcohol Flam. Liq. 2, H225	25-<50%
7681-49-4	Sodium fluoride Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	5-<10%
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	1-<2.5%
7631-86-9	silicon dioxide	0.2-<0.5%

- **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:**
  - 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; immediately call for medical help.*

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*Rinse out mouth and then drink plenty of water.**Immediately call a 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:** *CO<sub>2</sub>, 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.**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 collected material 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.*

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- **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.  
Do not spray on 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 receptacle 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**
- **Components 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 that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Additional information about design of technical systems:** No further data; see section 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** Suitable respiratory protective device recommended.
- **Protection of hands:**  
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.

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· Eye protection:



Tightly sealed goggles

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

· Physical state	Fluid
· Color:	White
· Odor:	Product specific
· Odor threshold:	Not determined.
· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	78 °C
· Flammability (solid, gaseous):	Highly flammable.
· Explosion limits:	
· Lower:	3.5 Vol %
· Upper:	15 Vol %
· Flash point:	13 °C
· Auto igniting:	Undetermined.
· Decomposition temperature:	Not determined.
· pH-value at 20 °C:	6.6
· Viscosity:	
· Kinematic:	Not determined.
· Dynamic at 20 °C:	5 mPas
· Solubility in / Miscibility with	
· Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Vapor pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.1 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapor density	Not determined.
· Particle characteristics	SiO <sub>2</sub> : Diameter particle structure = 2.5 - 50 nm (TEM, d <sub>50</sub> , number-based) Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d <sub>50</sub> , volume based) 68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms 7631-86-9 silicon dioxide: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, non-surface-treated nanoforms

#### · 9.2 Other information

· Appearance:

· Form:

Pasty

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

- |                                |   |
|--------------------------------|---|
| · <b>Ignition temperature:</b> | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>  | Product does not present an explosion hazard. |
| · <b>Solvent content:</b>      |   |
| · <b>Organic solvents:</b>     | 36.0 %  |
| · <b>VOC (EC)</b>              | 396.0 g/l                                     |
| · <b>Change in condition</b>   |   |
| · <b>Evaporation rate</b>      | Not determined.                               |

**· Information with regard to physical hazard classes**

- |  |                                     |
|--|-------------------------------------|
| · <b>Explosives</b>  | Void                                |
| · <b>Flammable gases</b>   | Void                                |
| · <b>Aerosols</b>  | Void                                |
| · <b>Oxidising gases</b>   | Void                                |
| · <b>Gases under pressure</b>  | Void                                |
| · <b>Flammable liquids</b>   | Highly flammable liquid and vapour. |
| · <b>Flammable solids</b>  | Void                                |
| · <b>Self-reactive substances and mixtures</b>                                     | Void                                |
| · <b>Pyrophoric liquids</b>  | Void                                |
| · <b>Pyrophoric solids</b>   | Void                                |
| · <b>Self-heating substances and mixtures</b>                                      | Void                                |
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | Void                                |
| · <b>Oxidising liquids</b>   | Void                                |
| · <b>Oxidising solids</b>  | Void                                |
| · <b>Organic peroxides</b>   | Void                                |
| · <b>Corrosive to metals</b>   | Void                                |
| · <b>Desensitised explosives</b>   | 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 toxicological effects**
- **Acute toxicity:** Harmful if swallowed.

**· LD/LC50 values that are 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))

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**7631-86-9 silicon dioxide**

Oral	LD50	10,000 mg/kg (rat (f+m))
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- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** 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.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - 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:**

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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 (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 of together with household garbage. Do not allow product to reach sewage system.

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

### SECTION 14: Transport information

- **14.1 UN-Number**  
· **ADR, IMDG, IATA** UN1170
- **14.2 UN proper shipping name**  
· **DOT** Ethanol  
· **ADR** 1170 ETHANOL SOLUTION  
· **IMDG, IATA** ETHANOL SOLUTION
- **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  
· **Hazard identification number (Kemler code):** 33  
· **EMS Number:** F-E,S-D  
· **Stowage Category** A
- **14.7 Transport in bulk according to Annex II of MARPOL73/78 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

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- |                                   |   |
|-----------------------------------|---|
| · <b>IMDG</b>                     |   |
| · <b>Limited quantities (LQ)</b>  | 1L  |
| · <b>Excepted quantities (EQ)</b> | Code: E2<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 500 ml |
| · <b>UN "Model Regulation":</b>   | UN 1170 ETHANOL SOLUTION, 3, II   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

- **Section 313 (Specific toxic chemical listings):**

111-90-0 | Diethylene glycol monoethyl ether

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

64-17-5 | ethyl alcohol

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

64-17-5	ethyl alcohol	A3
7681-49-4	Sodium fluoride	A4

- **MAK (German Maximum Workplace Concentration)**

64-17-5	ethyl alcohol	5
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- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

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

- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **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

· **Date of previous version** 27.10.2022

· **Version number of previous version:** 5

· **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

DOT: US Department of Transportation

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

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

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**Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem ([www.echemportal.org](http://www.echemportal.org))

**\* Data compared to the previous version altered.**

*This version replaces all previous versions.*

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