

Printing date 22.08.2023 Version number 6 Revision: 22.08.2023

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: MI Varnish
- 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
- Details of the supplier of the safety data sheet

Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H302 Harmful if swallowed.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · 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

· Hazard statements

Highly flammable liquid and vapour.

 $Harmful\ if\ swallowed.$

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Store in a well-ventilated place. Keep cool.

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

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- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB:** Not applicable.

3 Composition/Information on ingredients

- · 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 EINECS: 20	-	ethyl alcohol	Flam. Liq. 2, H225	25-<50%
CAS: 7681- EINECS: 2:		Sodium fluoride	Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-<10%

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 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.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire fighting measures

- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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.

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· 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.

6 Accidental release measures

· 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.

· 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.

· 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.

· 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.

7 Handling and storage

- · Handling:
- · 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.

- · 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.

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Store in a cool place.

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethyl alcohol

WES (New Zealand) Long-term value: 1880 mg/m³, 1000 ppm oto

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

Keep away from foodstuffs, beverages and feed.

- · Respiratory protection: 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.

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· General Information

· Appearance:

· Form: Pasty · Colour: White

Odour: Product specificOdour threshold: Not determined.

• pH-value at 20 °C: 6.6

· Change in condition

· Melting point/freezing point: Undetermined.

· Initial boiling point and boiling range: 78 °C · Flash point: 13 °C

· Flammability (solid, gas): Highly flammable. · Auto-ignition temperature: Undetermined.

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• **Decomposition temperature:** Not determined.

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: 3.5 Vol %
Upper: 15 Vol %
Vapour pressure: Not determined.
Density at 20 °C: 1.1 g/cm³
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

· Kinematic: Not determined.

· Solvent content:

• *Organic solvents:* 36.0 % • *VOC (EC)* 396.0 g/l

• Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Harmful if swallowed.

· LD/LC50	values	relevant	for	classification:
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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.

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- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

13 Disposal considerations

- · 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.

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	Transport	71101	OVMA	TON
17 I		-uu		word

· UN-Number

· NZS, IMDG, IATA UN1170

· UN proper shipping name

 $\cdot NZS$

1170 ETHANOL SOLUTION ETHANOL SOLUTION

· IMDG, IATA

· Transport hazard class(es)

· NZS



3 (F1) Flammable liquids. · Class

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Label	3
IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group	
NZS, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	33
EMS Number:	F-E,S-D A
Stowage Category	
Transport in bulk according to Annex II of Marp and the IBC Code	vol Not applicable.
Transport/Additional information:	
NZS	
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
Transport category	Maximum nei quantity per outer packaging: 500 mt
Tunnel restriction code	D/E
 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

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· New Zeala	· New Zealand Inventory of Chemicals		
	Polyvinyl acetate		
	ethyl alcohol		
	Rosin, hydrogenated		
111-90-0	Diethylene glycol monoethyl ether		
7681-49-4	Sodium fluoride		
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica		
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7631-86-9 silicon dioxide

56038-13-2 Sucralose

2216-51-5 L-menthol

· HSNO Approval numbers

64-17-5 ethyl alcohol

HSR001144

- GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms





- · Signal word Danger
- · Hazard-determining components of labelling:

Sodium fluoride

Hazard statements

Highly flammable liquid and vapour.

Harmful if swallowed.

· Precautionary statements

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

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

Store in a well-ventilated place. Keep cool.

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

- · 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
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · Abbreviations and acronvms:

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

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)

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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: 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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