Safety Data Sheet
according to WHS Regulations

Printing date 22.08.2023
Version number 6
Revision: 22.08.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· 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
  · Manufacturer/Supplier:
    GC Australasia Dental Pty Ltd
    1753 Botany Road
    Banksmeadow, NSW 2019
    Tel: +61 2 9301 8200
· Further information obtainable from: Regulatory affairs

2 Hazard(s) Identification

· Classification of the substance or mixture
  Flam. Liq. 2                      H225 Highly flammable liquid and vapour.
  Acute Tox. 4                      H302 Harmful if swallowed.
  Serious eye damage/irritation – Category 2A  H319 Causes serious eye irritation.
  Skin Sens. 1                      H317 May cause an allergic skin reaction.

· 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:
  Rosin, hydrogenated
  Sodium fluoride
· Hazard statements
  Highly flammable liquid and vapour.
  Harmful if swallowed.
  Causes serious eye irritation.

(Contd. on page 2)
May cause an allergic skin reaction.

Precautionary statements
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:
Contact with acids liberates very toxic gas.

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

3 Composition and 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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Percentage</th>
<th>Hazard phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl alcohol</td>
<td>25-&lt;50%</td>
<td>Flam. Liq. 2, H225; Serious eye damage/irritation – Category 2A, H319</td>
</tr>
<tr>
<td>65997-06-0 Rosin, hydrogenated</td>
<td>10-&lt;25%</td>
<td>Skin Sens. 1, H317</td>
</tr>
<tr>
<td>7681-49-4 Sodium fluoride</td>
<td>5-&lt;10%</td>
<td>Acute Tox. 3, H301; Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319</td>
</tr>
</tbody>
</table>

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

4 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. Seek medical treatment. If skin irritation continues, consult a doctor.
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- **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.
- **Information for doctor:**
  - Most important symptoms and effects, both acute and delayed: **Allergic reactions**
  - 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.
- **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.
  Avoid contact with the eyes and skin.
  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.
    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.
· 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.
· Specific end use(s) No further relevant information available.

8 Exposure controls and 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 Long-term value: 1880 mg/m³, 1000 ppm
· 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.
    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.
  · 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

9 Physical and Chemical Properties

General Information

- Appearance:
  - Form: Pasty
- Colour: White
- Odour: Product specific
- Odour threshold: Not determined.
- pH-value at 20 °C (68 °F): 6.6
- Change in condition
  - Melting point/freezing point: Undetermined.
  - Initial boiling point and boiling range: 78 °C (172.4 °F)
- Flash point: 13 °C (55.4 °F)
- Flammability (solid, gas): Highly flammable.
- Auto-ignition temperature: Undetermined.
- 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 (68 °F): 1.1 g/cm³ (9.1795 lbs/gal)
- 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 (68 °F): 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.
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- 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:
  64-17-5 ethyl alcohol
  
<table>
<thead>
<tr>
<th></th>
<th>Oral LD50</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethyl alcohol</td>
<td>7,060 mg/kg (rat (f+m))</td>
<td>20,000 mg/l (rat (f+m))</td>
</tr>
</tbody>
</table>

- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Causes serious eye irritation.
- Respiratory or skin sensitisation: May cause an allergic skin reaction.
- 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.

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.

14 Transport information

- UN-Number
  - ADG, IMDG, IATA UN1170
- UN proper shipping name
  - ADG 1170 ETHANOL SOLUTION
  - IMDG, IATA ETHANOL SOLUTION
- Transport hazard class(es)
  - ADG
    - Class 3 (F1) Flammable liquids.
    - Label 3
  - IMDG, IATA
    - Class 3 Flammable liquids.
    - Label 3
- Packing group
  - ADG, IMDG, IATA II
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Hazard identification number (Kemler code): Warning: Flammable liquids.
  - EMS Number: F-E,S-D
  - Stowage Category A
- Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.
### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Australian Inventory of Industrial Chemicals**
    - 9003-20-7 Polyvinyl acetate
    - 64-17-5 ethyl alcohol
    - 65997-06-0 Rosin, hydrogenated
    - 111-90-0 Diethylene glycol monoethyl ether
    - 7681-49-4 Sodium fluoride
    - 68611-44-9 Silane, dichlorodimethyl-, reaction products with silica
    - 7631-86-9 silicon dioxide
    - 56038-13-2 Sucralose
    - 2216-51-5 L-menthol
  - **Standard for the Uniform Scheduling of Medicines and Poisons**
    - None of the ingredients is listed.
  - **Australia: Priority Existing Chemicals**
    - None of the ingredients is listed.
  - **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
  - **Hazard pictograms**
    - GHS02
    - GHS07
  - **Signal word** Danger
  - **Hazard-determining components of labelling:**
    - Rosin, hydrogenated
    - Sodium fluoride

(Contd. on page 9)
Trade name: MI_Varnish

· Hazard statements
  Highly flammable liquid and vapour.
  Harmful if swallowed.
  Causes serious eye irritation.
  May cause an allergic skin reaction.

· Precautionary statements
  Keep away from heat/sparks/open flames/hot surfaces. No smoking.
  Contaminated work clothing should not be allowed out of the workplace.
  Wear protective gloves/protective clothing/eye protection/face protection.
  IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  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.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.

· 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
  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
  Serious eye damage/irritation – Category 2A
  Skin Sens. 1: Skin sensitisation – Category 1

· 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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