Material Safety Data Sheet

acc. to ISO/DIS 11014

1. Identification of the substance/mixture and of the company/undertaking

Product details

Name: Gentian Violet Surgical Ink
Application of substance/the preparation: water based fibrepen ink
Manufacturer: Precision Medical

2. Composition/information on ingredients

Chemical characterization:
Mixture of the following substances, containing non-hazardous substances and colouring agents

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>10-25%</td>
</tr>
<tr>
<td>C.I. Basic Violet 3</td>
<td>2.5-10%</td>
</tr>
</tbody>
</table>

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

3. Hazards identification

Classification of the substance or mixture

Classification according to directive 67/548/EEC or Directive 1999/45/EC

Harmful: Limited evidence of a carcinogenic effect.

Irritant: Irritating to eyes

Dangerous for the environment:
Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Flammable. Vapours may cause drowsiness and dizziness.

Classification system:
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

Risk phrases:
Flammable
Irritating to eyes
Limited evidence of a carcinogenic effect.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Vapours may cause drowsiness and dizziness
Safety phrases:
Keep container tightly closed.
Keep away from sources of ignition - No smoking.
Wear suitable protective clothing, gloves and eye/face protection.
Use appropriate container to avoid environmental contamination.

Classification system
NFPA ratings (scale 0 - 4)
Health = 1  Fire = 3  Reactivity = 0
HMIS ratings  (scale 0 - 4)
Health = *1  Fire = 3  Reactivity = 0

4. First aid measures
After inhalation:  Supply fresh air; consult doctor in case of complaints.
After skin contact: Generally the product does not irritate the skin.
After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing: If symptoms persist consult doctor.

5. Firefighting measures
Suitable extinguishing agents: C02, sand, extinguishing powder. Do not use water.
For safety reasons unsuitable extinguishing agents:
Water
Water with full jet
Protective equipment: No special measures required.

6. Accidental release measures
Person-related safety precautions:
Wear protective equipment. Keep unprotected persons away.
Measures for environmental protection:
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

Measures for cleaning/collecting
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders,sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents

7. Handling and storage

Handling:
Information for safe handling:
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

Information about protection against explosions and fires:
Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Storage:
Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: Keep receptacle tightly sealed.

8. Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.
Components with limit values that require monitoring at the workplace:

57-55-6 propane-1,2-diol (25-50%)
WEEL: 10 mg/m³

67-63-0 propan-2-ol (10-25%)
PEL: 980 mg/m³, 400 ppm
REL: Short-term value: 1225 mg/m³, 500 ppm
long-term value: 980 mg/m³, 400 ppm
TLV: Short-term value: 984 mg/m³, 400 ppm
long-term value: 492 mg/m³, 200 ppm
BEI

Additional information: The lists that were valid during the creation were used as basis.

Personal protective equipment:

General protective and hygienic measures:
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
Breathing equipment:
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands
Protection gloves
The glove material has to be impermeable and resistant to the product / the substance / the preparation.
Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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 trough 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: Fluid
Color: According to product specification
Odor: Alcohol-like
Important information on protection of health and environment and on safety:
Change in condition
Melting point/Melting range: n.d. °C
Boiling point/Boiling range: 82 °C (180 °F)
Flash point: 30 °C (86 °F)
Ignition temperature: 371 °C (700 °F)
Auto igniting: Product is not selfigniting
Danger of explosion: Product is not explosive.
However, formation of explosive air/vapor mixtures are possible.

Explosion limits:
Lower: 2.0 Vol %
Upper: 12.6 Vol %

Vapor pressure at 20°C (68°F): 43 hPa (32 mm Hg)
Density at 20°C (68°F): 0.966 g/cm³ (8.061 lbs/gal)
Solubility in / Miscibility with water: Not miscible or difficult to mix.
Solvent content:
Organic solvents: 46.0 %
Water: 48.9 %

10. Stability and reactivity

Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.

Materials to be avoided:

Dangerous reactions: No dangerous reactions known.
Dangerous products of decomposition: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:
LD/LC50 values that are relevant for classification
67-63-0 propan-2-ol
Oral LD50 4570 mg/kg (rat)
Dermal LD50 13400 mg/kg (rab)
Inhalative LC50/4 h 30 mg/l (rat)

Primary irritant effect:
On the skin: No irritant effect.
On the eye: Irritating effect.
Sensitization: No sensitizing effects known.

Additional toxicological information:
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

12. Ecological information

Ecological effects:
Remark: Toxic for fish

Additional ecological information:

General notes:
Water hazard class 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms

13. Disposal considerations

Product:
Recommendation:
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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

14. Transport information

DOT regulations:
hazard class: 3
Identification number: UN1263
Packing group: III
Proper shipping name (technical name): PAINT
Label: 3
Remarks: Special marking with the symbol (fish and tree).

Land transport ADR/RID (cross-border)
ADR/RID class: 3 (F1) Flammable liquids
Danger code (Kemler): 30
UN-Number: 1263
Packing group: III
Special marking: Symbol (fish and tree)
Description of goods: 1263 PAINT

Maritime transport IMDG:
IMDG class: 3
Un Number: 1263
Label: 3
Packing group: III
EMS number: F-E,S-E
marine pollutant: Yes. Symbol (fish and tree)
Propper shipping name: PAINT (C.I. Basic Violet 3)
Remarks: 1263 Paint (C.I. Basic Violet 3), Marine Pollutant

Air transport ICAO-TI and IATA-DGR:
ICAO/IATA class: 3
UN/ID number: 1263
Label: 3
Packing group: III
Propper shipping name: PAINT

Environmental hazards:
Product contains environmentally hazardous substances: C.I. Basic Violet 3

15. Regulatory information
Sara
Section 355 (extremely hazardous substances):
None of the ingredient is listed.
Section 313 (specific toxic chemical listings):
67-63-0: propan-2-ol
TSCA (Toxic Substances Control Act)
All ingredients are listed.

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:
None of the ingredients is listed.
Cancerogenic categories:
EPA (Environmental Protection Agency)
None of the ingredients is listed.
IARC (International Agency for research on Cancer)
67-63-0: propan-2-ol
NTP (National Toxicology Program)
None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH)
67-63-0: propan-2-ol

MAK (German Maximum Workplace Concentration)
None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

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

National regulations:

Technical instructions (air):

<table>
<thead>
<tr>
<th>Class</th>
<th>Share in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>NK</td>
<td>25-50</td>
</tr>
</tbody>
</table>

Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Data compared to the previous version altered.