1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: GEM™ CVP Multipack
Product Number: 0024001587

1.2 Use of the mixture:
For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:
+44 (0)3700 492 795
+1 215 207 0061 (USA and Canada)

2. COMPOSITION/INFORMATION ON PRODUCT

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT APPLICABLE</td>
<td>GEM CVP 1</td>
<td>Not classified</td>
<td>Not classified</td>
<td>5 x 2.5 mL</td>
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<td>Not classified</td>
<td>5 x 2.5 mL</td>
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<td>NOT APPLICABLE</td>
<td>GEM CVP 3</td>
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<td>Not classified</td>
<td>5 x 2.5 mL</td>
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<td>NOT APPLICABLE</td>
<td>GEM CVP 4</td>
<td>Not classified</td>
<td>Not classified</td>
<td>5 x 2.5 mL</td>
</tr>
</tbody>
</table>

Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user’s responsibility for the product’s safe use, the product’s suitability for the intended use and the product’s safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation” (ANSI Z400.1-2004) as recommended by US OSHA.

Prepared by: Chemsafe Srl
1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture
   
   Product Name: GEM CVP 1
   
   Product Number: NOT APPLICABLE

1.2 Use of the mixture:
   For in vitro diagnostic use.

1.3 Company identification:
   
   MANUFACTURER:
   Instrumentation Laboratory Co.
   180 Hartwell Road,
   Bedford, MA 01730-2443 (USA)

   Tel. +1 800 678 0710
   Fax +1 781 863 9928

   DISTRIBUTOR US/CANADA:
   Instrumentation Laboratory Co.
   526 Route 303
   Orangeburg, New York 10962 (USA)

   E-mail address of the competent person: infosds@mail.ilww.it

   DISTRIBUTOR EU:
   Via Roma, 103
   20040 Cavenago Brianza (Italy)

   Company identification:
   GEM CVP 1
   NOT APPLICABLE

1.4 Emergency phone:
   +44 (0)3700 492 795
   +1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification
   
   Not classified as dangerous
   Not classified as dangerous

2.1 Mixture classification
   See also ch. 15
   
   Not classified as dangerous
   according to 67/548/EEC and 1999/45/EEC Directives
   Not classified as dangerous
   according to 1272/2008 Regulation (EC)

2.2 Potential health and environmental effects
   
   Ingestion: May be harmful if swallowed.
   
   Inhalation exposure: May cause irritation.
   
   Contact with skin: May cause irritation.
   
   Contact with eyes: May cause irritation.
   
   Sensitization: Might cause sensitization by inhalation or skin contact.
   
   Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS
   
   Composition: Aqueous buffered solution containing inorganic salts and organic metabolites.

4. FIRST AID MEASURES
   
   Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
   
   Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
   
   Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
   
   Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES
   
   Suitable extinguishing means: Water spray or regular foam, CO₂, dry powder, alcohol-resistant foam.
   
   Mean of extinguishing NOT to be used: Not known.
   
   Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes (e.g. CO₂).
   
   Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

Work/Hygienic practices: Wash hands with soap and water after use.

7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: Avoid environmental release.

(see also Section 8)

Recommended temperature: Store at 2 – 8 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labelled with the name of the product.

Other storage precautions: Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV-TWA; TLV-STEL: not available

LV EU: not available

8.2 Exposure Controls

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Rubber or polythene gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

Environmental protection: Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance: Liquid

Odor: Odorless

Color: Clear

9.2 Important health, safety and environmental information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Related to</th>
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</thead>
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<tr>
<td>pH</td>
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<td>Boiling point/range</td>
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<td></td>
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<tr>
<td>Flash point</td>
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<td>Mixture</td>
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<tr>
<td>Vapor pressure</td>
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<td>Relative Density</td>
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<td>Vapor density</td>
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<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>not available</td>
<td></td>
</tr>
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</table>
### 9.3 Other information

Melting point/range: not available

### 10. STABILITY AND REACTIVITY

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.1 Conditions to avoid: Keep away from heat and light.

10.2 Materials to avoid: not available

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of CO.<small>2</small>.

### 11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)

Absorption: not available

Distribution: not available

Metabolism: not available

Excretion: not available

11.2 Acute toxicity

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Effects</th>
<th>Related to</th>
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<tbody>
<tr>
<td>Oral: LD50 (rat) = not available</td>
<td>mg/Kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal: LD50 (rat/rabbit) = not available</td>
<td>mg/Kg</td>
<td></td>
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<tr>
<td>Inhalation: LC50 (rat) = not available</td>
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<tr>
<td>Other data:</td>
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</tr>
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</table>

11.3 Irritation

Skin: not available

Eye: not available

Inhalation: not available

11.4 Sensitization:

Skin sensitization: not available

Sensitization by inhalation: not available

11.5 Prolonged exposure toxicity: not available

11.5 CMR effects

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<td>Chromosomal aberration:</td>
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<tr>
<td>Micronucleus test:</td>
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<tr>
<td>Teratogenesis:</td>
<td>not available</td>
</tr>
<tr>
<td>Carcinogenesis:</td>
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</tr>
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</table>

### 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Related to</th>
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<tbody>
<tr>
<td>Acute toxicity with fish: LC50 = not available</td>
<td>mg/l/96 hours</td>
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</tr>
<tr>
<td>Acute toxicity with Daphnia Magna: EC50 = not available</td>
<td>mg/l/48 hours</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity with algae: EC50 = not available</td>
<td>mg/l/72 hours</td>
<td></td>
</tr>
</tbody>
</table>

12.2 Mobility:

not available

12.3 Persistence and degradability:

not available

12.4 Bioaccumulation potential:

not available

12.5 Evaluation PBT result:

not available

12.6 Other toxic effects:

not available
13. **DISPOSAL CONSIDERATION**

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. **TRANSPORT INFORMATION**

Not classified as dangerous for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

15. **REGULATORY INFORMATION**

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/atp.

<table>
<thead>
<tr>
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<td>Labeling safety phrases:</td>
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</tr>
<tr>
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<td>None</td>
</tr>
</tbody>
</table>

**Other labeling details:** No

**Safety precautions:** Wear suitable protective clothing, gloves and eye/face protection.

**Authorization:** No

**Restriction:** No

16. **OTHER INFORMATION**

**Phrases R:** None

**Hazard Statements:** None

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

**Bibliographic references:** None
1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: GEM CVP 2
Product Number: NOT APPLICABLE

1.2 Use of the mixture:

For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:

+44 (0)3700 492 795
1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification

Not classified as dangerous
Not classified as dangerous

(see also ch. 15)

(see also ch. 15)

according to 67/548/EEC and 1999/45/EEC Directives
according to 1272/2008 Regulation (EC)

2.2 Potential health and environmental effects

Ingestion: May be harmful if swallowed.
Inhalation exposure: May cause irritation.
Contact with skin: May cause irritation.
Contact with eyes: May cause irritation.
Sensitization: Might cause sensitization by inhalation or skin contact.
Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: Aqueous buffered solution containing inorganic salts and organic metabolites.

4. FIRST AID MEASURES

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing means: Water spray or regular foam, CO₂ dry powder, alcohol-resistant foam.
Mean of extinguishing NOT to be used: Not known.
Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes (e.g. CO₂).
Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

Work/Hygienic practices: Wash hands with soap and water after use.

7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: Avoid environmental release.

(see also Section 8)

Recommended temperature: Store at 2 – 8 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labelled with the name of the product.

Other storage precautions: Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV-TWA; TLV-STEL: not available
LV EU: not available

8.2 Exposure Controls

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Rubber or polythene gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

Environmental protection: Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance: Liquid
Odor: Odorless
Color: Clear

9.2 Important health, safety and environmental information

<table>
<thead>
<tr>
<th>Value</th>
<th>Related to</th>
</tr>
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<tbody>
<tr>
<td>pH:</td>
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</tr>
<tr>
<td>Flash point:</td>
<td>Not flammable</td>
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<tr>
<td>Vapor pressure:</td>
<td>not available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>&gt; 1</td>
</tr>
<tr>
<td>Solubility:</td>
<td>not available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>Miscible</td>
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<td>Viscosity:</td>
<td>not available</td>
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<tr>
<td>Vapor density:</td>
<td>not available</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>not available</td>
</tr>
</tbody>
</table>
9.3 Other information
Melting point/range: not available

10. STABILITY AND REACTIVITY
Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.1 Conditions to avoid: Keep away from heat and light.

10.2 Materials to avoid: not available

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)
Absorption: not available
Distribution: not available
Metabolism: not available
Excretion: not available

11.2 Acute toxicity

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Effects</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral: LD50 (rat) = not available</td>
<td>mg/Kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal: LD50 (rat/rabbit) = not available</td>
<td>mg/Kg</td>
<td></td>
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</tr>
<tr>
<td>Inhalation: LC50 (rat) = not available</td>
<td>mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11.3 Irritation
Skin: not available
Eye: not available
Inhalation: not available

11.4 Sensitization:
Skin sensitization: not available
Sensitization by inhalation: not available

11.5 Prolonged exposure toxicity: not available

11.5 CMR effects
Mutagenicity: not available
Mouse lymphoma: not available
Chromosomal aberration: not available
Micronucleus test: not available
Teratogenesis: not available
Carcinogenesis: not available

11.6 Prolonged exposure toxicity: not available

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Related to</th>
</tr>
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<tbody>
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<td>mg/l/96 hours</td>
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</tr>
<tr>
<td>Acute toxicity with algae: EC50 = not available</td>
<td>mg/l/72 hours</td>
<td></td>
</tr>
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</table>

12.2 Mobility: not available

12.3 Persistence and degradability: not available

12.4 Bioaccumulation potential: not available

12.5 Evaluation PBT result: not available

12.6 Other toxic effects: not available
13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

Not classified as dangerous for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

15. REGULATORY INFORMATION

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<table>
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<tr>
<td>Labeling risk phrases:</td>
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<td>None</td>
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<tr>
<td>(hazard statements)</td>
<td>None</td>
<td>None</td>
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<tr>
<td>Labeling safety phrases:</td>
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<td>None</td>
</tr>
<tr>
<td>(precautionary statements)</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Other labeling details: No
Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.
Authorization: No
Restriction: No

16. OTHER INFORMATION

Phrases R: None
Hazard Statements: None

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Bibliographic references: none
1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture

Product Name: GEM CVP 3
Product Number: NOT APPLICABLE

1.2 Use of the mixture:

For in vitro diagnostic use.

1.3 Company identification:

MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road,
Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
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E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:

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+1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification

Not classified as dangerous
(see also ch. 15)
according to 67/548/EEC and 1999/45/EEC Directives
Not classified as dangerous
according to 1272/2008 Regulation (EC)

2.2 Potential health and environmental effects

- Ingestion: May be harmful if swallowed.
- Inhalation exposure: May cause irritation.
- Contact with skin: May cause irritation.
- Contact with eyes: May cause irritation.
- Sensitization: Might cause sensitization by inhalation or skin contact.
- Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition: Aqueous buffered solution containing inorganic salts and organic metabolites.

4. FIRST AID MEASURES

- Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
- Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
- Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
- Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES

- Suitable extinguishing means: Water spray or regular foam, CO₂ dry powder, alcohol-resistant foam.
- Mean of extinguishing NOT to be used: Not known.
- Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes (e.g. CO₂).
- Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

Work/Hygienic practices: Wash hands with soap and water after use.

7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: Avoid environmental release.

Recommended temperature: Store at 2 – 8 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labelled with the name of the product.

Other storage precautions: Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

8.1 Exposure limit values

TLV-TWA ; TLV-STEL : not available
LV EU : not available

8.2 Exposure Controls

Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

Skin protection: Protective clothing, rubber or polythene gloves.

Eye protection: Safety glasses.

Hand protection: Rubber or polythene gloves.

Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

Environmental protection: Avoid any release into the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Appearance: Liquid
Odor: Odorless
Color: Clear

9.2 Important health, safety and environmental information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6-8</td>
<td>Mixture</td>
</tr>
<tr>
<td>Boiling point/range</td>
<td>not available</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not flammable</td>
<td>Mixture</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>not available</td>
<td></td>
</tr>
<tr>
<td>Relative Density</td>
<td>&gt; 1</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solubility</td>
<td>not available</td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Miscible</td>
<td>Mixture</td>
</tr>
<tr>
<td>Viscosity</td>
<td>not available</td>
<td></td>
</tr>
<tr>
<td>Vapor density</td>
<td>not available</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>not available</td>
<td></td>
</tr>
</tbody>
</table>
9.3 Other information
Melting point/range: not available

10. STABILITY AND REACTIVITY

Stability: The product is stable until the expiration date shown on the box and on the labels when stored at 2 - 8°C.

10.1 Conditions to avoid: Keep away from heat and light.

10.2 Materials to avoid: not available

10.3 Hazardous decomposition products: Thermal decomposition or combustion may include toxic and hazardous fumes of COx.

11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetic effects (ADME)
Absorption: not available
Distribution: not available
Metabolism: not available
Excretion: not available

11.2 Acute toxicity

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Effects</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral: LD50 (rat)</td>
<td>not available</td>
<td>mg/Kg</td>
<td></td>
</tr>
<tr>
<td>Dermal: LD50 (rat/rabbit)</td>
<td>not available</td>
<td>mg/Kg</td>
<td></td>
</tr>
<tr>
<td>Inhalation: LC50 (rat)</td>
<td>not available</td>
<td>mg/m³</td>
<td></td>
</tr>
<tr>
<td>Other data:</td>
<td>not available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11.3 Irritation
Skin: not available
Eye: not available
Inhalation: not available

11.4 Sensitization:
Skin sensitization: not available
Sensitization by inhalation: not available

11.5 Prolonged exposure toxicity: not available

11.5 CMR effects
Mutagenicity:
- Ames test: not available
- Mouse lymphoma: not available
- Chromosomal aberration: not available
- Micronucleus test: not available

Teratogenesis: not available
Carcinogenesis: not available

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicology

<table>
<thead>
<tr>
<th>Value</th>
<th>m.u.</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity with fish: LC50</td>
<td>not available</td>
<td>mg/l/96 hours</td>
</tr>
<tr>
<td>Acute toxicity with Daphnia Magna: EC50</td>
<td>not available</td>
<td>mg/l/48 hours</td>
</tr>
<tr>
<td>Acute toxicity with algae: EC50</td>
<td>not available</td>
<td>mg/l/72 hours</td>
</tr>
</tbody>
</table>

12.2 Mobility:
not available

12.3 Persistence and degradability:
not available

12.4 Bioaccumulation potential:
not available

12.5 Evaluation PBT result:
not available

12.6 Other toxic effects:
not available
13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected. Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

14. TRANSPORT INFORMATION

Not classified as dangerous for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

15. REGULATORY INFORMATION

Regulatory information on labeling according to 67/548/EEC, to 1999/45/EEC Directive and to 1272/2008 Regulation (EC)(European reinforcement of GHS), and according to their following amendments/ atp.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Labeling symbols: (signal word)</td>
<td>Not classified as dangerous</td>
<td>Not classified as dangerous</td>
</tr>
<tr>
<td>Labeling risk phrases: (hazard statements)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Labeling safety phrases: (precautionary statements)</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Other labeling details: No
Safety precautions: Wear suitable protective clothing, gloves and eye/face protection.
Authorization: No
Restriction: No

16. OTHER INFORMATION

Phrases R: None
Hazard Statements: None

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

Bibliographic references: None
1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Identification of the mixture
Product Name: GEM CVP 4
Product Number: NOT APPLICABLE

1.2 Use of the mixture:
For in vitro diagnostic use.

1.3 Company identification:
MANUFACTURER:
Instrumentation Laboratory Co.
180 Hartwell Road, Bedford, MA 01730-2443 (USA)
Tel. +1 800 678 0710
Fax +1 781 863 9928

DISTRIBUTOR EU:
Via Roma, 103
20040 Cavenago Brianza (Italy)

DISTRIBUTOR US/CANADA:
Instrumentation Laboratory Co.
526 Route 303
Orangeburg, New York 10962 (USA)

E-mail address of the competent person: infosds@mail.ilww.it

1.4 Emergency phone:
+44 (0)13700 492 795
+1 215 207 0061 (USA and Canada)

2. HAZARDS IDENTIFICATION

2.1 Mixture classification
(see also ch. 15)
Not classified as dangerous according to 67/548/EEC and 1999/45/EEC Directives
Not classified as dangerous according to 1272/2008 Regulation (EC)

2.2 Potential health and environmental effects
Ingestion: May be harmful if swallowed.
Inhalation exposure: May cause irritation.
Contact with skin: May cause irritation.
Contact with eyes: May cause irritation.
Sensitization: Might cause sensitization by inhalation or skin contact.
Environmental exposure: Might cause adverse effects for the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS
Composition: Aqueous buffered solution containing inorganic salts and organic metabolites.

4. FIRST AID MEASURES
Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
Inhalation exposure: If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
Contact with skin: Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes: Wash immediately with plenty of water or normal saline. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

5. FIRE-FIGHTING MEASURES
Suitable extinguishing means: Water spray or regular foam, CO₂ dry powder, alcohol-resistant foam.
Mean of extinguishing NOT to be used: Not known.
Known hazards caused by combustion: Thermal decomposition or combustion may generate toxic and hazardous fumes (e.g. CO₂).
Equipment for self-protection: (fire fighters) Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

Environmental precautions: Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

Cleaning procedure to recover spilled material: Soak up with inert absorbent material, and clean with plenty of water. Send to the storage waiting for disposal procedures.

7. HANDLING AND STORAGE

7.1 Handling

Handling procedures: Wear suitable protective clothing, gloves, eye protection. When use do not eat, drink or smoke. Provide sufficient ventilation in all work areas.

Work/Hygienic practices: Wash hands with soap and water after use.

7.2 Storage

Room ventilation: Well ventilated workplace.

Special precautions: Avoid environmental release.

Recommended temperature: Store at 2 – 8 °C.

Humidity, light and other environmental factors: Avoid light exposure and keep away from heat sources and non compatible materials.

Containers: Keep containers tightly closed and labelled with the name of the product.

Other storage precautions: Keep away from food and drinks.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

TLV-TWA; TLV-STEL: not available

LV EU: not available

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Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.

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11.2 Acute toxicity
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Acute toxicity with Daphnia Magna: EC50 = not available mg/l/48 hours
Acute toxicity with algae: EC50 = not available mg/l/72 hours

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12.3 Persistence and degradability:

12.4 Bioaccumulation potential: not available

12.5 Evaluation PBT result: not available

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