IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

Identification of the product

Product Name: GEM® CVP Multipack
Product Number: 0024001587
Use of the product: For in vitro diagnostic use

Company identification:

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

DISTRIBUTOR EU:
Via Leonardo da Vinci, 36
20877 Roncello (MB), 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
Emergency phone: +44 (0) 3700 492 795
+1 215 207 0061 (USA and Canada)

INFORMATION ON COMPOSITION/HAZARD OF THE 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>
</tr>
<tr>
<td>Not applicable</td>
<td>GEM CVP 2</td>
<td>Not classified</td>
<td>Not classified</td>
<td>5 x 2.5 ml</td>
</tr>
<tr>
<td>Not applicable</td>
<td>GEM CVP 3</td>
<td>Not classified</td>
<td>Not classified</td>
<td>5 x 2.5 ml</td>
</tr>
<tr>
<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 SDS are in accordance with Annex II of the Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Prepared by: Chemsafe Srl
Section 1. Identification of the Mixture and of the Company

1.1 Identification of the mixture

Product Name: GEM CVP 1
GEM CVP 2
GEM CVP 3
GEM CVP 4

Product Number: NOT APPLICABLE

1.2 Use of the mixture:

Relevant use: For in vitro diagnostic use.

Uses advised against: There are no specific uses advised against.

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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20877 Roncello (MB), Italy

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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)

Section 2. Hazards Identification

2.1 Classification of the mixture:


Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.


<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Hazard category</th>
<th>Hazard statement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Not classified</td>
</tr>
</tbody>
</table>

For exposure limits see section 8.

Potential adverse physicochemical, human health and environmental effects

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

(see also ch. 9-12)

2.2 Label elements, according to Regulation (EC) No 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to Hazardous Product Regulation HPR (WHMIS 2015):

<table>
<thead>
<tr>
<th>Hazard pictogram(s):</th>
<th>none</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal word(s):</td>
<td>none</td>
</tr>
<tr>
<td>Hazard statement(s):</td>
<td>none</td>
</tr>
<tr>
<td>Precautionary statement(s):</td>
<td>none</td>
</tr>
<tr>
<td>Other labeling details:</td>
<td>none</td>
</tr>
</tbody>
</table>

Safety precautions:

Use the product in accordance with the Good Laboratory Practice.

Wear suitable protective clothing, gloves and eye/face protection.

Do not let the product enter drainage system, surface and ground-water or soil. Do not empty into drains.

2.3 Other hazards (which do not results in the classification)

The mixture does not meet the criteria for PBT or vPvB.

Section 3. Composition/Information on Ingredients
SAFETY DATA SHEET
GEM CVP 1, GEM CVP 2
GEM CVP 3, GEM CVP 4

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

3.1 Hazardous components: no known hazardous ingredients.

The mixture does not contain substances listed in the Hazardous Substance Lists and/or evaluated for carcinogenicity by IARC, NTP, OSHA. See Section 11 and 15.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

Inhalation exposure: If inhaled, move person to fresh air. If breathing is difficult, oxygen should be administered. Get medical advice if adverse symptoms appear.

Contact with skin: Remove contaminated clothes and shoes. Wash immediately affected area with soap or mild detergent and plenty of water until the removal of the mixture (15-20 minutes). Get medical advice if adverse symptoms appear.

Contact with eyes: Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eyelid open with the finger. Get medical advice if adverse symptoms appear.

4.2 Most important symptoms and effects (acute and delayed)

Acute: Inhalation: may cause irritation to respiratory ways.

Skin: May be irritant for skin.

Eyes: May cause irritation.

Ingestion: may cause irritation to the gastrointestinal mucous membranes.

Delayed: Delayed symptoms and effects are not known.

4.3 Indication of any immediate medical attention and special treatment needed

Medical monitoring: Not foreseen.

Antidotes, if known: Not known.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray or regular foam, CO₂, dry powder.

Unsuitable extinguishing media: Not known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Thermal decomposition or combustion may generate toxic and hazardous fumes (e.g. CO₂).

5.3 Advice for firefighters

Protective actions: Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection: Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

For emergency responders: Wear appropriate protective equipment (see Section 8) to minimize exposure to the product.

6.2 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.

6.3 Methods and material for containment and cleaning up

Collect spilled material in containers. Where appropriate, moisten to prevent the dispersion of dust, absorb with inert materials and wash the area with plenty of water. Send to the storage waiting for disposal procedures.

6.4 Reference to other sections

See also section 8 and 13.
SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Handle in a well ventilated place, and away from sparks and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, incompatibilities
Recommended temperature: store at 2 - 8°C. Avoid light exposure and keep away from heat sources.
Room ventilation: well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release.
Keep away from food and drinks.

7.3 Specific end use
**GEM® CVP 1, GEM® CVP 2, GEM® CVP 3, and GEM® CVP 4** are intended for in vitro diagnostic use.
Use these products in accordance with the Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
- Community/National occupational exposure limit values: not available
- Community/National biological exposure limit values: not available
- DNEL values (components): not available
- PNEC values (components): not available

Recommended monitoring procedures:
The measurement of substances at the workplace must be carried out with standardized methods or, failing that, with appropriate methods.

8.2 Exposure controls

8.2.1. Appropriate engineering controls
Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipment must be adopted, complying with the relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)
Respiratory protection: Respiratory protection is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter.
Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
Skin protection: Protective clothing, rubber gloves.
Eye protection: Safety glasses.
Hand protection: Protective gloves.
Other protective systems: Personal protective equipment (PPE) useful for reducing individual exposure.

8.2.3. Environmental exposure controls
Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Value</th>
<th>Related to:</th>
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<tbody>
<tr>
<td>Appearance:</td>
<td>GEM® CVP 1, GEM® CVP 2, GEM® CVP 3 and GEM® CVP 4</td>
</tr>
<tr>
<td>Odor:</td>
<td>GEM® CVP 1, GEM® CVP 2, GEM® CVP 3 and GEM® CVP 4</td>
</tr>
<tr>
<td>Color:</td>
<td>Mixture</td>
</tr>
<tr>
<td>pH:</td>
<td>6-8</td>
</tr>
<tr>
<td>Flammability:</td>
<td>not flammable</td>
</tr>
<tr>
<td>Explosive properties:</td>
<td>Aqueous solution, not expected to be explosive</td>
</tr>
</tbody>
</table>
SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

This mixture is considered not reactive under the normal conditions of the usage.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not foreseen.

10.4 Conditions to avoid:

Keep out from heat and light.

10.5 Incompatible materials

Strong bases, strong acids and water reactive materials.

10.6 Hazardous decomposition products:

Thermal decomposition or combustion may include toxic and hazardous fumes (e.g. COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The health effects of the product have not been thoroughly investigated.

11.1 Information on toxicological effects

Symptoms and effects for each route of exposure:

Dermal: May cause irritation.

Ingestion: Ingestion may cause irritation to the gastrointestinal mucous membranes.

Inhalation: Inhalation of the product may cause irritation to respiratory ways.

Contact with eyes: May cause eye irritation.

Toxicokinetic effects (Absorption, Distribution, Metabolism, Excretion): not available

Acute toxicity

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>m.u.</th>
<th>Effects</th>
<th>Related to</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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<tr>
<td>Dermal</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other data</td>
<td>not available</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Corrosion/Irritation

Skin Corrosion/Irritation not available

Serious eye damage/ irritation not available

Sensitization:

Skin sensitization: not available

Respiratory sensitization: not available

CMR effects

Germ cell mutagenicity: not available

Reproductive toxicity: not available

Carcinogenesis:

Substances listed in the National Toxicology Program (NTP) Report on Carcinogens, in the International Agency for Research on Cancer (IARC) Monographs or found to be potential carcinogen by OSHA:

<table>
<thead>
<tr>
<th>Substance</th>
<th>OSHA</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The components of the mixture are not listed.

STOT – single exposure

Not available.
STOT – repeated exposure: not available

Aspiration hazards: Not available.

Other information: Not available.

Reasons for the lack of classification:
Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Regulations mentioned in this data sheet.

SECTION 12. ECOLOGICAL INFORMATION

The environmental effects of the product have not been thoroughly investigated.

12.1 Toxicity: species, media, units, test duration and test conditions. Related to

- Acute toxicity with fish: not available
- Chronic toxicity with fish: not available
- Acute toxicity with crustaceans: not available
- Chronic toxicity with crustaceans: not available
- Acute toxicity with algae: not available
- Chronic toxicity with algae: Not available.
- Toxicity data on soil micro- and macroorganisms: Not available.
- Toxicity data on birds, bees and plants: Not available.

12.2 Persistence and degradability: not available

12.3 Bioaccumulation potential: not available

12.4 Mobility in soil: Not expected to adsorb on soil.

12.5 Results of PBT and vPvB assessment: Chemical Safety Report and PBT assessment: not performed.

12.6 Other toxic effects: not available

SECTION 13. DISPOSAL CONSIDERATION

National laws on disposal must be considered, local and UE requirements for wastes recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national, state and local laws.

SECTION 14. TRANSPORT INFORMATION

Not classified in accordance with ADR/RID, IMDG, IATA and DOT regulations.
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**EU Regulations**


**Restriction of use:** none

**Substance(s) under authorisation:** none

**US Federal Regulations:**

<table>
<thead>
<tr>
<th>State</th>
<th>Components listed</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massachusetts</td>
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<td></td>
</tr>
<tr>
<td>New York</td>
<td>No component listed</td>
<td></td>
</tr>
<tr>
<td>New Jersey</td>
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<td></td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>No component listed</td>
<td></td>
</tr>
</tbody>
</table>

E - Substance is on the Environmental Hazard List

### California Prop. 65

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Cancer</th>
<th>Reproductive</th>
<th>NSRL or MADL (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No component listed</td>
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<td></td>
</tr>
</tbody>
</table>

### Clean Water Act (CWA) 307

No component listed

### Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)

No component listed

### Clean Air Act Section 602 Class I Substances

No component listed

### Clean Air Act Section 602 Class II Substances

No component listed

### DEA List I Chemicals (Precursor Chemicals)

No component listed

### DEA List II Chemicals (Essential Chemicals)

No component listed

### EPA List of Lists

<table>
<thead>
<tr>
<th>Regulatory Name</th>
<th>CAS No./SARA/313 Category Code</th>
<th>SARA/EPCRA 302 EHS TPQ</th>
<th>SARA/EPCRA 304 EHS RQ</th>
<th>CERCLA RQ</th>
<th>SARA/EPCRA 313 TRI</th>
<th>RCRA Code</th>
<th>CAA 112(r) RMP TQ</th>
</tr>
</thead>
</table>

No component listed

**SARA/313 Category Code:** Emergency Planning and Community Right-to-Know Act Section 313 Category Code

**SARA/EPCRA 302 EHS TPQ:** Extremely Hazardous Substance Threshold Planning Quantity (Emergency Planning and Community Right-to-Know Act Section 302 Category Code)

**SARA/EPCRA 304 EHS RQ:** Extremely Hazardous Substance Reportable Quantity (Emergency Planning and Community Right-to-Know Act Section 304 Category Code)

**CERCLA RQ:** Reportable Quantity (Comprehensive Environmental Response, Compensation, and Liability Act)

**SARA/EPCRA 313 TRI:** Toxics Release Inventory (Emergency Planning and Community Right-to-Know Act Section 313 Category Code)

**RCRA Code:** Resource Conservation and Recovery Act Code

**CAA 112(r) RMP TQ:** Risk Management Plan Threshold Quantity (Clean Air Act Section 112(r))

### United States Inventory (TSCA 8b)

All components are listed or exempted.

### Canada Domestic Substances List (DSL)

All components are listed.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out for the mixture by the supplier.
SECTION 16. OTHER INFORMATION

Revisions:
- Edition n. 01, dated 05/13/2011
- Revision n. 01 dated 10/11/2013.

Acronyms:
- ACGIH: American Conference of Governmental Industrial Hygienists
- AIHA: American Industrial Hygiene Association
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI: Biological Exposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CLP: Classification, Labeling and Packaging
- DNEL: Derived No-Effect Levels
- EC50: the effect concentration associated with 50% response.
- EINECS: European Inventory of Existing Commercial Substances
- EPA: US Environmental Protection Agency
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- LC50: Lethal Concentration to 50% of a test population
- LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
- LOEL: Lowest Observed Effect Level
- MADL: Maximum Allowable Daily (or Dose) Level
- NOAEL: No Observed Adverse Effect Level
- NOEC: no observed effect concentration, means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect.
- NSRL: National Science Research Laboratory
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE: Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- PNEC: Predicted No Effect Concentration
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative
- WEEL: Workplace Environmental Exposure Level (air concentration of agents in a healthy worker's breathing zone)

Information related to the Regulation EC/1272/2008: none

Information on workers training: Follow National requirements to ensure protection of human health and the environment.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008, according to Hazard Communication Standard, 29 CFR 1910.1200 (HCS), and according to HPR (WHMIS 2015):

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified</td>
<td>-</td>
</tr>
</tbody>
</table>

The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 1907/2006 (REACH) and its subsequent amendments, in accordance with Hazard Communication Standard (HCS), 29 CFR 1910.1200 (HazCom 2012) as recommended by US OSHA, and in accordance with Hazardous Product Regulation HPR (WHMIS 2015) as recommended by Health Canada (HC).

Bibliographic references: Safety Data Sheet according to EC Directive 2001/58/EC, from the supplier up the supply chain.