**Kit Name:**  ICH USP 232 Parenteral Kit

**Kit PN:**  5191-4536

This product is a kit, composed of the following individual chemical components:

### Kit Components

<table>
<thead>
<tr>
<th>Component Part Number</th>
<th>Component Name</th>
<th>Volume or mass/container and unit</th>
<th>No. of component containers/kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>5190-9770</td>
<td>Pharma Internal Standard 1</td>
<td>100 mL</td>
<td>1</td>
</tr>
<tr>
<td>5191-4533</td>
<td>ICH/USP 232 Class 1 &amp; 2 Parenteral Elements</td>
<td>100 mL</td>
<td>1</td>
</tr>
<tr>
<td>5191-4534</td>
<td>ICH/USP 232 Parenteral Combined-1</td>
<td>100 mL</td>
<td>1</td>
</tr>
<tr>
<td>5191-4535</td>
<td>ICH/USP 232 Parenteral Combined-2</td>
<td>100 mL</td>
<td>1</td>
</tr>
</tbody>
</table>

SDSs for each component follow this cover sheet.

**Transportation Information for the Kit:**

**Proper Shipping Names:**

<table>
<thead>
<tr>
<th>DOT</th>
<th>IATA/ICAO</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN3264, CORROSIVE LIQUID,</td>
<td>UN3264, CORROSIVE LIQUID,</td>
<td>UN3264, CORROSIVE LIQUID,</td>
</tr>
<tr>
<td>ACIDIC, INORGANIC, N.O.S.</td>
<td>ACIDIC, INORGANIC, N.O.S. (Nitric Acid,</td>
<td>ACIDIC, INORGANIC, N.O.S. (Nitric Acid,</td>
</tr>
<tr>
<td>(Nitric Acid, Hydrochloric Acid, Hydrofluoric Acid), 8, III</td>
<td>Hydrochloric Acid, Hydrofluoric Acid), 8, III</td>
<td>Hydrochloric Acid, Hydrofluoric Acid), 8, III</td>
</tr>
</tbody>
</table>

**China**

UN3264, CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Nitric Acid, Hydrochloric Acid, Hydrofluoric Acid), 8, III
1 Identification

- **Product identifier**
- **Product name:** Pharma Internal Standard 1
- **Part number:** 5190-9770

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.
- **Application of the substance / the mixture** Reagents and Standards for Analytical Chemical Laboratory Use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:** Agilent Technologies Australia Pty Ltd
  - 679 Springvale Road
  - Mulgrave Victoria 3170, Australia
- **Emergency telephone number:** CHEMTREC®: +(61)-290372994
  - **Further information obtainable from:** e-mail: pdl-msds_author@agilent.com

2 Hazard(s) Identification

- **Classification of the substance or mixture**
  - **Corrosion**
    - **Met. Corr. 1 H290** May be corrosive to metals.
  - **Acute Tox. 4 H302** Harmful if swallowed.
  - **Acute Tox. 4 H312** Harmful in contact with skin.
  - **Acute Tox. 4 H332** Harmful if inhaled.
  - **Skin Irrit. 2 H315** Causes skin irritation.
  - **Eye Irrit. 2A H319** Causes serious eye irritation.

- **Label elements**
- **GHS label elements**
  - The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**
  - GHS05
  - GHS07
- **Signal word** Warning
3 Composition and Information on Ingredients

- Chemical characterisation: Mixtures
- Description: Aqueous solution. Also contains substances at levels not considered to be hazardous.
- Dangerous components:
  - CAS: 7697-37-2
  - RTECS: QU5775000
  - Nitric acid
  - Ox. Liq. 2; H272; Met. Corr. I, H290; Skin Corr. 1A, H314
  - <2% of total content
- Additional information: The concentration of the acid stated in this SDS is calculated as an absolute mass concentration (%w/v). This is less than the acid concentration stated on the product label and COA, which reflects a percent value of the commercially available concentrated aqueous form of the acid. For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product. Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
- After inhalation: Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient in recovery position for transport.
Seek medical treatment.

After skin contact:
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
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:
Rinse mouth. Do not induce vomiting.
Seek medical treatment.

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

Extinguishing media
Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.

Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire.

Advice for firefighters
Protective equipment:
HazChem Code: 2X
Mouth respiratory protective device.
Wear self-contained respiratory protective device.

6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures
Wear protective equipment. Keep unprotected persons away.

Environmental precautions:
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:
Use neutralising agent.
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
DO NOT USE SAWDUST.

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/extraction at the workplace.
    Store in cool, dry place in tightly closed receptacles.
    Prevent formation of aerosols.
  - **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:**
    Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
    Store only in the original receptacle unless other advice is given on the CoA.
    Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
  - **Information about storage in one common storage facility:** Store away from foodstuffs.
  - **Further information about storage conditions:** Keep container tightly sealed.
- **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 item 7.

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
  
  **CAS:** 7697-37-2 Nitric acid

  **NES**
  - Short-term value: 10 mg/m³, 4 ppm
  - Long-term value: 5.2 mg/m³, 2 ppm

  **WES**
  - Short-term value: 10 mg/m³, 4 ppm
  - Long-term value: 5.2 mg/m³, 2 ppm

  **Additional information:** Lists used were valid at the time of SDS preparation.

- **Exposure controls**
- **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 and skin.
  - **Respiratory protection:**
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
  - **Protection of hands:**
    The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
### Protective gloves

- **Material of gloves**
  - PVC gloves
  - Neoprene gloves

- **Penetration time of glove material**
  The exact breakthrough 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information on basic physical and chemical properties</strong></td>
<td></td>
</tr>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Colourless</td>
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<tr>
<td>Odour</td>
<td>Odourless</td>
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<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong></td>
<td>&lt;2</td>
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<tr>
<td><strong>Change in condition</strong></td>
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</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Not determined.</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td><strong>Flash point:</strong></td>
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<tr>
<td><strong>Flammability (solid, gas):</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Ignition temperature:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature:</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Explosive properties:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
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</tr>
<tr>
<td>Upper</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour pressure at 20 °C:</strong></td>
<td>23 hPa</td>
</tr>
<tr>
<td><strong>Density at 20 °C:</strong></td>
<td>1.00756 g/cm³</td>
</tr>
</tbody>
</table>
Product name: Pharma Internal Standard 1

10 Stability and Reactivity

- Reactivity
  Stable under normal conditions.
  No further relevant information available.
- Chemical stability
  Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:
  Formation of toxic gases is possible during heating or in case of fire.
- Possibility of hazardous reactions
  No dangerous reactions known.
- Conditions to avoid
  Heat.
- Incompatible materials:
  Strong oxidizing agents.
  Metals.
- Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological Information

- Information on toxicological effects
- Acute toxicity
- Primary irritant effect:
  Skin corrosion/irritation: Irritant to skin and mucous membranes.
  Serious eye damage/irritation: Irritating effect.
- Respiratory or skin sensitisation
  Based on available data, the classification criteria are not met.
- Additional toxicological information:
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  Harmful
  Irritant

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.
### 13 Disposal considerations

- **Waste treatment methods**
  - **Recommendation**: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging**
  - **Recommendation**: Dispose of in accordance with national regulations.
  - **Recommended cleansing agents**: Water, if necessary together with cleansing agents.

### 14 Transport information

- **UN-Number**
  - ADG, IMDG, IATA: UN3264
  - ADG: 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID, HYDROFLUORIC ACID)
  - IMDG, IATA: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID, HYDROFLUORIC ACID)

- **Transport hazard class(es)**
  - ADG, IMDG, IATA: Class 8 Corrosive substances.
  - Label: 8

- **Packing group**
  - ADG, IMDG, IATA: III

- **Environmental hazards**: Not applicable.

- **Special precautions for user**
  - Warning: Corrosive substances.
  - Danger code (Kemler): 80
  - EMS Number: F-A,S-B
  - Segregation groups: Acids

- **Transport in bulk according to Annex II of Marpol and the IBC Code**: Not applicable.
Product name: Pharma Internal Standard 1

- Transport/Additional information:
  - ADG
  - Limited quantities (LQ) 5L
  - Excepted quantities (EQ) Code: E1
    Maximum net quantity per inner packaging: 30 ml
    Maximum net quantity per outer packaging: 1000 ml
  - Transport category 3
  - Tunnel restriction code E
  - Remarks: HazChem Code: 2X
- UN "Model Regulation": UN 3 264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N. O. S. (NITRIC ACID, HYDROFLUORIC ACID), 8, III

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Australian Inventory of Chemical Substances
    All ingredients are listed.
  - Standard for the Uniform Scheduling of Medicines and Poisons
    CAS: 7697-37-2 Nitric acid S5, S6
    CAS: 7664-39-3 hydrofluoric acid S5, S6, S7

- Hazard pictograms
  - GHS05
  - GHS07

- Signal word Warning
  - Hazard-determining components of labelling: hydrofluoric acid
  - Hazard statements
    H290 May be corrosive to metals.
    H302 Harmful if swallowed.
    H312 Harmful in contact with skin.
    H332 Harmful if inhaled.
    H315 Causes skin irritation.
    H319 Causes serious eye irritation.
- Precautionary statements
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P321 Specific treatment (see on this label).
  - P406 Store in corrosive resistant container /container with a corrosion resistant inner liner.
**Product name:** Pharma Internal Standard 1

P501 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.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

The information contained in this document is based on Agilent's state of knowledge at the time of preparation. No warranty as to its accurateness, completeness or suitability for a particular purpose is expressed or implied.

- **Relevant phrases**
  - H272 May intensify fire; oxidiser.
  - H290 May be corrosive to metals.
  - H314 Causes severe skin burns and eye damage.

- **Abbreviations and acronyms:**
  - ADR: Accord européen sur le transport 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)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Ox. Liq. 2: Oxidizing liquids – Category 2
  - Met. Corr. 1: Corrosive to metals – Category 1
  - Acute Tox. 4: Acute toxicity – Category 4
  - Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

- **Sources**
  - Data compared to the previous version altered. All sections have been updated.
1 Identification

- **Product identifier**
- **Product name:** ICH/USP 232 Class 1 & 2 Parenteral Elements
- **Part number:** 5191-4533
- **Relevant identified uses of the substance or mixture and uses advised against**
  No further relevant information available.
- **Application of the substance / the mixture**
  Reagents and Standards for Analytical Chemical Laboratory Use
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Agilent Technologies Australia Pty Ltd
    679 Springvale Road
    Mulgrave Victoria 3170,
    Australia
  - **Further information obtainable from:** e-mail: pdl-msds_author@agilent.com
  - **Emergency telephone number:** CHEMTREC®: +(61)-290372994

2 Hazard(s) Identification

- **Classification of the substance or mixture**
  - GHS label elements
    The product is classified and labelled according to the Globally Harmonised System (GHS).
  - **Hazard pictograms**
    GHS05
- **Signal word Warning**
- **Hazard statements**
  - H290 May be corrosive to metals.
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  (Contd. on page 2)
Product name: ICH/USP 232 Class 1 & 2 Parenteral Elements

- Precautionary statements
  P280  Wear protective gloves / eye protection / face protection.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P321  Specific treatment (see on this label).
  P332+P313  If skin irritation occurs: Get medical advice/attention.
  P337+P313  If eye irritation persists: Get medical advice/attention.
  P406  Store in corrosive resistant container /container with a corrosion resistant inner liner.

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

3 Composition and Information on Ingredients

- Chemical characterisation: Mixtures
- Description:  Aqueous solution.
  Also contains substances at levels not considered to be hazardous.

- Dangerous components:
  CAS: 7697-37-2  Nitric acid
  RTÉCS: QU5775000  Ox. Liq. 2, H272; Met. Corr. 1, H290; Skin Corr. 1A, H314  <2%

- Additional information:
The concentration of the acid stated in this SDS is calculated as an absolute mass concentration (%w/v). This is less than the acid concentration stated on the product label and COA, which reflects a percent value of the commercially available concentrated aqueous form of the acid.
For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- Description of first aid measures
  - General information: Immediately remove any clothing soiled by the product.
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact:
    Immediately wash with water and soap and rinse thoroughly.
    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: Rinse mouth. Do not induce vomiting.
  - 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

- Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
**Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.

**Advice for firefighters**

**Protective equipment:**
*HazChem Code: 2X*
Wear self-contained respiratory protective device.

**6 Accidental Release Measures**

- **Personal precautions, protective equipment and emergency procedures**
  Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
  Use neutralising agent.
  Dispose of contaminated material as waste according to item 13.
  Absorb liquid components with liquid-binding material.
  **DO NOT USE SAWDUST.**
- **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** Store in cool, dry place in tightly closed receptacles.
  **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  **Requirements to be met by storerooms and receptacles:**
  Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
  Store only in the original receptacle unless other advice is given on the CoA.
  Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
  **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **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 item 7.
- **Control parameters**
  **Ingredients with limit values that require monitoring at the workplace:**
  **CAS: 7697-37-2 Nitric acid**

<table>
<thead>
<tr>
<th>Label</th>
<th>Short-term value</th>
<th>Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NES</td>
<td>10 mg/m³, 4 ppm</td>
<td>5.2 mg/m³, 2 ppm</td>
</tr>
<tr>
<td>WES</td>
<td>10 mg/m³, 4 ppm</td>
<td>5.2 mg/m³, 2 ppm</td>
</tr>
</tbody>
</table>
Product name: ICH/USP 232 Class 1 & 2 Parenteral Elements

- **Additional information:** Lists used were valid at the time of SDS preparation.
- **Exposure controls**
- **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 and skin.
  - **Respiratory protection:**
    - Not required.
    - Use suitable respiratory protective device in case of insufficient ventilation.
  - **Protection of hands:**
    - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
    - The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

- **Material of gloves**
  - PVC gloves
  - Neoprene gloves
- **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

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>- Form: Liquid</td>
</tr>
<tr>
<td>- Colour: Colourless</td>
</tr>
<tr>
<td>- Odour: Odourless</td>
</tr>
<tr>
<td>- Odour threshold: Not determined.</td>
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<tr>
<td><strong>pH-value:</strong> &lt;2</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
</tr>
<tr>
<td>- Melting point/freezing point: 0 °C</td>
</tr>
<tr>
<td>- Initial boiling point and boiling range: 100 °C</td>
</tr>
</tbody>
</table>

(Contd. on page 5)
Product name: ICH/USP 232 Class 1 & 2 Parenteral Elements

- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Not determined.
- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density at 20 °C:** 1.00956 g/cm³
- **Relative density:** Not determined.
- **Vapour density:** Not determined.
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with water:** Fully miscible.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
  - Dynamic at 20 °C: 0.952 mPas
  - Kinematic: Not determined.
- **Other information** No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity**
  - Stable under normal conditions.
  - No further relevant information available.
- **Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
  - Formation of toxic gases is possible during heating or in case of fire.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** Heat.
- **Incompatible materials:**
  - Strong oxidizing agents.
  - Metals.
- **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.

### 11 Toxicological Information

- **Information on toxicological effects**
  - Acute toxicity
  - Primary irritant effect:
  - Skin corrosion/irritation Irritant to skin and mucous membranes.
**Product name:** ICH/USP 232 Class 1 & 2 Parenteral Elements

(Contd. from page 5)

- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  Irritant

### 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:**
  - Not hazardous for water.
  - Must not reach sewage water or drainage ditch undiluted or unneutralised.
- **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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
  - **Recommendation:** Dispose of in accordance with national regulations.
  - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- **UN-Number**
  - ADG, IMDG, IATA: UN3264
- **ADG**
  - 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID)
- **IMDG, IATA**
  - CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID)

(Contd. on page 7)
### Transport hazard class(es)
- ADG, IMDG, IATA

<table>
<thead>
<tr>
<th>Class</th>
<th>8 Corrosive substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>8</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Packing group</th>
<th>ADG, IMDG, IATA</th>
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</thead>
<tbody>
<tr>
<td>Label</td>
<td>III</td>
</tr>
</tbody>
</table>

### Environmental hazards:
Not applicable.

<table>
<thead>
<tr>
<th>Special precautions for user</th>
<th>Warning: Corrosive substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danger code (Kemler):</td>
<td>80</td>
</tr>
<tr>
<td>EMS Number:</td>
<td>F-A,S-B</td>
</tr>
<tr>
<td>Segregation groups</td>
<td>Acids</td>
</tr>
</tbody>
</table>

### Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

### Transport/Additional information:
- **ADG**
- **Limited quantities (LQ):** 5L
- **Excepted quantities (EQ):** Code: E1
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 1000 ml
- **Transport category:** 3
- **Tunnel restriction code:** E
- **Remarks:** HazChem Code: 2X

### UN “Model Regulation”:
- **UN 3264** CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID), 8, III

---

### 15 Regulatory information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture
- **Australian Inventory of Chemical Substances**
  All ingredients are listed.

#### Standard for the Uniform Scheduling of Medicines and Poisons

<table>
<thead>
<tr>
<th>CAS</th>
<th>Chemical</th>
<th>S5, S6</th>
<th>S4, S6, S7</th>
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<th>S2, S4, S7</th>
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<tr>
<td>CAS: 7697-37-2</td>
<td>Nitric acid</td>
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<tr>
<td>CAS: 7440-38-2</td>
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<td>S5, S6</td>
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<td>CAS: 7439-92-1</td>
<td>Lead</td>
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<td>S4</td>
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<tr>
<td>CAS: 7440-48-4</td>
<td>Cobalt</td>
<td>S4</td>
<td></td>
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<tr>
<td>CAS: 7439-97-0</td>
<td>Mercury</td>
<td>S2, S4, S7</td>
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(Contd. on page 8)
· Hazard pictograms

GHS05

· Signal word Warning

· Hazard statements

H290 May be corrosive to metals.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

· Precautionary statements

P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 Specific treatment (see on this label).
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P406 Store in corrosive resistant container / container with a corrosion resistant inner liner.

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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

16 Other information

The information contained in this document is based on Agilent’s state of knowledge at the time of preparation. No warranty as to its accurateness, completeness or suitability for a particular purpose is expressed or implied.

· Relevant phrases

H272 May intensify fire; oxidiser.
H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport 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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Ox. Liq. 2: Oxidizing liquids – Category 2
Met. Corr.1: Corrosive to metals – Category 1
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

· Sources


· Data compared to the previous version altered. All sections have been updated.
1 Identification

- **Product identifier**
  - **Product name:** ICH/USP 232 Parenteral Combined-1
  - **Part number:** 5191-4534

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the mixture**
  - Reagents and Standards for Analytical Chemical Laboratory Use

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Agilent Technologies Australia Pty Ltd
    - 679 Springvale Road
    - Mulgrave Victoria 3170,
    - Australia
  - **Emergency telephone number:** CHEMTREC®: +(61)-290372994

- **Further information obtainable from:** e-mail: pdl-msds_author@agilent.com

2 Hazard(s) Identification

- **Classification of the substance or mixture**

  ![Corrosion](corrosion.png)

  Met. Corr. 1  H290  May be corrosive to metals.
  Eye Dam. 1  H318  Causes serious eye damage.

  ![Acute Tox](acutetox.png)

  Acute Tox. 4  H302  Harmful if swallowed.
  Acute Tox. 4  H312  Harmful in contact with skin.
  Acute Tox. 4  H332  Harmful if inhaled.
  Skin Irrit. 2  H315  Causes skin irritation.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labelled according to the Globally Harmonised System (GHS).
  - **Hazard pictograms**
    - GHS05  GHS07

- **Signal word Danger**

(Contd. on page 2)


**Product name:** ICH/USP 232 Parenteral Combined-1

(Contd. from page 1)

- **Hazard-determining components of labelling:**
  - Nitric acid
  - hydrofluoric acid

- **Hazard statements**
  - H290 May be corrosive to metals.
  - H302 Harmful if swallowed.
  - H312 Harmful in contact with skin.
  - H332 Harmful if inhaled.
  - H315 Causes skin irritation.
  - H318 Causes serious eye damage.

- **Precautionary statements**
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P310 Immediately call a POISON CENTER/doctor.
  - P321 Specific treatment (see on this label).
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

### 3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:**
  - Aqueous solution.
  - Also contains substances at levels not considered to be hazardous.

- **Dangerous components:**
  - CAS: 7697-37-2
  - RTECS: QU5775000
  - Nitric acid
  - >2.5-%<5%

- **Additional information:**
  - The concentration of the acid stated in this SDS is calculated as an absolute mass concentration (%w/v). This is less than the acid concentration stated on the product label and COA, which reflects a percent value of the commercially available concentrated aqueous form of the acid.
  - For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

- **Description of first aid measures**
- **General information:**
  - Immediately remove any clothing soiled by the product.
  - Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.

- **After inhalation:**
  - Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

(Contd. on page 3)
48.1.23 In case of unconsciousness place patient in recovery position for transport.
Seek medical treatment.

After skin contact:
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:
Rinse mouth. Do not induce vomiting.
Seek medical treatment.

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

Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.

Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire.

Advice for firefighters

Protective equipment:

HazChem Code: 2X
Mouth respiratory protective device.
Wear self-contained respirator protective device.

6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures
Wear protective equipment. Keep unprotected persons away.

Environmental precautions:
Dilate with plenty of water.
Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:
Use neutralising agent.
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
DO NOT USE SAWDUST.

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/extraction at the workplace.
    Store in cool, dry place in tightly closed receptacles.
    Prevent formation of aerosols.
  - **Information about fire - and explosion protection:** No special measures required.

- **Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:**
      Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
      Store only in the original receptacle unless other advice is given on the CoA.
      Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
    - **Information about storage in one common storage facility:** Store away from foodstuffs.
    - **Further information about storage conditions:** Keep container tightly sealed.
    - **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 item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
  - **CAS: 7697-37-2 Nitric acid**
    - **NES** Short-term value: 10 mg/m³, 4 ppm
      Long-term value: 5.2 mg/m³, 2 ppm
    - **WES** Short-term value: 10 mg/m³, 4 ppm
      Long-term value: 5.2 mg/m³, 2 ppm
- **Additional information:** Lists used were valid at the time of SDS preparation.
- **Exposure controls**
- **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 skin.
    Avoid contact with the eyes and skin.
- **Respiratory protection:**
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**
  The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 5)
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

Protective gloves

- Material of gloves
  - PVC gloves
  - Neoprene gloves

- 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

- Information on basic physical and chemical properties
  - General Information
  - Appearance:
    - Form: Liquid
    - Colour: Colourless
    - Odour: Odourless
    - Odour threshold: Not determined.
  - pH-value: <2

- Change in condition
  - Melting point/freezing point: Not determined.
  - Not determined.
  - Initial boiling point and boiling range: 100 °C

- Flash point: Not applicable.
- Flammability (solid, gas): Not determined.
- Ignition temperature: Not determined
- Decomposition temperature: Not determined.
- Auto-ignition temperature: Product is not selfigniting.
- Explosive properties: Not determined.

- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.

- Vapour pressure at 20 °C: 23 hPa
- Density at 20 °C: 1.01372 g/cm³
48.1.23

· Relative density: Not determined.
· Vapour density: Not determined.
· Evaporation rate: Not determined.

· Solubility in / Miscibility with water: Fully miscible.
· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:
  Dynamic: Not determined.
  Kinematic: Not determined.

· Other information: No further relevant information available.

10 Stability and Reactivity

· Reactivity
  Stable under normal conditions.
  No further relevant information available.
· Chemical stability
  Stable under normal conditions.
· Thermal decomposition / conditions to be avoided:
  Formation of toxic gases is possible during heating or in case of fire.
· Possibility of hazardous reactions
  No dangerous reactions known.
· Conditions to avoid
  Heat.
· Incompatible materials:
  Strong oxidizing agents.
  Metals.
· Hazardous decomposition products:
  Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological Information

· Information on toxicological effects
· Acute toxicity

· LD/LC50 values relevant for classification:
  CAS: 7697-37-2 Nitric acid
  Inhalative LC50/4 h 130 mg/l (rat)

· Primary irritant effect:
  Skin corrosion/irritation: Irritant to skin and mucous membranes.
· Serious eye damage/irritation: Strong irritant with the danger of severe eye injury.
· Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.
· Additional toxicological information:
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  Harmful
  Irritant
12 Ecological Information

- Toxicity
  - Aquatic toxicity:
    - CAS: 7697-37-2 Nitric acid
      - LC50/48: 180 mg/l (crustacean)
    - CAS: 7440-50-8 Copper
      - LC50/48: 0.044 mg/l (crustacean)
      - EC50/48 h: 0.02 mg/l (crustacean)
      - EC50/72 h: 0.57 mg/l (Algae)
      - LC50/96 h: 0.665 mg/l (fish)

- 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:
  - Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
  - Do not allow undiluted product to reach ground water, water course or sewage system.
  - Must not reach sewage water or drainage ditch undiluted or unneutralised.

- 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 of together with household garbage. Do not allow product to reach sewage system.
  - Uncleaned packaging:
    - Recommendation: Dispose of in accordance with national regulations.
    - Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

- UN-Number
  - UN3264
- ADG, IMDG, IATA
  - 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID, HYDROFLUORIC ACID)
  - CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID, HYDROFLUORIC ACID)
Product name: **ICH/USP 232 Parenteral Combined-1**

### Transport hazard class(es)
- ADG, IMDG, IATA

<table>
<thead>
<tr>
<th>Class</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Corrosive substances.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Packing group</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADG, IMDG, IATA</td>
<td>III</td>
</tr>
</tbody>
</table>

### Environmental hazards:
- Not applicable.

- **Special precautions for user**
  - Warning: Corrosive substances.
  - Danger code (Kemler): 80
  - EMS Number: F-A,S-B
  - Segregation groups: Acids

### Transport in bulk according to Annex II of Marpol and the IBC Code
- Not applicable.

### Transport/Additional information:
- ADG
- Limited quantities (LQ): 5L
- Excepted quantities (EQ): Code: E1
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 1000 ml
- Transport category: 3
- Tunnel restriction code: E
- Remarks: HazChem Code: 2X

### UN "Model Regulation":
- **UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID, HYDROFLUORIC ACID), 8, III**

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### 15 Regulatory information

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

- **Australian Inventory of Chemical Substances**
  - All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**
  - CAS: 7697-37-2 Nitric acid S5, S6
  - CAS: 7664-39-3 hydrofluoric acid S5, S6, S7
  - CAS: 7440-36-0 antimony S4
  - CAS: 7440-22-4 Silver, powder S2
  - CAS: 7440-28-0 thallium S7

(Contd. on page 9)
Hazard pictograms

- GHS05
- GHS07

Signal word Danger

Hazard-determining components of labelling:
- Nitric acid
- Hydrofluoric acid

Hazard statements
- H290 May be corrosive to metals.
- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H332 Harmful if inhaled.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.

Precautionary statements
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER/doctor.
- P321 Specific treatment (see on this label).
- P501 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.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information contained in this document is based on Agilent’s state of knowledge at the time of preparation. No warranty as to its accurateness, completeness or suitability for a particular purpose is expressed or implied.

Relevant phrases
- H272 May intensify fire; oxidiser.
- H290 May be corrosive to metals.
- H314 Causes severe skin burns and eye damage.

Abbreviations and acronyms:
- ADR: Accord européen sur le transport 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)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

(Contd. on page 10)
**Product name:** ICH/USP 232 Parenteral Combined-1

(OContd. from page 9)

- Ox. Liq. 2: Oxidizing liquids – Category 2
- Met. Corr. 1: Corrosive to metals – Category 1
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Corr. 1A: Skin corrosion/irritation – Category 1A
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1

**Sources**
- **Data compared to the previous version altered.** All sections have been updated.
1 Identification

- **Product identifier**
- **Product name:** ICH/USP 232 Parenteral Combined-2
  - **Part number:** 5191-4535
- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.
- **Application of the substance / the mixture**
  - Reagents and Standards for Analytical Chemical Laboratory Use
- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Agilent Technologies Australia Pty Ltd
    - 679 Springvale Road
    - Mulgrave Victoria 3170,
    - Australia
  - **Further information obtainable from:** e-mail: pdl-msds_author@agilent.com
  - **Emergency telephone number:** CHEMTREC®: +(61)-290372994

2 Hazard(s) Identification

- **Classification of the substance or mixture**
  - Met. Corr. 1 H290 May be corrosive to metals.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**
  - GHS05

- **Signal word** Warning
- **Hazard statements**
  - H290 May be corrosive to metals.
- **Precautionary statements**
  - P234 Keep only in original container.
  - P390 Absorb spillage to prevent material damage.
  - P406 Store in corrosive resistant container/container with a corrosion resistant inner liner.
- **Other hazards**
- **Results of PBT and vPvB assessment**
  - PBT: Not applicable.
  - vPvB: Not applicable.

(Contd. on page 2)
3 Composition and Information on Ingredients

- Chemical characterisation: Mixtures
- Description:
  Aqueous solution.
  Also contains substances at levels not considered to be hazardous.

- Dangerous components:
  CAS: 7647-01-0
  RTECS: MW 9620000
  Hydrochloric acid
  Acute Tox. 3, H331;
  Skin Corr. 1B, H314; Eye Dam. 1, H318;
  STOT SE 3, H335
  ≥3–<10%

- Additional information:
  The concentration of the acid stated in this SDS is calculated as an absolute mass concentration (%w/v). This is less than the acid concentration stated on the product label and COA, which reflects a percent value of the commercially available concentrated aqueous form of the acid.
  For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- Description of first aid measures
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Immediately wash with water and soap and rinse thoroughly.
  - After eye contact: Rinse opened eye for several minutes under running water.
  - After swallowing: Rinse mouth. Do not induce vomiting.

- 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

- Extinguishing media
  - Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
  - Special hazards arising from the substance or mixture
    Formation of toxic gases is possible during heating or in case of fire.

- Advice for firefighters
  - Protective equipment:
    HazChem Code: 2R
    Wear self-contained respiratory protective device.

6 Accidental Release Measures

- Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.

- Environmental precautions:
  Dilute with plenty of water.
  Do not allow to enter sewers/surface or ground water.

- Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
7 Handling and Storage

- **Handling:**
  - **Precautions for safe handling:** Store in cool, dry place in tightly closed receptacles.
  - **Information about fire - and explosion protection:** No special measures required.

- **Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:**
      Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
      Store only in the original receptacle unless other advice is given on the CoA.
      Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
    - **Information about storage in one common storage facility:** Store away from foodstuffs.
    - **Further information about storage conditions:** Keep container tightly sealed.
  - **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 item 7.

- **Control parameters**
  - **Ingredients with limit values that require monitoring at the workplace:**

    | CAS: 7647-01-0 Hydrochloric acid |
    |---------------------------------|
    | NES Peak limitation: 7.5 mg/m³, 5 ppm |
    | WES Peak limitation: 7.5 mg/m³, 5 ppm |

- **Additional information:** Lists used were valid at the time of SDS preparation.

- **Exposure controls**
  - **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 and skin.

    - **Respiratory protection:**
      Not required.
      Use suitable respiratory protective device in case of insufficient ventilation.

    - **Protection of hands:**
      The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

**9 Physical and Chemical Properties**

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Liquid
    - **Colour:** Colourless
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** <2
  - **Change in condition**
    - Melting point/freezing point: Not determined. Not determined.
  - **Initial boiling point and boiling range:** 100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Not determined.
- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density at 20 °C:** 1.0111 g/cm³
Product name: ICH/USP 232 Parenteral Combined-2

(Contd. from page 4)

- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.
- Solubility in / Miscibility with water: Fully miscible.
- Partition coefficient: n-octanol/water: Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- Other information: No further relevant information available.

10 Stability and Reactivity

- Reactivity: Stable under normal conditions.
- No further relevant information available.
- Chemical stability: Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:
  Formation of toxic gases is possible during heating or in case of fire.
- Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid: Heat.
- Incompatible materials:
  - Strong oxidizing agents.
  - Metals.
- Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological Information

- Information on toxicological effects
- Acute toxicity
- Primary irritant effect:
  - 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.
- Additional toxicological information:
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

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.

(Contd. on page 6)
Product name: ICH/USP 232 Parenteral Combined-2

Additional ecological information:

General notes:
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.

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 of together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging:
Recommendation: Dispose of in accordance with national regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

UN-Number
ADG, IMDG, IATA UN1789
ADG
IMDG, IATA 1789 HYDROCHLORIC ACID solution

Transport hazard class(es)
ADG, IMDG, IATA

Class
8 Corrosive substances.
Label
8

Packing group
ADG, IMDG, IATA II

Environmental hazards:
Not applicable.

Special precautions for user
Warning: Corrosive substances.
Danger code (Kemler):
80
EMS Number:
F-A,S-B
Segregation groups
Acids
Stowage Category
E

Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.
Transport/Additional information:

- ADG
- Limited quantities (LQ) 1L
- Excepted quantities (EQ) Code: E2
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 500 ml
- Transport category 2
- Tunnel restriction code E
- Remarks: HazChem Code: 2R
- UN "Model Regulation": UN 1789 HYDROCHLORIC ACID SOLUTION, 8, II

15 Regulatory information

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

  - Australian Inventory of Chemical Substances
    - CAS: 7647-01-0 Hydrochloric acid
    - CAS: 7440-57-5 Gold
    - CAS: 12125-08-5 diammonium hexachloroosmate
    - CAS: 7440-05-3 Palladium
    - CAS: 7440-06-4 platinum
    - CAS: 7732-18-5 Water

  - Standard for the Uniform Scheduling of Medicines and Poisons
    - CAS: 7647-01-0 Hydrochloric acid S5, S6

- Hazard pictograms
  - GHS05

- Signal word Warning
- Hazard statements
  - H290 May be corrosive to metals.
- Precautionary statements
  - P234 Keep only in original container.
  - P390 Absorb spillage to prevent material damage.
  - P406 Store in corrosive resistant container /container with a corrosion resistant inner liner.

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information contained in this document is based on Agilent’s state of knowledge at the time of preparation. No warranty as to its accurateness, completeness or suitability for a particular purpose is expressed or implied.
Relevant phrases
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H331 Toxic if inhaled.
- H335 May cause respiratory irritation.

Abbreviations and acronyms:
ADR: Accord européen sur le transport 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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Met. Corr. 1: Corrosive to metals – Category 1
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Sources

Data compared to the previous version altered. All sections have been updated.