## SECTION 1: IDENTIFICATION

**Product Identifier**

| | | |
|---|---|---|
| Product Name | : | Procainamide Hydrochloride Injection USP |
| Product Use | : | Pharmaceutical product used as cardiovascular drug. |
| Supplier Details | : | Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA. |
| Emergency Telephone Number | : | +91-4467901901/02/03 |

## SECTION 2: HAZARDS IDENTIFICATION

**2.1 (a) Classification of the Substance or Mixture: Classification (GHS-US)**

Respiratory sensitization: Category 1 – (H334)

Skin sensitization: Category 1 – (H317)

**2.2 (b) Label Elements GHS-US Labeling:**



**Signal Word**: Danger

**Hazard Statements**

**H317** - May cause an allergic skin reaction

**H334** - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**2.3. (c) Other Hazards:**

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P272 - Contaminated work clothing must not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection P284 - Wear respiratory protection

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a Poison Center or doctor/physician

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

P501 - Dispose of contents/container in accordance with all local and national regulations

**2.4. (d) Unknown Acute Toxicity (GHS-US):** No data available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances:** Not Applicable

**3.2 Mixtures:**

| Chemical Name | CAS Number | % Composition | Functionality |
|---|---|---|---|
| Procainamide Hydrochloride | 614-39-1 | <50% | N/A |
| Methylparaben | 99-76-3 | <1% | Preservative |
| Sodium Metabisulfite | 7681-57-4 | <1% | Antioxidant |
| Sodium Hydroxide | 1310-73-2 | N/A | pH adjuster |
| Hydrochloric Acid | 7647-01-0 | N/A | pH adjuster |
| Water for Injection | 7732-18-5 | q.s to 100% | Vehicle |
| *Percentages are listed in weight by volume percentage (w/v%) for solid ingredients. | | | |

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first Aid Measures

General : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

Inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact : Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion : Rinse mouth. Do not induce vomiting. Obtain medical attention.

### 4.2. Most important symptoms and effects both acute and delayed

General : Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation : Prolonged exposure may cause irritation.

Skin Contact : Prolonged exposure may cause skin irritation.

Eye Contact : May cause slight irritation to eyes.

Ingestion : Ingestion may cause adverse effects.

Chronic Symptoms : None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE FIGHTING MEASURES

### 5.1. Extinguishing media

| | | |
|---|---|---|
| Suitable Extinguishing Media | : | Water spray, carbon dioxide ($CO_2$), foam, dry chemical. |
| Unsuitable extinguishing media | : | Do not use a heavy water stream. Use of heavy stream of water may spread fire. |

### 5.2. Specific hazards arising from the Substance or Mixture

| | | |
|---|---|---|
| Reactivity | : | Hazardous reactions will not occur under normal conditions. |

### 5.3. Advice for firefighters

| | | |
|---|---|---|
| Precautionary Measures Fire | : | Exercise caution when fighting any chemical fire. |
| Protection During Firefighting | : | Use water spray or fog for cooling exposed containers. |
| Hazardous Combustion Products | : | None expected under normal conditions of use |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

| | | |
|---|---|---|
| General Measures | : | Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). |

#### 6.1.1. For non-emergency personnel

| | | |
|---|---|---|
| Protective Equipment | ; | Use appropriate personal protective equipment (PPE). |
| Emergency Procedures | : | Evacuate unnecessary personnel. |

#### 6.1.2. For emergency personnel

| | | |
|---|---|---|
| Protective Equipment | : | Equip cleanup crew with proper protection. |
| Emergency Procedures | : | Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area. |

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and materials for containment and cleaning up

| | | |
|---|---|---|
| For Containment | : | Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. |
| Methods for Cleaning Up | : | Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill. |

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

| | | |
|---|---|---|
| Precautions for Safe Handling | : | Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. |
| Hygiene Measures | : | Handle in accordance with good industrial hygiene and safety procedures. |

### 7.2 Conditions for Safe Storage, Including Any Incompatibilities

| | | |
|---|---|---|
| Technical Measures | : | Comply with applicable regulations. |
| Storage Conditions | : | No special storage required for hazard control. Protect from light. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert. |
| Incompatible Materials | : | Not Applicable. |

## SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

### 8.1 Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Procainamide Hydrochloride

Pfizer OEL TWA-8 Hr: 100 µg/m3, Sensitizer

Procainamide Hydrochloride

| | |
|---|---|
| Russia | MAC: 0.5 mg/m3 |

**Sodium Metabisulfite USP**

| | |
|---|---|
| ACGIH TLV | 5 mg/m3 |
| Denmark | 5 mg/m3 |
| France | 5 mg/m3 |
| Ireland | 5 mg/m3<br>STEL: 15 mg/m3 |
| Spain | 5 mg/m3 |
| Switzerland | 5 mg/m3 |
| OSHA PEL (vacated) | TWA: 5 mg/m3 |
| United Kingdom | TWA: 5 mg/m3 STEL: 15 mg/m3 |

| | |
|---|---|
| **Methyl-p-hydroxybenzoate** | |
| Russia | MAC: 4 mg/m3 |
| **Sodium Hydroxide** | |
| ACGIH OEL (Ceiling) | 2 mg/m3 |
| ACGIH TLV Ceiling: | 2 mg/m3 |
| Austria | 2 mg/m3 |
| | STEL 4 mg/m3 |
| Bulgaria | 2.0 mg/m3 |
| Czech Republic | 1 mg/m3 |
| | Ceiling: 2 mg/m3 |
| Denmark | Ceiling: 2 mg/m3 |
| Estonia | 1 mg/m3 STEL: 2 mg/m3 |
| Finland Ceiling: | 2 mg/m3 |
| France | 2 mg/m3 |
| Hungary | 1 mg/m3 |
| | STEL: 2 mg/m3 |
| Ireland | STEL: 2 mg/m3 |
| Ceiling Limit Value | 2 mg/m3 |
| Latvia | 0.5 mg/m3 |
| Poland | STEL: 1 mg/m3 |
| | 0.5 mg/m3 |
| Romania | 1 mg/m3 STEL: 3 mg/m3 |
| Slovakia | 2 mg/m3 |
| Spain | STEL: 2 mg/m3 |
| Switzerland | 2 mg/m3 |
| | STEL: 2 mg/m3 |
| OSHA PEL | 2 mg/m3 |
| | (vacated) Ceiling: 2 mg/m3 |
| United Kingdom | STEL: 2 mg/m3 |

**+ Hydrochloric Acid**

| | |
|---|---|
| ACGIH OEL (Ceiling) | 2 ppm |
| ACGIH TLV Ceiling: | 2 ppm |
| Austria | 5 ppm 8 mg/m3 |
| STEL 10 ppm | |
| STEL 15 mg/m3 | |
| Bulgaria | STEL: 10 ppm |
| STEL: 15.0 mg/m3 | |
| 5 ppm | |
| 8.0 mg/m3 | |
| Czech Republic | 8 mg/m3 |
| Ceiling: 15 mg/m3 | |
| Denmark | Ceiling: 5 ppm |
| Ceiling: 8 mg/m3 | |
| Estonia | 5 ppm |
| 8 mg/m3 | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| European Union | TWA: 5 ppm |
| TWA: 8 mg/m3 | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| Finland | STEL: 5 ppm |
| STEL: 7.6 mg/m3 | |
| Germany | 2 ppm |
| 3.0 mg/m3 | |
| Ceiling/Peak: 4 ppm | |
| Ceiling/Peak: 6 mg/m3 | |
| Germany | 2 ppm |
| 3 mg/m3 | |

| | |
|---|---|
| Hungary | 8 mg/m3 |
| STEL: 16 mg/m3 | |
| Ireland | 8 mg/m3 |
| 5 ppm | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| Italy | 5 ppm |
| 8 mg/m3 | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| Ceiling Limit Value | 2 ppm |
| 3.0 mg/m3 | |
| Latvia | 5 ppm |
| 8 mg/m3 | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| Netherlands | 8 mg/m3 |
| STEL: 15 mg/m3 | |
| Poland | STEL: 10 mg/m3 |
| 5 mg/m3 | |
| Romania | 5 ppm |
| 8 mg/m3 | |
| STEL: 10 ppm | |
| STEL: 15 mg/m3 | |
| Russia | MAC: 5 mg/m3 |
| Slovakia | 5 ppm |
| 8.0 mg/m3 | |
| Spain | 5 ppm |
| 7.6 mg/m3 | |
| STEL: 10 ppm | |

STEL: 15 mg/m3

Switzerland 2 ppm

3 mg/m3

STEL: 4 ppm

STEL: 6 mg/m3

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm

7 mg/m3

OSHA PEL (vacated) Ceiling: 5 ppm

(vacated) Ceiling: 7 mg/m3

Ceiling: 5 ppm

Ceiling: 7 mg/m3

United Kingdom TWA: 1 ppm

TWA: 2 mg/m3

STEL: 5 ppm

STEL: 8 mg/m3

**8.2 Appropriate Engineering Controls:** Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**8.3 Personal Protective Equipment:** Gloves, Safety glasses.



**RESPIRATORY PROTECTION**: In case of inadequate ventilation wear respiratory protection.

**EYE PROTECTION:** Chemical goggles or safety glasses.

**HAND PROTECTION:** Wear chemically resistant protective gloves.

**SKIN and BODY PROTECTION:** Wear suitable protective clothing. Wash contaminated clothing before reuse.

**SPECIAL NOTE:** When using, do not eat, drink, or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | | |
| Physical State | : | Liquid |
| Color | : | Colorless to slight yellow |
| Odor | : | Not applicable |
| Odor Threshold | : | Not applicable |
| pH | : | 4.0 – 6.0 |
| Melting Point | : | Not available |
| Boiling Point | : | Not available |
| Flash Point | : | Not available |
| Freezing Point | : | Not available |
| Flammability (solid, gas) | : | Not applicable |
| Lower and Upper Explosive (flammable) limits | : | Not available |
| Vapour Pressure | : | Not available |
| Relative Vapor Density at 20°C | : | Not available |
| Relative Density | : | Not available |
| Specific Gravity | : | Not available |
| Water Solubility | : | Soluble |
| Partition Coefficient: n-octanol/water | : | Not available |
| Viscosity | : | Not available |

## SECTION 10: STABILITY AND REACTIVITY

| | | |
|---|---|---|
| Reactivity | : | Hazardous reactions will not occur under normal conditions. |
| Chemical Stability | : | Stable under recommended handling and storage conditions. |
| Possibility of Hazardous Reactions | : | Hazardous polymerization will not occur. |
| Conditions to Avoid | : | Direct sunlight, extremely high or low temperatures. |
| Incompatible Materials | : | Strong bases, strong oxidizers. |
| Hazardous Decomposition Products | : | None expected under normal conditions of use. |

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

The most common adverse effects seen during clinical use of this drug include gastrointestinal disturbances, abdominal pain, nausea, vomiting, diarrhea, dizziness, seizure, mental depression, confusion, impaired mental state (psychosis), hallucinations, hives, redness and swelling of the skin (urticaria), itching sensation (pruritus), skin rash, increased heart rate (tachycardia).

**(a) Likely Route of entry: Skin, eyes, or inhalation.**

**Inhalation:** Prolonged exposure may cause irritation.

**CONTACT WITH SKIN or EYES:**

**Irritation/Sensitization: (Study Type, Species, Severity) Methyl-p-hydroxybenzoate**

Skin Irritation Rabbit Non-Irritating Eye Irritation

Rabbit Slight Skin Sensitization Guinea Pig Negative

**Sodium Hydroxide**

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

**Hydrochloric Acid**

Skin Irritation Severe Eye Irritation Severe

**INGESTION**: Ingestion may cause adverse effects.

**(b) Symptoms related to the chemical, and toxicological characteristics:**

**Acute:** (Species, Route, End Point, Dose) Procainamide Hydrochloride

Mouse Oral LD50 701 mg/kg Rat Oral LD50 1509 mg/kg Rat IV LD50 95 mg/kg.

**(c) Delayed and immediate effects and chronic effects from short- and long-term exposure:**

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ) Methyl-p-hydroxybenzoate 28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus.

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s)) Methyl-p-hydroxybenzoate**

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity.

**(Species, Route, End Point, Dose) Procainamide Hydrochloride**

Mouse Oral LD50 701 mg/kg Rat Oral LD50 1509 mg/kg Rat IV LD50 95 mg/kg.

**(d) Acute Toxicity:**

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|---|---|---|
| Procainamide Hydrochloride | = 1509 mg/kg (Rat) | - | - |
| Water | > 90 mL/kg (Rat) | - | - |
| Sodium Metabisulfite USP | = 1310 mg/kg (Rat) | > 2000 mg/kg (Rat)<br>> 2 g/kg (Rat) | - |
| Methyl-p-hydroxybenzoate | = 2100 mg/kg (Rat) | - | - |
| Sodium Hydroxide | = 325 mg/kg (Rat) | = 1350 mg/kg (Rabbit) | - |
| Hydrochloric Acid | 238 - 277 mg/kg (Rat) | > 5010 mg/kg (Rabbit) | = 1.68 mg/L (Rat) 1 h |

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## SECTION 12: ECOLOGICAL INFORMATION

| | | |
|---|---|---|
| Eco Toxicity | : | Not applicable. |
| Persistence and Biodegradability | : | Not established. |
| Bio accumulative Potential | : | Not established. |
| Mobility in Soil | : | Not established. |

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1. Waste treatment methods**

(a) **Sewage Disposal Recommendations:** Do not empty into drains; dispose of this material and its container in asafe way.

(b) **Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT:** Not regulated for transport

**(a) UN Number:** Not applicable

**(b) UN Proper Shipping Name:** Not applicable.

**(c) Transportation Hazardous Class(es):** Not applicable.

**(d) Packing group:** Not applicable.

**(e) Environmental Hazards (e.g., Marine pollutant**): Not regulated for transport.

**(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable

**(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:** Not applicable**.**

**14.2. In Accordance with IMDG:** Not regulated for transport

**14.3. In Accordance with IATA:** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

**15.1. U.S. REGULATIONS:**

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

| **Procainamide Hydrochloride** | |
|---|---|
| CERCLA/SARA Section 313 de minimus % | Not listed |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 210-381 |
| AICS | Present |
| **Water for Injection** | |
| CERCLA/SARA Section 313 de minimus % | Not listed |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 231-791-2 |
| AICS | Present |
| **Sodium Metabisulfite USP** | |
| CERCLA/SARA Section 313 de minimus % | Not listed |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 231-673-0 |
| AICS | Present |
| Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) | Schedule 5 |

| | |
|---|---|
| **Methyl-p-hydroxybenzoate** | |
| CERCLA/SARA Section 313 de minimus % | Not listed |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 202-785-7 |
| AICS | Present |
| **Sodium Hydroxide** | |
| CERCLA/SARA Section 313 de minimus % | Not listed |
| Hazardous Substances RQs | 1000 lb. |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 215-185-5 |
| AICS | Present |
| Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) | Schedule 5<br>Schedule 6 |
| **Hydrochloric Acid** | |
| CERCLA/SARA Section 313 de minimus % | 1% |
| Hazardous Substances RQs | 5000 lb. |
| California Proposition 65 | Not listed |
| TSCA | Present |
| EINECS | 231-595-7 |
| AICS | Present |
| Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) | Schedule 5<br>Schedule 6 |

## SECTION 16: OTHER INFORMATION

**16.1. Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200**

**16.2. Key or legend to abbreviations and acronyms used in the safety data sheet**

| | |
|---|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AICS | Australian Inventory of Chemical Substances |
| CAS | Chemical Abstract Service Registry |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| DOT | Department of Transportation |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |
| IATA | International Civil Aviation Organization/International Air Transport Association |
| NA | Not Applicable |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RQ | Reportable Quantity |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UN | United Nations |
| USP | United States Pharmacopeia |

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**SDS Details:**

| | | |
|---|---|---|
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| **Version** | : | 00 |
| **Prepared By** | : | Caplin Steriles Limited |