

**SAFETY DATA SHEET**  
**Procainamide Hydrochloride Injection, USP**  
**1000 mg/2 mL (500 mg/mL) or 1000 mg/10 mL (100 mg/mL)**



Caplin Steriles Limited

## 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.



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**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.



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## **SECTION 5: FIRE FIGHTING MEASURES**

### **5.1. Extinguishing media**

- Suitable Extinguishing Media : Water spray, carbon dioxide (CO<sub>2</sub>), 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.



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## 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/m<sup>3</sup>, Sensitizer

Procainamide Hydrochloride

Russia	MAC: 0.5 mg/m <sup>3</sup>
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**Sodium Metabisulfite USP**

ACGIH TLV	5 mg/m <sup>3</sup>
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Denmark	5 mg/m <sup>3</sup>
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France	5 mg/m <sup>3</sup>
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Ireland	5 mg/m <sup>3</sup>
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STEL: 15 mg/m<sup>3</sup>

Spain	5 mg/m <sup>3</sup>
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Switzerland	5 mg/m <sup>3</sup>
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OSHA PEL (vacated)	TWA: 5 mg/m <sup>3</sup>
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United Kingdom	TWA: 5 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
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**Methyl-p-hydroxybenzoate**

Russia MAC: 4 mg/m<sup>3</sup>

**Sodium Hydroxide**

ACGIH OEL (Ceiling) 2 mg/m<sup>3</sup>

ACGIH TLV Ceiling: 2 mg/m<sup>3</sup>

Austria 2 mg/m<sup>3</sup>

STEL 4 mg/m<sup>3</sup>

Bulgaria 2.0 mg/m<sup>3</sup>

Czech Republic 1 mg/m<sup>3</sup>

Ceiling: 2 mg/m<sup>3</sup>

Denmark Ceiling: 2 mg/m<sup>3</sup>

Estonia 1 mg/m<sup>3</sup> STEL: 2 mg/m<sup>3</sup>

Finland Ceiling: 2 mg/m<sup>3</sup>

France 2 mg/m<sup>3</sup>

Hungary 1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Ireland STEL: 2 mg/m<sup>3</sup>

Ceiling Limit Value 2 mg/m<sup>3</sup>

Latvia 0.5 mg/m<sup>3</sup>

Poland STEL: 1 mg/m<sup>3</sup>

0.5 mg/m<sup>3</sup>

Romania 1 mg/m<sup>3</sup> STEL: 3 mg/m<sup>3</sup>

Slovakia 2 mg/m<sup>3</sup>

Spain STEL: 2 mg/m<sup>3</sup>

Switzerland 2 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

OSHA PEL 2 mg/m<sup>3</sup>

(vacated) Ceiling: 2 mg/m<sup>3</sup>

United Kingdom STEL: 2 mg/m<sup>3</sup>



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**+ Hydrochloric Acid**

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



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Hungary	8 mg/m <sup>3</sup>
STEL: 16 mg/m <sup>3</sup>	
Ireland	8 mg/m <sup>3</sup>
5 ppm	
STEL: 10 ppm	
STEL: 15 mg/m <sup>3</sup>	
Italy	5 ppm
8 mg/m <sup>3</sup>	
STEL: 10 ppm	
STEL: 15 mg/m <sup>3</sup>	
Ceiling Limit Value	2 ppm
3.0 mg/m <sup>3</sup>	
Latvia	5 ppm
8 mg/m <sup>3</sup>	
STEL: 10 ppm	
STEL: 15 mg/m <sup>3</sup>	
Netherlands	8 mg/m <sup>3</sup>
STEL: 15 mg/m <sup>3</sup>	
Poland	STEL: 10 mg/m <sup>3</sup>
5 mg/m <sup>3</sup>	
Romania	5 ppm
8 mg/m <sup>3</sup>	
STEL: 10 ppm	
STEL: 15 mg/m <sup>3</sup>	
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm
8.0 mg/m <sup>3</sup>	
Spain	5 ppm
7.6 mg/m <sup>3</sup>	
STEL: 10 ppm	



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STEL: 15 mg/m<sup>3</sup>

Switzerland

2 ppm

3 mg/m<sup>3</sup>

STEL: 4 ppm

STEL: 6 mg/m<sup>3</sup>

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

5 ppm

7 mg/m<sup>3</sup>

OSHA PEL

(vacated) Ceiling: 5 ppm

(vacated) Ceiling: 7 mg/m<sup>3</sup>

Ceiling: 5 ppm

Ceiling: 7 mg/m<sup>3</sup>

United Kingdom

TWA: 1 ppm

TWA: 2 mg/m<sup>3</sup>

STEL: 5 ppm

STEL: 8 mg/m<sup>3</sup>

**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.





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## 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.



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### 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) > 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.



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### 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 a safe 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

<b>Procainamide Hydrochloride</b>	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	210-381
AICS	Present
<b>Water for Injection</b>	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	231-791-2
AICS	Present
<b>Sodium Metabisulfite USP</b>	
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



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<b>Methyl-p-hydroxybenzoate</b>	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	202-785-7
AICS	Present
<b>Sodium Hydroxide</b>	
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 Schedule 6
<b>Hydrochloric Acid</b>	
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 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



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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:**

**Issued Date** : 17.07.24  
**Revision Date** : NA  
**Version** : 00  
**Prepared By** : Caplin Steriles Limited