MATERIAL SAFETY DATA SHEET

Product Name: Procainamide Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Procainamide Hydrochloride Injection

Synonyms
ρ-amino-N-[2-(diethylamino) ethyl] benzamide mono-hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Procainamide Hydrochloride

Chemical Formula
$C_{13}H_{21}N_3O \bullet HCl$

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include methylparaben and sodium metabisulfite. Sodium hydroxide and/or hydrochloric acid may be use to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Procainamide Hydrochloride	≤50	614-39-1	CV2295000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Procainamide Hydrochloride	Not Listed	Not Listed	Not Listed

Emergency Overview
Procainamide Hydrochloride Injection is a solution containing procainamide hydrochloride, an anti-arrhythmic agent used in the treatment of both atrial and ventricular arrhythmias. In the workplace, this product should be considered potentially irritating to the eyes and respiratory tract. This product also contains a sulfite and may cause an allergic reaction in persons sensitive to sulfites. Based on clinical use, possible target organs include the heart, hematopoietic system, immune system and possibly the skin.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, adverse effects may include gastrointestinal effects such as anorexia, bitter taste, abdominal pain, nausea, vomiting and diarrhea. Effects on the nervous system may include dizziness, giddiness, seizure, mental depression, confusion, and psychosis with hallucinations. Dermatologic effects may include

	urticaria, pruritis, and a maculopapular rash. Procainamide hydrochloride is also cardiotoxic. Toxicities may include an increase in ventricular rate when used for atrial fibrillation or flutter; tachycardia; widening of the QRS (and other conduction delays); and an increased risk of complete heart block, especially with a history of 1st or 2nd degree heart block. Elevations in liver function tests [AST (SGOT), ALT (SGPT)] and amylase may occur rarely. Persons who are sensitized to procaine or other ester-type anesthetics may develop cross-reactivity. Manifestations may be allergic dermatitis, asthma, or anaphylaxis.
Medical Conditions Aggravated by Exposure	Hypersensitivity to the material and/or similar materials; hypersensitivity to sulfites; pre-existing skin, blood, or cardiovascular ailments.

4. FIRST AID MEASURES

Eye contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Extinguishing media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling	No special handling required for hazard control under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary

container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits				
Component	**Type**	**mg/m3**	**ppm**	**µg/m3**	**Note**
Procainamide Hydrochloride	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Clear and colorless
Odor	NA
Odor Threshold:	NA
pH:	5.0 (4.0 to 6.0)
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	NA
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Reactivity Not determined

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined

Conditions to avoid Not determined

Incompatibilities Not determined

Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Procainamide Hydrochloride	100	LD50	Oral	1509 701	mg/kg mg/kg	Rat Mouse
Procainamide Hydrochloride	100	LD50	Intravenous	95 95	mg/kg mg/kg	Rat Mouse

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. However, this product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes, in certain susceptible people. Sulfite sensitivity is seen more frequently in asthmatics than in non-asthmatic people.

Reproductive Effects Studies in animals to evaluate the affect on fertility or development have not been conducted.

Mutagenicity Studies to evaluate the mutagenic potential have not been conducted.

Carcinogenicity Long-term studies in animals to evaluate the carcinogenic potential have not been conducted.

Target Organ Effects Based on clinical use, possible target organs include the heart, hematopoietic

system, immune system and possibly the skin

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product

Persistence/Biodegradability Not determined for product

Bioaccumulation Not determined for product

Mobility in Soil Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Procainamide Hydrochloride	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed

U.S. OSHA Classification Target Organ Toxin
Possible Irritant

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category	Not Applicable
Signal Word	Not Applicable
Symbol	Not Applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
Hazard Statement	Not Applicable
Response:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Procainamide Hydrochloride

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Classification(s):	Not Applicable
Symbol:	Not Applicable
Indication of Danger:	Not Applicable
Risk Phrases:	Not Applicable
Safety Phrases:	S23 - Do not breathe vapor. S24 - Avoid contact with skin. S25 - Avoid contact with eyes. S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

Product Name: Procainamide Hydrochloride Injection

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