Procainamide Hydrochloride Injection, USP;
1000 mg/2 mL (500 mg/mL) or 1000 mg/10 mL (100 mg/mL)
Safety Data Sheet (SDS)

1. IDENTIFICATION

(a)	**Product Identifier:**	Procainamide Hydrochloride Injection, USP
(b)	**Product Code:**	NDC 14789-900-02 and 14789-900-10
	Common/Trade Name:	Procainamide Hydrochloride Injection, USP
	Chemical Name:	Benzamide, 4-amino-*N*-[2-(diethylamino)ethyl]-, monohydrochloride
	Chemical Family:	Not Determined
(c)	**Product Use:**	a Group 1A cardiac antiarrhythmic drug
	Product Type:	Regulated Prescription Drug
	Container Information:	Vial
(d)	**Distributor:**	Nexus Pharmaceuticals, Inc., 175 E. Hawthorn Parkway, Suite 155, Vernon Hills, IL 60061, 847-996-3790
(e)	**Emergency Telephone:**	800-913-2720

2. HAZARDS IDENTIFICATION

(a)	**Classification:**	GHS Classification: Respiratory Sensitization: Category 1; Skin Sensitization: Category 1.
(b)	**Signal Word**	Danger
	Hazard statement(s), Symbol(s)	H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	Precautionary statement(s):	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 CENTRE 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

(c) Description of Hazards: N/A

(d) Unknown Acute Toxicity: N/A

3. COMPOSITION / INFORMATION ON INGREDIENTS

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Procainamide Hydrochloride	N/A	≤50%	614-39-1	N/A
Methylparaben	N/A	<1%	99-76-3	Preservative
Sodium Metabisulfite	N/A	<1%	7681-57-4	Antioxidant
Sodium Hydroxide	N/A	N/A	1310-73-2	To adjust pH
Hydrochloric Acid	N/A	N/A	7647-01-0	To adjust pH
Water for Injection	N/A	q.s. to 100%	7732-18-5	N/A

4. FIRST AID MEASURES

Eye Exposure: Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

Skin Exposure: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Injection:	N/A
Inhalation:	Move to fresh air If discomfort occurs, get medical attention. Persons developing anaphylatic (allergic) reactions must receive immediate medical assistance.
Notes to Physician:	None.

5. FIRE-FIGHTING MEASURES

(a)	**Extinguishing Media**	As with any fire, use extinguishing media appropriate for primary cause of fire.
(b)	**Hazardous Combustion Products:**	Formation of toxic gases is possible during heating or fire. Emits toxic fumes of carbon monoxide, oxides of nitrogen and hydrogen chloride
(c)	**Special Protective Equipment / Precautions:**	No special provisions required beyond normal firefighting equipment. As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

6. ACCIDENTAL RELEASE MEASURES

Spill:	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.
Release to Air:	N/A

Release to Water: N/A

7. HANDLING AND STORAGE

General Handling: No special handling required for hazard control under conditions of normal product use.

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Procainamide HCl	Pfizer OEL	TWA 8hr	1.3 mg/m^3
Sodium Metabisulfite	ACGIH	TWA	5 mg/m^3
Sodium Hydroxide	OSHA Final PELS	TWA	2 mg/m^3
	ACGIH	Ceiling	2 mg/m^3
Hydrochloric Acid	ACGIH	Ceiling	2 ppm

(b) Engineering Controls

Ventilation: N/A

(c) Individual Protection Measures

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.

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.
Skin Protection:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Other Protective Equipment:	N/A
Additional Exposure Precautions:	N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

(a)	**Appearance**	Liquid; Colorless to Slightly Yellow
(b)	**Odor**	N/A
(c)	**Odor Threshold**	N/A
(d)	**pH**	4.0 -6.0
(e)	**Melting Point:**	N/A
(f)	**Initial Boiling Point:**	N/A
(g)	**Flash Point**	N/A
(h)	**Evaporation Rate:**	N/A
(i)	**Flammability**	N/A
(j)	**Upper Lower Flammability or Explosion Limits**	N/A
(k)	**Vapor Pressure:**	N/A
(l)	**Vapor Density:**	N/A
(m)	**Relative Density**	N/A
(n)	**Solubility(ies)**	Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	N/A
(p)	**Auto-ignition Temperature**	N/A
(q)	**Decomposition Temperature**	N/A
(r)	**Viscosity**	N/A

10. STABILITY AND REACTIVITY

(a)	**Reactivity**	Not determined.
(b)	**Chemical Stability**	Stable under standard use and storage conditions.
(c)	**Possibility of Hazardous Reactions**	Not determined.
(d)	**Conditions to Avoid**	Not determined.
(e)	**Incompatible Materials**	Not determined.
(f)	**Hazardous Decomposition Products**	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride

11. TOXICOLOGICAL INFORMATION

(a)	**Likely Routes of Exposure**	Ingestion, Inhalation, skin, eye
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	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).
(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	See (b) above

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Procainamide Hydrochloride	LD_{50}	Oral	Rat Mouse	1509 mg/ kg 701 mg/ kg
		IV	Rat	95 mg/kg
Hydrochloric Acid	LD_{50}	Oral	Rat	238 - 277 mg/ kg

(e) Hazardous Chemical Listings

NTP: Not listed
IARC: Hydrochloric Acid and Sodium Metabisulfite: Group 3 (Not Classifiable)
OSHA: Not listed

12. ECOLOGICAL INFORMATION

(a)	**Ecotoxicity**	N/A
(b)	**Persistence and degradability**	Not determined for product.
(c)	**Bioaccumulative potential**	Not determined for product.
(d)	**Mobility in soil**	Not determined for product.
(e)	**Other Adverse Effects**	N/A

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. TRANSPORT INFORMATION

(a)	**UN Number**	N/A
(b)	**UN Proper Shipping Name**	N/A
(c)	**Transport Hazard Class(es)**	N/A
(d)	**Packing Group**	N/A
(e)	**Environmental Hazards**	N/A

(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	N/A
(g)	**Special Precautions**	N/A

DOT status: Not regulated
IMDG Status: Not regulated
ICAO/IATA Status: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Nexus usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:
CERCLA/SARA 313: Hydrochloric Acid: 1.0%
CERCLA/SARA Hazardous Substances and their reportable quantities:
Hydrochloric Acid: 5000 lb/2270 kg; Sodium Hydroxide: 1000 lb/454 kg
CERCLA/SARA 302 TPQs: Hydrochloric Acid: 500 lb
CERCLA/SARA 302 EPCRA RQs: Hydrochloric Acid: 5000 lb
Inventory - United states TSCA - Sect. 8(b): All: Present

16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

NEXUS PHARMACEUTICALS

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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity

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RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System