SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Procainamide Hydrochloride Injection, USP (Hospira Inc.)

Product Code(s) PZ03124
Trade Name: Procainamide Hydrochloride Injection, USP
Chemical Family: Not determined

Contains Procainamide Hydrochloride

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as cardiovascular drug

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Respiratory sensitization Category 1 - (H334)
Skin sensitization Category 1 - (H317)

2.2. Label elements

Signal word Danger

Hazard statements H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P284 - In case of inadequate ventilation wear respiratory protection
P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor
P280 - Wear eye protection/ face protection
P321 - Specific treatment (see .? on this label)

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Procainamide Hydrochloride	210-381-7	614-39-1	<50	Acute Tox 4 (H302)Sens 1 (H317)Sens (H334)	
Sodium metabisulfite USP	231-673-0	7681-57-4	<1	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	
Sodium hydroxide	215-185-5	1310-73-2	**	Skin Corr.1A (H314)	
Hydrochloric Acid	231-595-7	7647-01-0	**	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Methyl-p-hydroxybenzoate	202-785-7	99-76-3	*	Aquatic Chronic 2 (H411)	

Full text of H- and EUH-phrases: see section 16

Additional information * Proprietary

** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Move to fresh air. If discomfort occurs, get medical attention. Persons developing anaphylatic (allergic) reactions must receive immediate medical assistance.

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

Skin contact 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.

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

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

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.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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 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	2 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
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. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colourless
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

Property	**Values**
pH	4.0-6.0
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	None

9.2. Other information

Liquid Density	No data available
Bulk density	No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No data available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.
10.4. Conditions to avoid
Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials
Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products
Hazardous decomposition products Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General Information: The information included in this section describes the potential hazards of the individual ingredients
Known Clinical 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).

Acute 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
Methyl-p-hydroxybenzoate
Mouse Oral LD50 > 8 g/kg
Rat Oral LD 50 2100 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

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.

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

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Methyl-p-hydroxybenzoate
In Vivo Dominant Lethal Assay Rat Negative
Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Sodium metabisulfite USP
IARC Group 3 (Not Classifiable)
Hydrochloric Acid
IARC Group 3 (Not Classifiable)

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Methyl-p-hydroxybenzoate
Oryzias latipes (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/l
Daphnia magna (Water Flea) ISO EC50 48 hours 11.2 mg/L

12.2. Persistence and degradability

Persistence and degradability .

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Methyl-p-hydroxybenzoate
OECD Activated sludge Ultimate (CO_2 Evolution) 89 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical Name	PBT and vPvB assessment
Sodium metabisulfite USP	The substance is not PBT / vPvB PBT assessment does not apply
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: REGULATORY INFORMATION

15.1. 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	210-381-7
AICS	Present

Water

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 Schedule 6

Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
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

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3
H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H318 - Causes serious eye damage H331 - Toxic if inhaled H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 - May cause respiratory irritation H411 - Toxic to aquatic life with long lasting effects

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 16 - Other Information.
Revision date	19-Mar-2020
Prepared By	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

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