



# SAFETY DATA SHEET

Revision date 02-Oct-2025

Version 2.01

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## 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

### 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

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Respiratory sensitization**

Category 1 - (H334)

**Skin sensitization**

Category 1 - (H317)

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

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## 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 - EU (§28, 1272/2008)

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)

## Unknown acute toxicity

45 - 50 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

45 - 50 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

## Unknown aquatic toxicity

Contains 45 - 50 % of components with unknown hazards to the aquatic environment.

## 2.3. Other hazards

### Other hazards

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

### Procainamide Hydrochloride

Pfizer OEL TWA-8 Hr:

100 µg/m<sup>3</sup>, Sensitizer

### PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

### Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

### 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

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

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Procainamide Hydrochloride (CAS #: 614-39-1)	45 - 50		210-381-7	Acute Tox 4 (H302)Sens 1 (H317)Sens (H334)	Not classified	No data available	No data available
Sodium metabisulfite USP (CAS #: 7681-57-4)	<1		231-673-0 (016-063-00-2)	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Procainamide Hydrochloride 614-39-1	1509	No data available	No data available	No data available	No data available
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sodium metabisulfite USP 7681-57-4	1310	2000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

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This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## 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 victim to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.
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.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as 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.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## 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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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/m<sup>3</sup>, Sensitizer

#### Procainamide Hydrochloride

Russia

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

#### Sodium metabisulfite USP

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ACGIH TLV  
Denmark

TWA: 5 mg/m<sup>3</sup>  
TWA: 5 mg/m<sup>3</sup>;  
STEL: 10 mg/m<sup>3</sup>;  
5 mg/m<sup>3</sup>  
TWA: 5 mg/m<sup>3</sup>;  
STEL: 15 mg/m<sup>3</sup> (calculated; thoracic fraction);  
TWA-(VLA-ED): 5 mg/m<sup>3</sup>;  
TWA-MAK: 5 mg/m<sup>3</sup>; inhalable dust  
(vacated) TWA: 5 mg/m<sup>3</sup>  
TWA: 5 mg/m<sup>3</sup>;  
STEL: 15 mg/m<sup>3</sup>;

## Methyl-p-hydroxybenzoate

Russia

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

## Sodium hydroxide

ACGIH OEL (Ceiling)  
ACGIH TLV  
Austria

2 mg/m<sup>3</sup>  
Ceiling: 2 mg/m<sup>3</sup>  
TWA-TMW: 2 mg/m<sup>3</sup>; inhalable fraction  
STEL-KZGW: 4 mg/m<sup>3</sup> (8 X 5 min); inhalable fraction  
TWA: 2.0 mg/m<sup>3</sup>; alkaline aerosols  
1 mg/m<sup>3</sup>  
Ceiling: 2 mg/m<sup>3</sup>  
Ceiling: 2 mg/m<sup>3</sup>;  
TWA: 1 mg/m<sup>3</sup>;  
STEL: 2 mg/m<sup>3</sup>;  
Ceiling: 2 mg/m<sup>3</sup>;  
2 mg/m<sup>3</sup>  
TWA-AK: 1 mg/m<sup>3</sup>;  
STEL-CK: 2 mg/m<sup>3</sup>;  
STEL: 2 mg/m<sup>3</sup>;  
2 mg/m<sup>3</sup>  
TWA: 0.5 mg/m<sup>3</sup>;  
TWA-NDS: 0.5 mg/m<sup>3</sup>;  
STEL-NDSch: 1 mg/m<sup>3</sup>;  
TWA: 1 mg/m<sup>3</sup>;  
STEL: 3 mg/m<sup>3</sup>;  
TWA: 2 mg/m<sup>3</sup>;  
STEL (VLA-EC): 2 mg/m<sup>3</sup>;  
TWA-MAK: 2 mg/m<sup>3</sup>; inhalable dust  
STEL-KZGW: 2 mg/m<sup>3</sup>; inhalable dust  
TWA: 2 mg/m<sup>3</sup>  
(vacated) Ceiling: 2 mg/m<sup>3</sup>  
STEL: 2 mg/m<sup>3</sup>;

Bulgaria  
Czech Republic

Denmark  
Estonia

Finland  
France  
Hungary

Ireland  
Ceiling Limit Value  
Latvia  
Poland

Romania

Slovakia  
Spain  
Switzerland

OSHA PEL

United Kingdom

## + Hydrochloric Acid

ACGIH OEL (Ceiling)  
ACGIH TLV  
Austria

2 ppm  
Ceiling: 2 ppm  
TWA-TMW: 5 ppm;  
TWA-TMW: 8 mg/m<sup>3</sup>;  
STEL-KZGW: 10 ppm (8 X 5 min);  
STEL-KZGW: 15 mg/m<sup>3</sup> (8 X 5 min);  
TWA: 5 ppm;  
TWA: 8.0 mg/m<sup>3</sup>;  
STEL: 10 ppm;  
STEL: 15.0 mg/m<sup>3</sup>;  
8 mg/m<sup>3</sup>  
Ceiling: 15 mg/m<sup>3</sup>  
STEL: 5 ppm;  
STEL: 8 mg/m<sup>3</sup>;  
TWA: 5 ppm;

Bulgaria

Czech Republic

Denmark

Estonia

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European Union	TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ; 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 DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m <sup>3</sup> ; I(2); Peak: 4 ppm; Peak: 6 mg/m <sup>3</sup> ;
Germany TRGS	TWA-AGW: 2 ppm (exposure factor 2); TWA-AGW: 3 mg/m <sup>3</sup> (exposure factor 2);
Hungary	TWA-AK: 8 mg/m <sup>3</sup> ; TWA-AK: 5 ppm; STEL-CK: 165 mg/m <sup>3</sup> ; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m <sup>3</sup> ; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Italy MDLPS	TWA: 5 ppm; TWA: 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	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m <sup>3</sup> ; STEL: 10 ppm; STEL: 15 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 5 mg/m <sup>3</sup> ; STEL-NDSch: 10 mg/m <sup>3</sup> ;
Romania	TWA: 5 ppm; TWA: 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	TWA: 5 ppm; TWA: 8.0 mg/m <sup>3</sup> ; Ceiling: 15 mg/m <sup>3</sup> ;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m <sup>3</sup> ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m <sup>3</sup> ;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m <sup>3</sup> ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m <sup>3</sup> ;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m <sup>3</sup>
OSHA PEL	Ceiling: 5 ppm

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United Kingdom

Ceiling: 7 mg/m<sup>3</sup>  
(vacated) Ceiling: 5 ppm  
(vacated) Ceiling: 7 mg/m<sup>3</sup>  
TWA: 1 ppm; gas and aerosol mist  
TWA: 2 mg/m<sup>3</sup>; gas and aerosol mist  
STEL: 5 ppm; gas and aerosol mist  
STEL: 8 mg/m<sup>3</sup>; gas and aerosol mist

## Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Sodium metabisulfite USP 7681-57-4	-	-	225 mg/m <sup>3</sup> [4] [6]
Methyl-p-hydroxybenzoate 99-76-3	-	29.41 mg/kg bw/day [4] [6]	176.3 mg/m <sup>3</sup> [4] [6]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m <sup>3</sup> [5] [6] 15 mg/m <sup>3</sup> [5] [7]

## Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Sodium metabisulfite USP 7681-57-4	8.6 mg/kg bw/day [4] [6]	-	66 mg/m <sup>3</sup> [4] [6]
Methyl-p-hydroxybenzoate 99-76-3	12.5 mg/kg bw/day [4] [6]	-	43.45 mg/m <sup>3</sup> [4] [6]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m <sup>3</sup> [5] [6] 15 mg/m <sup>3</sup> [5] [7]

## Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Methyl-p-hydroxybenzoate 99-76-3	2.4 µg/L	0.112 mg/L	0.24 µg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Methyl-p-hydroxybenzoate 99-76-3	63.2 µg/kg sediment dw	6.32 µg/kg sediment dw	2 mg/L	11.5 µg/kg soil dw	-

## 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.

### 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



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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.).

## Thermal hazards

No information available.

## Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colourless
Odor	No information available.
Odor threshold	No information available

Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	4.0-6.0
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	
Water solubility	Soluble in water
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available

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## Particle characteristics

Particle Size

No information available

Particle Size Distribution

No information available

## 9.2. Other information

Molecular formula

Mixture

Molecular weight

Mixture

### 9.2.1. Information with regard to physical hazard classes

Oxidizing properties

None

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity

No information available.

### 10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact

No information available.

Sensitivity to static discharge

No information 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 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Classification is based on mixture calculation methods based on component data.

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**STOT - single exposure** Based on available data, the classification criteria are not met.  
**STOT - repeated exposure** Based on available data, the classification criteria are not met.  
**Reproductive toxicity** Based on available data, the classification criteria are not met.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

## **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 )	-
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.

### **Unknown acute toxicity**

45 - 50 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

45 - 50 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

## **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

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## 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

### + Hydrochloric Acid

IARC

Group 3

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### **11.2.2. Other information**

**Other adverse effects**

No information available.

## **Section 12: ECOLOGICAL INFORMATION**

### **Environmental Overview:**

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

### **Unknown aquatic toxicity**

Contains 45 - 50 % of components with unknown hazards to the aquatic environment.

### **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 (CO2 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**

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**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Sodium metabisulfite USP	Not PBT/vPvB PBT assessment does not apply
Methyl-p-hydroxybenzoate	Not PBT/vPvB
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Procainamide Hydrochloride	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present

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<b>EINECS</b>	210-381-7
Water	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present
Sodium metabisulfite USP	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-673-0
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
Methyl-p-hydroxybenzoate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-785-7
<b>AICS</b>	Present
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
+ Hydrochloric Acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

## National regulations

### France

#### **Occupational Illnesses (R-463-3, France)**

Chemical name	French RG number
Sodium metabisulfite USP 7681-57-4	RG 66

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

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**Storage of Hazardous Material**  
**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20**  
**Major Accidents Ordinance SR 814.012**

Not applicable  
Not applicable  
Not applicable

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium metabisulfite USP 7681-57-4	75	-
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

## Persistent Organic Pollutants

Not applicable

## Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

## Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

## Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sodium metabisulfite USP 7681-57-4	Product-type 9: Fiber, leather, rubber and polymerized materials preservatives
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

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## 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 any hazard and/or precautionary statements referred to under Sections 2-15**

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.

#### **Classification procedure**

Calculation method

#### **Data Sources:**

Pfizer proprietary drug development information. Publicly available toxicity information.

#### **Reason for revision**

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

#### **Revision date**

02-Oct-2025

#### **Prepared By**

Pfizer Global Environment, Health, and Safety

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