



A Pfizer Company

SAFETY DATA SHEET

Revision date: 08-Aug-2018

Version: 1.0

Page 1 of 10

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Trade Name: Pancuronium Bromide Injection

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

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

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 2 of 10

Revision date: 08-Aug-2018

Version: 1.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Pancuronium Bromide	15500-66-0	239-532-5	Acute Tox 3 (H301)	0.1
ACETIC ACID	64-19-7	200-580-7	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	**
BENZYL ALCOHOL	100-51-6	202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	1
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
Sodium Acetate	127-09-3	204-823-8	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 3 of 10

Revision date: 08-Aug-2018

Version: 1.0

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None known

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

ACETIC ACID

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m ³
Australia TWA	10 ppm
	25 mg/m ³
Austria OEL - MAKs	10 ppm
	25 mg/m ³
Belgium OEL - TWA	10 ppm
	25 mg/m ³
Bulgaria OEL - TWA	25.0 mg/m ³
Cyprus OEL - TWA	10 ppm
	25 mg/m ³
Czech Republic OEL - TWA	25 mg/m ³

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 4 of 10

Revision date: 08-Aug-2018

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	10 ppm
	25 mg/m ³
Estonia OEL - TWA	10 ppm
	25 mg/m ³
Finland OEL - TWA	5 ppm
	13 mg/m ³
Germany - TRGS 900 - TWAs	10 ppm
	25 mg/m ³
Germany (DFG) - MAK	10 ppm
	25 mg/m ³
Greece OEL - TWA	10 ppm
	25 mg/m ³
Hungary OEL - TWA	25 mg/m ³
Ireland OEL - TWAs	10 ppm
	25 mg/m ³
Latvia OEL - TWA	10 ppm
	25 mg/m ³
Lithuania OEL - TWA	10 ppm
	25 mg/m ³
Luxembourg OEL - TWA	10 ppm
	25 mg/m ³
Malta OEL - TWA	10 ppm
	25 mg/m ³
Netherlands OEL - TWA	25 mg/m ³
OSHA - Final PELs - TWAs:	10 ppm
	25 mg/m ³
Poland OEL - TWA	25 mg/m ³
Portugal OEL - TWA	10 ppm
	25 mg/m ³
Romania OEL - TWA	10 ppm
	25 mg/m ³
Slovakia OEL - TWA	10 ppm
	25 mg/m ³
Slovenia OEL - TWA	10 ppm
	25 mg/m ³
Spain OEL - TWA	10 ppm
	25 mg/m ³
Sweden OEL - TWAs	5 ppm
	13 mg/m ³
Switzerland OEL - TWAs	10 ppm
	25 mg/m ³
Vietnam OEL - TWAs	25 mg/m ³

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr:	10 ppm
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 5 of 10

Revision date: 08-Aug-2018

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Pancuronium Bromide

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium Acetate

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

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).

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.)

Eyes: 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.)

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 6 of 10

Revision date: 08-Aug-2018

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Colourless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	3.8-4.2
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

SODIUM CHLORIDE

No data available

Water for Injection

No data available

BENZYL ALCOHOL

No data available

Sodium Acetate

No data available

ACETIC ACID

No data available

SODIUM HYDROXIDE

No data available

Pancuronium Bromide

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 7 of 10

Revision date: 08-Aug-2018

Version: 1.0

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

Conditions to Avoid: None known

Incompatible Materials: None known

Hazardous Decomposition Products: Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide, and halogen containing gases.

11. TOXICOLOGICAL INFORMATION

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 increase in blood pressure (hypertension), salivation, increased sweating, musculoskeletal system weakness, paralysis, respiratory arrest, troubled breathing. Serious allergic reactions, including anaphylaxis, have been reported.

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3g/kg

Mouse Oral LD 50 4g/kg

Rabbit Dermal LD 50 > 10g/kg

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg

Mouse Oral LD 50 1360mg/kg

Rabbit Dermal LD 50 2gm/kg

Sodium Acetate

Rat Oral LD 50 3500 mg/kg

Mouse Oral LD 50 4960mg/kg

ACETIC ACID

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H

Rat Oral LD 50 3310mg/kg

Rabbit Dermal LD 50 1060uL/kg

Pancuronium Bromide

Rat Oral LD50 202 mg/kg

Mouse Oral LD50 21.2mg/kg

Rat Intravenous LD50 154ug/kg

Mouse Intravenous LD50 13ug/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 8 of 10

Revision date: 08-Aug-2018

Version: 1.0

11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pancuronium Bromide

Embryo / Fetal Development	Rat	Injection	1.6 times human dose	NOAEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	0.2 times human dose	NOAEL	Not Teratogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

BENZYL ALCOHOL

Fathead Minnow	NPDES	LC-50	96 Hours	460 - 770 mg/L
Bluegill	NPDES	LC-50	96 Hours	10 mg/L
<i>Daphnia Magna</i> (Water Flea)	Surrogate	ErC50	48 Hours	23 - 400 mg/L

ACETIC ACID

Fathead Minnow	NPDES	LC-50	96 Hours	88 mg/L
Bluegill Sunfish	NPDES	LC-50	96 Hours	75 mg/L
Goldfish	NPDES	LC-50	24 Hours	423 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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.

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.

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 9 of 10

Revision date: 08-Aug-2018

Version: 1.0

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Pancuronium Bromide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	239-532-5

ACETIC ACID

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

BENZYL ALCOHOL

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

SAFETY DATA SHEET

Material Name: Pancuronium Bromide Injection, USP (Hospira Inc.)

Page 10 of 10

Revision date: 08-Aug-2018

Version: 1.0

15. REGULATORY INFORMATION

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.3; H226 - Flammable liquid and vapor
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 08-Aug-2018

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet