



SAFETY DATA SHEET

Revision date: 11-Nov-2016

Version: 1.1

Page 1 of 10

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

Product Identifier

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Trade Name: Bupivacaine Injection

Synonyms: Bupivacaine Spinal (Bupivacaine in Dextrose, USP)

Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as anesthetic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc

Pfizer Pharmaceuticals Group

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Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4

Label Elements

Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Revision date: 11-Nov-2016

Page 2 of 10

Version: 1.1



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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Bupivacaine Hydrochloride	14252-80-3	Not Listed	Acute Tox. 2 (H300)	</= 0.75
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
Dextrose	14431-43-7	Not Listed	Not Listed	*

Additional Information:

* Proprietary
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:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 3 of 10

Revision date: 11-Nov-2016

Version: 1.1

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
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5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not flammable.

Advice for Fire-Fighters

During all fire fighting 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: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

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.

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.

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 4 of 10

Revision date: 11-Nov-2016

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bupivacaine Hydrochloride

Pfizer OEL TWA-8 Hr: 20 µg/m³

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m³

Austria OEL - MAKs 5 ppm
8 mg/m³

Belgium OEL - TWA 5 ppm
8 mg/m³

Bulgaria OEL - TWA 5 ppm
8.0 mg/m³

Cyprus OEL - TWA 5 ppm
8 mg/m³

Czech Republic OEL - TWA 8 mg/m³

Estonia OEL - TWA 5 ppm
8 mg/m³

Germany - TRGS 900 - TWAs 2 ppm
3 mg/m³

Germany (DFG) - MAK 2 ppm
3.0 mg/m³

Greece OEL - TWA 5 ppm
7 mg/m³

Hungary OEL - TWA 8 mg/m³

Ireland OEL - TWAs 5 ppm
8 mg/m³

Italy OEL - TWA 5 ppm
8 mg/m³

Japan - OELs - Ceilings 2 ppm
3.0 mg/m³

Latvia OEL - TWA 5 ppm
8 mg/m³

Lithuania OEL - TWA 5 ppm
8 mg/m³

Luxembourg OEL - TWA 5 ppm
8 mg/m³

Malta OEL - TWA 5 ppm
8 mg/m³

Netherlands OEL - TWA 8 mg/m³

Poland OEL - TWA 5 mg/m³

Portugal OEL - TWA 5 ppm
8 mg/m³

Romania OEL - TWA 5 ppm
8 mg/m³

Slovakia OEL - TWA 5 ppm
8.0 mg/m³

Slovenia OEL - TWA 5 ppm
8 mg/m³

Spain OEL - TWA 5 ppm
7.6 mg/m³

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 5 of 10

Revision date: 11-Nov-2016

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	2 ppm
	3.0 mg/m ³
Vietnam OEL - TWAs	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

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 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.

Hands:

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.)

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.)

Skin:

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.)

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 6 of 10

Revision date: 11-Nov-2016

Version: 1.1

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Water for injection

No data available

Sodium chloride

No data available

Bupivacaine Hydrochloride

No data available

Dextrose

No data available

HYDROCHLORIC ACID

No data available

SODIUM HYDROXIDE

No data available

Methylparaben

No data available

Decomposition Temperature (°C):	No data available.
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Evaporation Rate (Gram/s):	No data available
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Vapor Pressure (kPa):	No data available
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Vapor Density (g/ml):	No data available
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Relative Density:	No data available
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Viscosity:	No data available
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Flammability:

Autoignition Temperature (Solid) (°C):	No data available
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Flammability (Solids):	No data available
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Flash Point (Liquid) (°C):	No data available
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Upper Explosive Limits (Liquid) (% by Vol.):	No data available
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Lower Explosive Limits (Liquid) (% by Vol.):	No data available
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10. STABILITY AND REACTIVITY

Reactivity:	No data available
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Chemical Stability:	Stable under normal conditions of use.
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Possibility of Hazardous Reactions

Oxidizing Properties:	No data available
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Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
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Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
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Hazardous Decomposition Products:	No data available
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SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 7 of 10

Revision date: 11-Nov-2016

Version: 1.1

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Short Term:

May cause mild eye irritation. May cause slight skin irritation. (based on components) .

Known Clinical Effects:

Anesthetic drug: may cause central nervous system and cardiovascular system effects
Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

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

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Bupivacaine Hydrochloride

Rabbit Oral LD50 18 mg/kg
Rat Para-periosteal LD50 6mg/kg
Rat Subcutaneous LD50 43mg/kg
Mouse Intravenous LD50 6.1mg/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

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

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Bupivacaine Hydrochloride

Prenatal & Postnatal Development Intravenous 0.6 mg/kg LOAEL Neonatal toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogen Status:

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

HYDROCHLORIC ACID

IARC:

Group 3 (Not Classifiable)

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 8 of 10

Revision date: 11-Nov-2016

Version: 1.1

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
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.
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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.

15. REGULATORY INFORMATION

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

Bupivacaine Hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Methylparaben	
CERCLA/SARA 313 Emission reporting	Not Listed

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 9 of 10

Revision date: 11-Nov-2016

Version: 1.1

15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
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
	231-595-7

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

Dextrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 11-Nov-2016

SAFETY DATA SHEET

Material Name: Bupivacaine Hydrochloride Injection (Hospira, Inc.)

Page 10 of 10

Revision date: 11-Nov-2016

Version: 1.1

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet