



# SAFETY DATA SHEET

Revision date 18-Jun-2022

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

### 1.1. Product identifier

**Product Name** Bupivacaine Hydrochloride Injection (Hospira, Inc.)  
**Product Code(s)** PZ03230  
**Synonyms** Bupivacaine Spinal (Bupivacaine in Dextrose, USP)  
**Trade Name:** MARCAINE; MARCAINE SPINAL  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product used as anesthetic agent

### 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

**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

**Acute toxicity - Oral**

Category 4

### 2.2. 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 CENTER or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P501 - Dispose of contents/container in accordance with all local and national regulations

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## 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

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Bupivacaine Hydrochloride (CAS #: 14252-80-3)	</= 0.75		Not Listed	Acute Tox. 2 (H300)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	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	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	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	Classification according to Regulation	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
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				(EC) No. 1272/2008 [CLP]			
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	Not classified as hazardous	Not Listed	No data available	No data available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Bupivacaine Hydrochloride 14252-80-3	18	No data available	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

**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. Non-hazardous ingredients provided for completeness.

**Section 4: FIRST AID MEASURES**

**4.1. Description of first aid measures**

- Inhalation** Remove to fresh air. Seek immediate medical attention/advice.
- Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
- 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.

**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.

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## 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** Not flammable.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 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)

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**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.

#### Bupivacaine Hydrochloride

Pfizer OEL TWA-8 Hr: 20  $\mu\text{g}/\text{m}^3$

#### Methyl-p-hydroxybenzoate

Russia

MAC: 4  $\text{mg}/\text{m}^3$

#### Sodium hydroxide

ACGIH OEL (Ceiling)

2  $\text{mg}/\text{m}^3$

ACGIH TLV

Ceiling: 2  $\text{mg}/\text{m}^3$

Austria

2  $\text{mg}/\text{m}^3$

STEL 4  $\text{mg}/\text{m}^3$

Bulgaria

2.0  $\text{mg}/\text{m}^3$

Czech Republic

1  $\text{mg}/\text{m}^3$

Ceiling: 2  $\text{mg}/\text{m}^3$

Denmark

Ceiling: 2  $\text{mg}/\text{m}^3$

Estonia

1  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

Finland

Ceiling: 2  $\text{mg}/\text{m}^3$

France

2  $\text{mg}/\text{m}^3$

Hungary

1  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

Ireland

STEL: 2  $\text{mg}/\text{m}^3$

Ceiling Limit Value

2  $\text{mg}/\text{m}^3$

Latvia

0.5  $\text{mg}/\text{m}^3$

Poland

STEL: 1  $\text{mg}/\text{m}^3$

0.5  $\text{mg}/\text{m}^3$

Romania

1  $\text{mg}/\text{m}^3$

STEL: 3  $\text{mg}/\text{m}^3$

Slovakia

2  $\text{mg}/\text{m}^3$

Spain

STEL: 2  $\text{mg}/\text{m}^3$

Switzerland

2  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

OSHA PEL

2  $\text{mg}/\text{m}^3$

(vacated) Ceiling: 2  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

United Kingdom

#### + Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

5 ppm

8  $\text{mg}/\text{m}^3$

STEL 10 ppm

STEL 15  $\text{mg}/\text{m}^3$

Bulgaria

STEL: 10 ppm

STEL: 15.0  $\text{mg}/\text{m}^3$

5 ppm

8.0  $\text{mg}/\text{m}^3$

Czech Republic

8  $\text{mg}/\text{m}^3$

Ceiling: 15  $\text{mg}/\text{m}^3$

Denmark

Ceiling: 5 ppm

Ceiling: 8  $\text{mg}/\text{m}^3$

Estonia

5 ppm

8  $\text{mg}/\text{m}^3$

STEL: 10 ppm

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European Union	STEL: 15 mg/m <sup>3</sup> TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm
Finland	STEL: 15 mg/m <sup>3</sup> STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm 3.0 mg/m <sup>3</sup> Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm 3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup>
Ireland	STEL: 16 mg/m <sup>3</sup> 8 mg/m <sup>3</sup> 5 ppm STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm 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	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Romania	5 ppm 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	5 ppm 8.0 mg/m <sup>3</sup>
Spain	5 ppm 7.6 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm 3 mg/m <sup>3</sup> STEL: 4 ppm STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m <sup>3</sup>
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>
United Kingdom	TWA: 1 ppm TWA: 2 mg/m <sup>3</sup> STEL: 5 ppm STEL: 8 mg/m <sup>3</sup>

## **8.2. Exposure controls**

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<b>Engineering controls</b>	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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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.
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.).
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solution
<b>Color</b>	Clear, colorless
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	No data available
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available

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<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## 9.2. Other information

No information available

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

No information available

### 9.2.2. Other safety characteristics

No information 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** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	May cause mild eye irritation. May cause slight skin irritation. (based on components). Anesthetic drug: may cause central nervous system and cardiovascular system effects
<b>Known Clinical Effects:</b>	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)

#### Bupivacaine Hydrochloride



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

## **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
Rat Oral LD 50 3 g/kg  
Mouse Oral LD 50 4 g/kg  
Rabbit Dermal LD 50 > 10 g/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
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)**

### **SODIUM CHLORIDE**

Skin irritation Rabbit Mild  
Eye irritation Rabbit Mild

### **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)**

### **Bupivacaine Hydrochloride**

1 Month(s) Rabbit Subcutaneous 9 mg/kg LOAEL Central nervous system  
1 Month(s) Dog Subcutaneous 9 mg/kg NOAEL None identified

### **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))**

### **Bupivacaine Hydrochloride**

Prenatal & Postnatal Development Intravenous 0.6 mg/kg LOAEL Neonatal toxicity  
Embryo / Fetal Development Rat Subcutaneous 13.3 mg/kg/day NOAEL Maternal Toxicity  
Embryo / Fetal Development Rat Subcutaneous 40 mg/kg/day NOAEL Developmental toxicity  
Embryo / Fetal Development Rabbit Subcutaneous 22.2 mg/kg/day NOAEL Maternal Toxicity  
Embryo / Fetal Development Rabbit Subcutaneous 5.8 mg/kg/day NOAEL Developmental toxicity  
Peri-/Postnatal Development Rat Subcutaneous 13.3 mg/kg/day NOAEL Fetotoxicity

### **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)**

### **Bupivacaine Hydrochloride**

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Mammalian Cell Mutagenicity Negative

## 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.

## + Hydrochloric Acid

IARC Group 3 (Not Classifiable)

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly 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 (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

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does

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	not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. 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 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.

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

## Section 15: REGULATORY INFORMATION

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

Bupivacaine Hydrochloride	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
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

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<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
Dextrose	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
+ 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

### 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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances 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 hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

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

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

# SAFETY DATA SHEET

Product Name Bupivacaine Hydrochloride Injection (Hospira, Inc.)  
Revision date 18-Jun-2022

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

### **Full text of H-Statements referred to under 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 Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 18-Jun-2022

**Prepared By** Pfizer Global Environment, Health, and Safety

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