



# SAFETY DATA SHEET

Revision date 22-May-2022

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** Buprenorphine Hydrochloride Injection (Hospira Inc.)  
**Product Code(s)** PZ03252  
**Trade Name:** Buprenorphine Hydrochloride Injection  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product used as Analgesic

### 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

Not classified as hazardous

### 2.2. Label elements

**Signal word** Not Classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 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.

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## 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)
+ Hydrochloric Acid 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
Buprenorphine Hydrochloride 53152-21-9	0.0324		258-396-8	Acute Tox 4 (H302) STOT SE 3 (H336)	Not Listed	No data available	No data available

NonHazardous

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)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
Dextrose 14431-43-7	*		Not Listed	No data available	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
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022
Buprenorphine Hydrochloride 53152-21-9	1000	No data available	No data available	No data available	No data available

**Additional information**

\* Proprietary

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\*\* 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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Move to fresh air. If discomfort occurs, get medical attention.
<b>Eye contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

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

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

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** As for primary cause of fire.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Not applicable.

**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

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**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**

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Buprenorphine Hydrochloride**

Pfizer OEL TWA-8 Hr: 0.4 µg/m<sup>3</sup>, Skin

#### **+ Hydrochloric Acid**

ACGIH OEL (Ceiling)

ACGIH TLV

Austria

Bulgaria

Czech Republic

Denmark

Estonia

2 ppm

Ceiling: 2 ppm

5 ppm

8 mg/m<sup>3</sup>

STEL 10 ppm

STEL 15 mg/m<sup>3</sup>

STEL: 10 ppm

STEL: 15.0 mg/m<sup>3</sup>

5 ppm

8.0 mg/m<sup>3</sup>

8 mg/m<sup>3</sup>

Ceiling: 15 mg/m<sup>3</sup>

Ceiling: 5 ppm

Ceiling: 8 mg/m<sup>3</sup>

5 ppm

8 mg/m<sup>3</sup>

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European Union	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	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>

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## 8.2. Exposure controls

<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. It is recommended that all operations be fully enclosed and no air recirculated.
<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 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.).
<b>Skin and body protection</b>	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.).
<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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, 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>	Liquid
<b>Color</b>	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>	3.5-5.5
<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

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Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	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

**General Information:** The information included in this section describes the potential hazards of the individual ingredients

**Short term** May cause central nervous system effects.

**Known Clinical Effects:** The most common adverse effects seen during clinical use of this drug include drowsiness, nausea, vomiting, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), respiratory depression, decreased heart rate (bradycardia), increased heart rate (tachycardia), dizziness, sweating, headache, dry mouth, hallucinations.

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

#### Buprenorphine Hydrochloride

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Rat Oral LD50 > 1000 mg/kg  
Mouse Oral LD50 800 mg/kg  
Rat IV LD50 31-62 mg/kg  
Mouse IV LD50 24-72 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h
Buprenorphine Hydrochloride	> 1 g/kg ( Rat )	-	-

**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)**

### **+ Hydrochloric Acid**

Skin irritation Severe

Eye irritation Severe

### **Buprenorphine Hydrochloride**

Guinea Pig Negative

Skin Irritation Rabbit Slight

## **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

### **Water**

6 Month(s) Mini Pig Dermal 0.8 mg/kg/day NOAEL None identified

6 Month(s) Rabbit Dermal 15 mg/kg/day NOAEL None identified

6 Month(s) Dog Dermal 1 mg/kg/day NOAEL None identified

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

### **Buprenorphine Hydrochloride**

Reproductive & Fertility Rat Oral 80 mg/kg/day NOAEL Negative, Fertility

Embryo / Fetal Development Rat Intramuscular Subcutaneous 5 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Intramuscular Subcutaneous 5 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rat Oral 160 mg/kg/day NOAEL Not Teratogenic

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

### **+ Hydrochloric Acid**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Micronucleus Rat Negative

### **Buprenorphine Hydrochloride**

Bacterial Mutagenicity (Ames) Equivocal

Mammalian Cell Mutagenicity Hamster Bone Marrow Negative

Mammalian Cell Mutagenicity Mouse Lymphoma Negative

## **Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Buprenorphine Hydrochloride**

27 Month(s) Rat Oral, in feed 56 mg/kg/day NOAEL Not carcinogenic

86 Week(s) Mouse Oral, in feed 100 mg/kg/day NOAEL Not carcinogenic

100 Week(s) Rat Dermal 20 mg/kg/day NOAEL Not carcinogenic

### **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.



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## 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.

### 12.1. Toxicity

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 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
+ 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.

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

## Section 15: REGULATORY INFORMATION

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

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

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

Buprenorphine Hydrochloride

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>U.S. - DEA (Drug Enforcement Administration)</b>	Schedule III Controlled Substance
<b>EINECS</b>	258-396-8
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 8

### 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
+ 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

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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

### 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.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

**Reason for revision** Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

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

**Pfizer Inc believes that the information contained in this 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.**