



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 11-Jun-2018

Version: 1.3

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

### Product Identifier

**Material Name:** Morphine Sulfate Injection - preservative-free (Hospira, Inc.)

**Trade Name:** Not established

**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical active used as opioid analgesic

### 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

Reproductive Toxicity: Category 1B  
Effects on or via lactation

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H362 - May cause harm to breast-fed children  
H360D - May damage the unborn child

**Precautionary Statements:** P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P263 - Avoid contact during pregnancy/while nursing  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P308 + P313 - IF exposed or concerned: Get medical attention/advice

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**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	%
Morphine Sulfate	64-31-3	200-582-8	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362) Muta. 2 (H341)	0.1
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium citrate, dihydrate	6132-04-3	Not Listed	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:**

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.

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**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:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

**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.

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m <sup>3</sup>
Austria OEL - MAKs	5 ppm
	8 mg/m <sup>3</sup>
Belgium OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5 ppm
	8.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Czech Republic OEL - TWA	8 mg/m <sup>3</sup>
Estonia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm
	3.0 mg/m <sup>3</sup>
Greece OEL - TWA	5 ppm
	7 mg/m <sup>3</sup>
Hungary OEL - TWA	8 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 ppm
	8 mg/m <sup>3</sup>
Italy OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 ppm
	3.0 mg/m <sup>3</sup>
Latvia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Malta OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Netherlands OEL - TWA	8 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Romania OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm
	8.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Spain OEL - TWA	5 ppm
	7.6 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	2 ppm
	3.0 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>

#### Sodium hydroxide

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

#### Sodium chloride

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

#### Morphine Sulfate

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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.
<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>Hands:</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>Eyes:</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>Skin:</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.)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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

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

**Water for injection**

No data available

**Sodium chloride**

No data available

**Sodium hydroxide**

No data available

**HYDROCHLORIC ACID**

No data available

**Citric acid, anhydrous**

No data available

**Sodium citrate, dihydrate**

No data available

**Morphine Sulfate**

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

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

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### 10. STABILITY AND REACTIVITY

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

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term:</b>	May be harmful if swallowed. May cause eye irritation (based on components) .
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.
<b>Known Clinical Effects:</b>	Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

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

##### Sodium chloride

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

##### Sodium hydroxide

Mouse	IP	LD50	40 mg/kg
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##### HYDROCHLORIC ACID

Rat	Oral	LD 50	238-277 mg/kg
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##### Citric acid, anhydrous

Rat	Oral	LD50	3000 mg/kg
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##### Morphine Sulfate

Rat	Oral	LD50	461 mg/kg
Rat	Para-osteal	LD50	70mg/kg
Rat	Intraperitoneal	LD50	235mg/kg
Mouse	Oral	LD50	600mg/kg
Mouse	Intravenous	LD50	156mg/kg

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

##### Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

##### Sodium hydroxide

Eye Irritation	Rabbit	Severe
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### 11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Severe

#### Citric acid, anhydrous

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

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

##### Morphine Sulfate

18 Week(s) Rat Oral 60 g/kg LOEL Lungs  
15 Day(s) Rat Subcutaneous 3144 mg/kg LOEL Kidney, Ureter, Bladder  
9 Week(s) Rat Subcutaneous 3150 mg/kg LOEL

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

##### Morphine Sulfate

Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg LOEL Teratogenic  
Embryo / Fetal Development Hamster Subcutaneous 35 mg/kg LOEL Teratogenic  
Embryo / Fetal Development Mouse Oral 200 mg/kg LOEL Teratogenic  
Embryo / Fetal Development Rat Subcutaneous 35 mg/kg LOEL Fetotoxicity

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

##### HYDROCHLORIC ACID

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

##### Morphine Sulfate

*In Vivo* Micronucleus Mouse Positive  
*In Vivo* Chromosome Aberration Mouse Lymphocytes Positive  
*In Vitro* Direct DNA Damage Human Lymphocytes Positive  
*In Vitro* Chromosome Aberration Mouse Negative  
Dominant Lethal Assay *Drosophila* Negative

**Carcinogen Status:** See below

##### HYDROCHLORIC ACID

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available



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**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.

### 15. REGULATORY INFORMATION

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

#### Morphine Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
U.S. Drug Enforcement Administration:	Schedule II
Australia (AICS):	Present
EU EINECS/ELINCS List	200-582-8

#### 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

#### HYDROCHLORIC ACID

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**15. REGULATORY INFORMATION**

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
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 5
	Schedule 6
EU EINECS/ELINCS List	231-595-7

**Sodium citrate, dihydrate**

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

**Citric acid, anhydrous**

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	201-069-1

**Sodium hydroxide**

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
	454 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 5
	Schedule 6
EU EINECS/ELINCS List	215-185-5

**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

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

**16. OTHER INFORMATION**

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child  
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children  
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects  
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.

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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**