



# SAFETY DATA SHEET

Revision date 13-Jun-2025

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

### 1.1. Product identifier

**Product Name** Hydromorphone Hydrochloride Injection, USP CII (Hospira Inc.)  
**Product Code(s)** PZ03091  
**Trade Name:** Hydromorphone Hydrochloride Injection, USP  
**Chemical Family:** Mixture

### 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

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**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

GHS - Classification.

**Reproductive toxicity**

Category 2 - (H361d)

#### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

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## Signal word

## Hazard statements

## Warning

H361d - Suspected of damaging the unborn child

## Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

## Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Hydromorphone Hydrochloride (CAS #: 71-68-1)	0.1-0.4		200-762-6	Acute Tox 3 (H301)(H361d)	Not classified	No data available	No data available
Citric acid (CAS #: 77-92-9)	< 1		201-069-1 (607-750-00-3)	Eye Irrit. 2A (H319)SE 3 (H335)	Not classified	No data available	No data available

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## NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Sodium Citrate (CAS #: 6132-04-3)	*		612-118-5	Not classified	Not classified	No data available	No data available

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

## Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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
Hydromorphone Hydrochloride 71-68-1	199	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

\* Proprietary

Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<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** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

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effects 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 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 applicable.

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

#### **Explosion data**

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### **5.3. Advice for firefighters**

Special protective equipment and precautions 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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing.

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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.

#### Hydromorphone Hydrochloride

Pfizer OEL TWA-8 Hr: 7 TWA; 40 STEL  $\mu\text{g}/\text{m}^3$ , Sensitizer

#### Citric acid

Czech Republic  
Germany DFG

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

TWA-MAK: 2  $\text{mg}/\text{m}^3$ ; I(2);inhalable fraction

Peak: 4  $\text{mg}/\text{m}^3$ ; respirable fraction

Germany TRGS

TWA-AGW; 2  $\text{mg}/\text{m}^3$  (exposure factor 2); inhalable fraction

Russia

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

Switzerland

TWA-MAK: 2  $\text{mg}/\text{m}^3$ ; inhalable dust

STEL-KZGW: 4  $\text{mg}/\text{m}^3$ ; inhalable dust

### 8.2. 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.

#### Eye/face protection

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.).

#### Hand protection

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

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the standards in accordance with EN374, ASTM F1001 or international equivalent.).

## Skin and body protection

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.).

## Thermal hazards

No information available.

## Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Colorless
Odor	No information available.
Odor threshold	No information available

Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.5-5.5
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

### 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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## 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 information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information 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 be absorbed through the skin and cause systemic effects. Use of this drug is habit forming. Addiction may occur.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.

**Known Clinical Effects:** The most common adverse effects seen during clinical use of this drug include lightheadedness, dizziness, sedation, sweating, nausea, vomiting, constriction of the pupil (miosis), respiratory depression, respiratory arrest, circulatory failure, symptoms of dependence/withdrawal.

**Acute toxicity** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.

**STOT - single exposure** Based on available data, the classification criteria are not met.

**STOT - repeated exposure** Based on available data, the classification criteria are not met.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Carcinogenicity** Based on available data, the classification criteria are not met.

**Aspiration hazard** Based on available data, the classification criteria are not met.

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

#### Hydromorphone Hydrochloride

Rat Oral LD50 199 mg/kg

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Mouse Oral LD50 215-261 mg/kg  
Mouse Intravenous LD50 55 mg/kg

## Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Citric acid	= 3 g/kg ( Rat )	> 2000 mg/kg ( Rat )	-

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

### Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

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

### Hydromorphone Hydrochloride

Reproductive & Fertility Rat Oral 7 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Embryo / Fetal Development Rabbit Oral 50 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Hamster Subcutaneous 14 mg/kg LOEL Teratogenic

Embryo / Fetal Development Mouse Subcutaneous > 15 mg/kg/day LOEL Teratogenic

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

### Hydromorphone Hydrochloride

Bacterial Mutagenicity (Ames) Negative

Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Mouse Negative

## Carcinogenicity

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

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 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

No information available

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.



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## 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

Chemical name	PBT and vPvB assessment
Citric acid	Not PBT/vPvB
Sodium Citrate	Not PBT/vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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

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## Section 15: REGULATORY INFORMATION

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

#### Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

#### Hydromorphone Hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	200-762-6

#### Sodium Citrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

#### Citric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-069-1
AICS	Present

### National regulations

#### Germany

##### Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

#### TRGS 905

Not applicable

#### Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

#### 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	Substance subject to authorization per
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	Annex XVII	REACH Annex XIV
Citric acid 77-92-9	75	-

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

## Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Citric acid 77-92-9	Product-type 2: Disinfectants and algicides not intended for direct application to humans or animals Product-type 6: Preservatives for products during storage

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 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 any hazard and/or precautionary statements referred to under Sections 2-15

H301 - Toxic if swallowed. H361d - Suspected of damaging the unborn child. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients.

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Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.  
Updated Section 16 - Other Information.

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

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