



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 08-Jan-2018

Version: 1.0

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

### Product Identifier

**Material Name:** Diphenhydramine Hydrochloride Injection, USP (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 product used as antihistamine, sedative

### 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

Specific target organ systemic toxicity (repeated exposure): Category 2

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H373 - May cause damage to organs through prolonged or repeated exposure: liver.

**Precautionary Statements:** P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P314 - Get medical attention/advice if you feel unwell  
P501 - Dispose of contents/container in accordance with all local and national regulations



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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 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.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Diphenhydramine hydrochloride	147-24-0	205-687-2	Acute Tox.4 (H302) STOT RE.2 (H373)	5
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	95

**Additional Information:** \*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove contaminated clothing and shoes. Wash skin with soap and water. If skin irritation persists, call a physician.
- Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. If discomfort persists, get medical attention.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

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### 5. FIRE FIGHTING MEASURES

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

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** May emit toxic fumes of nitrogen oxides and hydrogen chloride.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** 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 active

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

#### Diphenhydramine hydrochloride

**Pfizer OEL TWA-8 Hr:** 150µg/m<sup>3</sup>

#### HYDROCHLORIC ACID

**ACGIH Ceiling Threshold Limit:** 2 ppm

**Australia PEAK:** 5 ppm

**Austria OEL - MAKs:** 7.5 mg/m<sup>3</sup>

**Austria OEL - MAKs:** 5 ppm

**Austria OEL - MAKs:** 8 mg/m<sup>3</sup>

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>

<b>Analytical Method:</b>	Analytical method available. Contact Pfizer Inc for further information.
<b>Exposure Controls</b>	
<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.)
<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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	Odorless	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	Highly soluble: Alcohol		
<b>Water Solubility:</b>	Soluble		
<b>pH:</b>	4-6.5		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Diphenhydramine hydrochloride</b>			
No data available			

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Water for Injection

No data available

#### SODIUM HYDROXIDE

No data available

#### HYDROCHLORIC ACID

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

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

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

#### Possibility of Hazardous Reactions

**Oxidizing Properties:** None

**Conditions to Avoid:** Avoid direct sunlight, conditions that might generate heat, and sources of ignition.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### Short Term:

May cause skin irritation. Not an eye irritant . Not a skin sensitizer (based on animal data) . May be harmful if swallowed. May cause central nervous system effects. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

##### Known Clinical Effects:

The most common adverse effects seen with the therapeutic use of diphenhydramine HCl include drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.

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

##### Diphenhydramine hydrochloride

Rat Oral LD50 500 mg/kg

Mouse Oral LD50 114mg/kg

Guinea Pig Oral LD50 284mg/kg

Human Oral LDmin. 10.1mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

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

##### Diphenhydramine hydrochloride

Eye Irritation Rabbit Non-irritating

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

**Skin Irritation / Sensitization** Skin irritation has been reported in clinical use.

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

##### Diphenhydramine hydrochloride

13 Week(s) Rat Oral 310 mg/kg/day LOAEL Liver

2 Year(s) Rat Oral 15 mg/kg/day NOAEL Liver

2 Year(s) Mouse Oral 21 mg/kg/day NOAEL Liver

**Chronic Effects/Carcinogenicity** Liver toxicity was seen in a two-year oral study in rats treated with diphenhydramine. A No-Observed-Adverse-Effect-Level (NOAEL) of 15 mg/kg/day was obtained for female animals. There was equivocal evidence of carcinogenic activity in male and female rats. No evidence of carcinogenic activity was observed in male or female mice.

##### **Subchronic Effects**

In a 13-week oral study, dose-related liver toxicity was seen in rats at doses of >13 mg/kg/day in males and > 15 mg/kg/day in females. The NOAEL in this study was ~6.5 mg/kg/day (males) and 7 mg/kg/day (females) There were no compound-related histological effects observed in mice.

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

##### Diphenhydramine hydrochloride

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not teratogenic, Maternal toxicity, Fetotoxicity

Embryo / Fetal Development Mouse Oral 80 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Embryo / Fetal Development Rat Oral 50 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

**Reproductive Effects** No evidence of impaired fertility was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.

##### **Teratogenicity**

No evidence of harm to the fetus was seen in studies performed in rats and rabbits at doses up to 5 times the human dose of diphenhydramine hydrochloride.

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

##### Diphenhydramine hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive without activation Negative with activation

*In Vitro* Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative

*In Vitro* Unscheduled DNA Synthesis Rat Hepatocyte Negative

#### HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Micronucleus Rat Negative

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

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### 11. TOXICOLOGICAL INFORMATION

#### Diphenhydramine hydrochloride

2 Year(s) Rat Oral 15 mg/kg/day NOAEL Not carcinogenic  
2 Year(s) Mouse Oral 46 mg/kg/day NOAEL Not carcinogenic

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

#### HYDROCHLORIC ACID

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 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



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### 15. REGULATORY INFORMATION

#### Diphenhydramine hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	205-687-2

#### HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

#### SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5

#### 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	Present
	231-791-2

### 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  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation  
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

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

**Revision date:** 08-Jan-2018  
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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**