SAFETY DATA SHEET

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

Product Identifier

Material Name: Promethazine Hydrochloride Injection (solution)

Trade Name: Promethazine Hydrochloride Solution for Injection
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product

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

Emergency telephone number:
Chemtrec (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Acetic acid	64-19-7	200-580-7	Skin Corr.1A (H314) Flam. Liq. 3 (H226)	**
Phenol	108-95-2	Not Listed	Acute Tox. 3 (H301) Acute Tox. 3 (H311) STOT RE 2 (H373) Muta. 2 (H341) Skin Corr. 1B (H314) Acute Tox. 3 (H331)	<0.1
Promethazine Hydrochloride	58-33-3	200-489-2	Acute Tox. 4 (H302)	2.5
CALCIUM CHLORIDE	10043-52-4	233-140-8	Eye Irrit. 2 (H319)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium acetate trihydrate	6131-90-4	Not Listed	Not Listed	**
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Monothioglycerol	96-27-5	202-495-0	Not Listed	*
Edetate disodium	139-33-3	205-358-3	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.

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: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen sulfur

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

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 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

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Acetic acid

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm 37 mg/m^3
Australia TWA	10 ppm 25 mg/m^3
Austria OEL - MAKs	10 ppm 25 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	10 ppm 25 mg/m^3
Bulgaria OEL - TWA	25.0 mg/m^3
Cyprus OEL - TWA	10 ppm 25 mg/m^3
Czech Republic OEL - TWA	25 mg/m^3
Denmark OEL - TWA	10 ppm 25 mg/m^3
Estonia OEL - TWA	10 ppm 25 mg/m^3
Finland OEL - TWA	5 ppm 13 mg/m^3
Germany - TRGS 900 - TWAs	10 ppm 25 mg/m^3
Germany (DFG) - MAK	10 ppm 25 mg/m^3
Greece OEL - TWA	10 ppm 25 mg/m^3
Hungary OEL - TWA	25 mg/m^3
Ireland OEL - TWAs	10 ppm 25 mg/m^3
Latvia OEL - TWA	10 ppm 25 mg/m^3
Lithuania OEL - TWA	10 ppm 25 mg/m^3
Luxembourg OEL - TWA	10 ppm 25 mg/m^3
Malta OEL - TWA	10 ppm 25 mg/m^3
Netherlands OEL - TWA	25 mg/m^3
OSHA - Final PELS - TWAs:	10 ppm 25 mg/m^3
Poland OEL - TWA	25 mg/m^3
Portugal OEL - TWA	10 ppm 25 mg/m^3
Romania OEL - TWA	10 ppm 25 mg/m^3
Slovakia OEL - TWA	10 ppm 25 mg/m^3
Slovenia OEL - TWA	10 ppm 25 mg/m^3
Spain OEL - TWA	10 ppm 25 mg/m^3
Sweden OEL - TWAs	5 ppm 13 mg/m^3
Switzerland OEL -TWAs	10 ppm 25 mg/m^3
Vietnam OEL - TWAs	25 mg/m^3

Phenol

ACGIH Threshold Limit Value (TWA)	5 ppm
ACGIH - Biological Exposure Limit:	250 mg/g creatinine

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	1 ppm 4 mg/m^3
Austria OEL - MAKs	2 ppm 8 mg/m^3
Belgium OEL - TWA	2 ppm 8 mg/m^3
Bulgaria OEL - TWA	2 ppm 8 mg/m^3
Bulgaria - Biological Exposure Limit:	200 mg/L
Cyprus OEL - TWA	8 mg/m^3 2 ppm
Czech Republic OEL - TWA	7.5 mg/m^3
Denmark OEL - TWA	1 ppm 4 mg/m^3
Estonia OEL - TWA	2 ppm 7.8 mg/m^3
Finland OEL - TWA	2 ppm 8 mg/m^3
Finland - Biological Exposure Limit:	1.3 mmol/L
France OEL - TWA	2 ppm 7.8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 8 mg/m^3
Germany - Biological Exposure Limit:	120 mg/g
Greece OEL - TWA	2 ppm 8 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	2 ppm 8 mg/m^3
Italy OEL - TWA	2 ppm 8.0 mg/m^3
Latvia OEL - TWA	2 ppm 8 mg/m^3
Lithuania OEL - TWA	2 ppm 8 mg/m^3
Luxembourg OEL - TWA	2 ppm 8 mg/m^3
Malta OEL - TWA	2 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
OSHA - Final PELS - TWAs:	5 ppm 19 mg/m^3
Poland OEL - TWA	7.8 mg/m^3
Portugal OEL - TWA	2 ppm 8 mg/m^3
Romania OEL - TWA	2 ppm 8 mg/m^3
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	2 ppm 7.8 mg/m^3
Slovak Republic - Biological Exposure Limit:	200 mg/L
Slovenia OEL - TWA	2 ppm 8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	2 ppm 8 mg/m^3
Spain - Biological Exposure Limit:	120 mg/g Creatinine
Sweden OEL - TWAs	1 ppm 4 mg/m^3
Switzerland OEL -TWAs	5 ppm 19 mg/m^3
Vietnam OEL - TWAs	4 mg/m^3

Promethazine Hydrochloride

Pfizer OEL TWA-8 Hr:	60µg/m^3

CALCIUM CHLORIDE

Czech Republic OEL - TWA	5 mg/m^3
Latvia OEL - TWA	2 mg/m^3

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. It is recommended that all operations be fully enclosed and no air recirculated.

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.

Hands: 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.)

Eyes: 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.)

Skin: 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.)

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

Physical State:	Liquid	**Color:**	Colourless
Odor:	None	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	4.0-5.5
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
Phenol
No data available
Water for Injection
No data available
Acetic acid
No data available
Sodium acetate trihydrate
No data available
Edetate disodium
No data available
Monothioglycerol
No data available
Promethazine Hydrochloride
No data available
CALCIUM CHLORIDE
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

Flammablity:
- **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
- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** None known
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The following information is available for the individual ingredients.
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including sleepiness (somnolence), drowsiness, dry mouth, blurred vision, gastrointestinal disturbances, changes in blood pressure, respiratory depression

11. TOXICOLOGICAL INFORMATION

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

Phenol
Rat Oral LD50 317 mg/kg
Rat Dermal LD50 669mg/kg
Rat Inhalation LC50 316mg/m^3

Acetic acid
Rat Oral LD50 3530 mg/kg
Mouse Inhalation LC50 5000ppm

Edetate disodium
Rat Oral LD50 2000-2200 mg/kg

Promethazine Hydrochloride
Mouse Oral LD50 255 mg/kg
Rat Subcutaneous LD50 700mg/kg
Rat IV LD50 45mg/kg
Mouse Intravenous LD50 40mg/kg
Rat Dermal (IM) LD50 169mg/kg

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

Phenol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Promethazine Hydrochloride
Eye Irritation Rabbit Severe

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

Promethazine Hydrochloride
Embryo / Fetal Development Rat Oral 6.25 mg/kg NOAEL Not teratogenic
Embryo / Fetal Development Rat No route specified 2-3 times human dose LOAEL Neonatal toxicity

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

Promethazine Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

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

Promethazine Hydrochloride
2 Year(s) Rat Oral 33.3 mg/kg NOAEL Not carcinogenic
2 Year(s) Male Mouse Oral 45 mg/kg NOAEL Not carcinogenic
2 Year(s) Female Mouse Oral 15 mg/kg NOAEL Not carcinogenic

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

11. TOXICOLOGICAL INFORMATION

Phenol

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Acetic acid

Pimephales promelas (Fathead Minnow) LC-50 1 Hours > 315 mg/L
Pimephales promelas (Fathead Minnow) LC-50 24 Hours 122 mg/L
Mysidopsis bahia (Mysid Shrimp) LC-50 48 Hours 100-300 mg/L

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.

Phenol

RCRA - U Series Wastes Listed

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

Acetic acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 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 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

Phenol

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb 10000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Promethazine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
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 2 Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-489-2

Sodium acetate trihydrate

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

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

15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Monothioglycerol

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	202-495-0

CALCIUM 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	233-140-8

Edetate disodium

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	205-358-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

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

Revision date: 21-Jun-2019
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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.

End of Safety Data Sheet