



# SAFETY DATA SHEET

## Chlorpromazine Hydrochloride for Injection

### 1) PRODUCT AND COMPANY IDENTIFICATION

#### Product Identifier

Product Name: Chlorpromazine Hydrochloride Injection

Common/Trade Name: Chlorpromazine

#### Product Use

Pharmaceutical

Container Type: Vial

#### Manufacturer

Piramal Critical Care, Inc

268 Brodhead Road

Bethlehem, PA 18017

#### Emergency Telephone Number

Customer Service: 610-974-9760 x510

E-Mail: pcccustomerconnect@piramal.com

Emergency Number: CHEMTREC 1-800-424-9300

### 2) HAZARDS IDENTIFICATION

#### GHS US Classification

Eye Dam. 1	H318
Skin Sens. 1	H317
Lact	H362
Full text of hazard classes and H-statements : see section 16	

#### Label Elements

GHS US Labeling

Hazard pictograms (GHS US) :



**Signal Word (GHS US):**

Danger

**Hazard Statements (GHS US):**

H317-May cause an allergic skin reaction

H318- Causes serious eye damage

H362- May cause harm to breast-fed children

**Precautionary Statements (GHS US):**

P201 - Obtain special instructions before use

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P261 – Avoid breathing dust/fume/gas/mist/vapors/spray.

P263 - Avoid contact during pregnancy/while nursing.

P264 – Wash thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P310 - Immediately call a poison center or doctor

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

P363 - Wash contaminated clothing before reuse.

P501: Dispose the contents/container to a special waste collection point (according to the respective local/regional/national/international regulations)

#### Other Hazards

No additional information available

#### Unknown acute toxicity (GHS US)

Not applicable

### 3) COMPOSITION/INFORMATION ON INGREDIENTS

#### Substances

Not Applicable

#### Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	< 99	Not classified
10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride	(CAS-No.) 69-09-0	2.5	Acute Tox. 3 (Oral), H301 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Dam. 1, H318 Skin Sens. 1, H317 Lact., H362
Sodium chloride	(CAS-No.) 7647-14-5	< 1	Not classified
L-Ascorbic acid	(CAS-No.) 50-81-7	< 1	Not classified
Sodium metabisulfite	(CAS-No.) 7681-57-4	< 1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
Sodium sulfite	(CAS-No.) 7757-83-7	< 1	Acute Tox. 4 (Oral), H302

Full text of hazard classes and H-statements : see section 16

**4) FIRST AID MEASURES****Description of First Aid Measures**

First-aid measures after inhalation	:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
First-aid measures after eye contact	:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after 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.

**Most important symptoms and effects, both acute and delayed**

Symptoms/injuries after inhalation	:	None anticipated during normal product use.
Symptoms/injuries after skin contact	:	May cause skin irritation an allergic skin reaction.
Symptoms/injuries after eye contact	:	Causes serious eye damage.
Symptoms/injuries after ingestion	:	May be harmful if swallowed.

**Indication of any immediate attention and special treatment needed**

No additional information available

**5) FIRE FIGHTING MEASURES****Extinguishing Media**

Suitable extinguishing media	:	Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	:	None.

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

Fire hazard	:	None known.
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**Advice for Firefighters**

Protection during firefighting	:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
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**6) ACCIDENTAL RELEASE MEASURES****Personal Precautions, Protective Equipment and Emergency Procedures**

General measures	:	No special measures required.
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**For Non-Emergency Personnel**

No additional information available

**For Emergency Responders**

No additional information available

**Environmental Precautions**

Prevent entry to sewers and public waters.

**Methods and Material for Containment and Cleaning Up**

For containment	Stop the flow of material if this is without risk.
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Methods for cleaning  
up

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Absorb spillage with suitable absorbent material. Place in a suitable  
container and dispose according to local, state and federal regulations.

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**Reference to Other Sections**  
No additional information available

## 7) HANDLING AND STORAGE

### Precautions for Safe Handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective  
equipment.  
Observe good industrial hygiene practices.

### Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions Store at 20° to 25°C (68° to 77°F).

## 8) EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control Parameters

<b>Water (7732-18-5)</b>		
Not applicable		
<b>Sodium chloride (7647-14-5)</b>		
Not applicable		
<b>L-Ascorbic acid (50-81-7)</b>		
Not applicable		
<b>Sodium metabisulfite (7681-57-4)</b>		
ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>
NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>
<b>Sodium sulfite (7757-83-7)</b>		
Not applicable		
<b>10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride (69-09-0)</b>		
Not applicable		

### Exposure Controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure  
standards.  
Hand protection : No protection is ordinarily required under normal conditions of use.  
Eye protection : Wear safety glasses or goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : No protection is ordinarily required under normal conditions of use.

## 9) PHYSICAL AND CHEMICAL PROPERTIES

### Information on Basic Physical and Chemical Properties

Physical state : Liquid  
Appearance : Clear  
Color : Colorless to light yellow  
Odor : odorless  
Odor threshold : No data available  
pH : 3.4 – 5.4

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Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

**Other Information**

No additional information available

**10) STABILITY AND REACTIVITY****Reactivity:** No additional information available.**Chemical Stability:** The product is stable at normal handling and storage conditions.**Possibility of Hazardous Reactions:** Will not occur..**Conditions to Avoid:** Air contact**Incompatible Materials:** None known.**Hazardous Decomposition Products:** None known.**11) TOXICOLOGICAL INFORMATION****Information On Toxicological Effects**

Acute toxicity : Not classified

<b>Water (7732-18-5)</b>	
LD50 oral rat	> 90 ml/kg
<b>Sodium chloride (7647-14-5)</b>	
LD50 oral rat	3 g/kg
LC50 inhalation rat (mg/l)	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
<b>L-Ascorbic acid (50-81-7)</b>	
LD50 oral rat	11900 mg/kg
ATE US (oral)	11900 mg/kg
<b>Sodium metabisulfite (7681-57-4)</b>	
LD50 oral rat	1310 mg/kg
LD50 dermal rat	> 2000 mg/kg
ATE US (oral)	1131 mg/kg
<b>Sodium sulfite (7757-83-7)</b>	
LD50 oral rat	5680 mg/kg
LC50 inhalation rat (mg/l)	> 22 mg/l (Exposure time: 1 h)
ATE US (oral)	820 mg/kg body weight
<b>10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride (69-09-0)</b>	
LD50 oral rat	145 mg/kg

<b>10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride (69-09-0)</b>	
LC50 inhalation rat (mg/l)	40 mg/m <sup>3</sup> (Exposure time: 2 h)
ATE US (oral)	145 mg/kg body weight
ATE US (vapors)	0.04 mg/l/4h
ATE US (dust, mist)	0.04 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

<b>Sodium metabisulfite (7681-57-4)</b>	
IARC group	3 - Not classifiable
<b>Sodium sulfite (7757-83-7)</b>	
IARC group	3 - Not classifiable

Reproductive toxicity	: May cause harm to breast-fed children.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## 12) ECOLOGICAL INFORMATION

### Toxicity

<b>Sodium chloride (7647-14-5)</b>	
LC50 fish 1	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>Sodium metabisulfite (7681-57-4)</b>	
LC50 fish 1	32 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

### Persistence and degradability

No additional information available

### Bioaccumulative potential

<b>Sodium chloride (7647-14-5)</b>	
BCF fish 1	(no bioaccumulation)
<b>Sodium metabisulfite (7681-57-4)</b>	
Partition coefficient n-octanol/water (Log Pow)	-3.7 (at 25 °C)
<b>Sodium sulfite (7757-83-7)</b>	
Partition coefficient n-octanol/water (Log Pow)	-4 (at 25 °C)

### Mobility in soil

No additional information available.

### Other adverse effects

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No additional information available.

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### 13) DISPOSAL CONSIDERATIONS

#### Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### 14) TRANSPORT INFORMATION

#### Department of Transportation (DOT)

In accordance with DOT  
Not applicable

### 15) REGULATORY INFORMATION

#### US Federal Regulations

<b>Water (7732-18-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Sodium chloride (7647-14-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>L-Ascorbic acid (50-81-7)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Sodium metabisulfite (7681-57-4)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Sodium sulfite (7757-83-7)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>10H-Phenothiazine-10-propanamine, 2-chloro-N,N-dimethyl-, monohydrochloride (69-09-0)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### US State Regulations

<b>Sodium metabisulfite (7681-57-4)</b>
U.S. - Massachusetts - Right To Know List U.S. - Minnesota - Hazardous Substance List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

### 16) OTHER INFORMATION

#### Full Test of H-Phrases

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Lact.	Reproductive toxicity (Lact.)
Skin Sens. 1	Skin sensitization, Category 1
H301	Toxic if swallowed
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H332	Harmful if inhaled
H362	May cause harm to breast-fed children

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