



SAFETY DATA SHEET

Section 1: Identification	
Material	Chlorpromazine Hydrochloride Injection USP 25mg/mL and 50 mg/2mL(25mg/ml)
Recommended use	Antipsychotic; Regulated prescription drug.
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
OSHA/HCS status	This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	ACUTE TOXICITY: INHALATION - Category 4
Hazard statements	Harmful if inhaled.
Precautionary statements	
Prevention	Use only outdoors or in a well-ventilated area. Avoid breathing vapor
Response	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell
Storage	Not applicable
Disposal	Not applicable
Hazards not otherwise classified	None known
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Chlorpromazine Hydrochloride	69-09-0
Ascorbic acid USP	50-81-7
Nitrogen NF	7727-37-9
Sodium Chloride USP	7647-14-5
Sodium metabisulfite USP	7681-57-4
Sodium Sulphite NF	7757-83-7
Water for Injection	NA



Section 4: First-Aid Measures	
Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours
Skin contact	Flush contaminated skin with plenty of water. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse
Ingestion	Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband
<u>Most important symptoms/effects, acute and delayed</u>	
<u>Potential acute health effects</u>	
Eye contact	No known significant effects or critical hazards
Inhalation	Harmful if inhaled. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure



Skin contact	No known significant effects or critical hazards
Ingestion	No known significant effects or critical hazards
<u>Over-exposure signs/symptoms</u>	
Eye contact	No known significant effects or critical hazards
Inhalation	No known significant effects or critical hazards
Skin contact	No known significant effects or critical hazards
Ingestion	No known significant effects or critical hazards
<u>Indication of immediate medical attention and special treatment needed, if necessary</u>	
Notes to physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours
Specific treatments	No specific treatment.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
Section 5: Fire-Fighting Measures	
<u>Extinguishing media</u>	
Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No specific fire or explosion hazard
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides halogenated compounds
Special protective actions for fire-fighters	No special protection is required
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Section 6: Accidental Release Measures	
<u>Personal precautions, protective equipment and emergency procedures</u>	
For non-emergency personnel	No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide



	adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".
Environmental precautions	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
<u>Methods and materials for containment and cleaning up</u>	
Spill	Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal
Section 7: Handling and Storage	
<u>Precautions for safe handling</u>	
Protective measures	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.
Conditions for safe storage, including any incompatibilities	Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly



	closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination
Section 8: Exposure Controls/Personal Protection	
<u>Control parameters</u>	
<u>Occupational exposure limits</u>	
None.	
Appropriate engineering controls	Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.
<u>Individual protection measures</u>	
Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side shields.
<u>Skin protection</u>	
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated
Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before



	handling this product
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator
Section 9: Physical and Chemical Properties	
Physical Form	a sterile solution
Colour	clear colorless
Description	<p>Chlorpromazine Hydrochloride Injection, USP 25 mg/mL is a sterile, clear colorless solution and is available in the following packages:</p> <p>25 mg per mL 1 mL single-dose vial packaged in carton of 25 NDC 31722-366-32</p> <p>50 mg per 2 mL (25 mg / mL) 2 mL single-dose vial packaged in carton of 25 NDC 31722-367-32</p>
Section 10: Stability and Reactivity	
Reactivity	No specific test data related to reactivity available for this product or its ingredients
Chemical stability	The product is stable.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	No specific data.
Incompatible materials	Reactive or incompatible with the following materials: oxidizing materials and acids
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.



Section 11: Toxicological Information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Chlorpromazine Hydrochloride	LD50 Oral	Rat	145 mg/kg	--

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available

Carcinogenicity

There is no data available

Reproductive toxicity

There is no data available

Teratogenicity

There is no data available

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure

Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact

No known significant effects or critical hazards

Inhalation

Harmful if inhaled. Exposure to decomposition products may cause a health hazard.
Serious effects may be delayed following exposure

Skin contact

No known significant effects or critical hazards



Ingestion	No known significant effects or critical hazards						
<u>Symptoms related to the physical, chemical and toxicological characteristics</u>							
Eye contact : No known significant effects or critical hazards Inhalation : No known significant effects or critical hazards Skin contact : No known significant effects or critical hazards Ingestion : No known significant effects or critical hazards							
<u>Delayed and immediate effects and also chronic effects from short and long term exposure</u>							
<u>Short term exposure</u>							
Potential immediate effects : No known significant effects or critical hazards Potential delayed effects : No known significant effects or critical hazards							
<u>Long term exposure</u>							
Potential immediate effects : No known significant effects or critical hazards Potential delayed effects : No known significant effects or critical hazards							
<u>Potential chronic health effects</u>							
General : No known significant effects or critical hazards Carcinogenicity : No known significant effects or critical hazards. Mutagenicity : No known significant effects or critical hazards Teratogenicity : No known significant effects or critical hazards Developmental effects : No known significant effects or critical hazards Fertility effects : No known significant effects or critical hazards							
<u>Numerical measures of toxicity</u>							
<u>Acute toxicity estimates</u>							
<table border="1"> <thead> <tr> <th>Route</th><th>ATE value</th></tr> </thead> <tbody> <tr> <td>Oral</td><td>4882.2 mg/kg</td></tr> <tr> <td>Inhalation (vapors)</td><td>16.84 mg/L</td></tr> </tbody> </table>		Route	ATE value	Oral	4882.2 mg/kg	Inhalation (vapors)	16.84 mg/L
Route	ATE value						
Oral	4882.2 mg/kg						
Inhalation (vapors)	16.84 mg/L						
Section 12: Ecological Information							
Toxicity	There is no data available.						
Persistence and degradability	There is no data available.						
Bioaccumulative potential	There is no data available.						
Mobility in soil Soil/water partition coefficient (KOC)	Not available						
Other adverse effects	No known significant effects or critical hazards						



Section 13: Disposal Considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14: Transport Information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No	No	No
Additional information	-	-	-



Special precautions for user	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

Section 15: Regulatory Information

U.S. Federal regulations	TSCA 8(a) PAIR: Sodium metabisulfite TSCA 8(a) CDR Exempt/Partial exemption: Not determined United States inventory (TSCA 8b): All components are listed or exempted
Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)	Not listed
Clean Air Act Section 602 Class I Substances	Not listed
Clean Air Act Section 602 Class II Substances	Not listed
DEA List I Chemicals (Precursor Chemicals)	Not listed
DEA List II Chemicals (Essential Chemicals)	Not listed

SARA 302/304

Composition/information on ingredients

No products were found

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Immediate (acute) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Chlorpromazine Hydrochloride	1 - 5	No	No	No	Yes	No



<u>State regulations</u>	
Massachusetts	None of the components are listed
New York	None of the components are listed
New Jersey	None of the components are listed
Pennsylvania	None of the components are listed
California Prop. 65	No products were found.
International regulations	Australia inventory (AICS): All components are listed or exempted
International lists	China inventory (IECSC): All components are listed or exempted
	Japan inventory: All components are listed or exempted
	Korea inventory: All components are listed or exempted
	Malaysia Inventory (EHS Register): Not determined
	New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted
	Philippines inventory (PICCS): All components are listed or exempted
	Taiwan inventory (CSNN): Not determined.

Section 16: Other Information

Issue Date : 03-04-2025

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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