



# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Melphalan Hydrochloride for Injection 50 mg/vial
- b) **Common/ trade Name** : Melphalan Hydrochloride for Injection
- Chemical Name** : 4-[Bis(2-chloroethyl)amino]-L-Phenylalanine hydrochloride
- c) **Chemical Family** : Alkylating agent (Anti-cancer)
- d) **Product Use** : Pharmaceutical, injectable
- Product type** : Regulated prescription drug
- Container Information** : Vial
- e) **Manufacture Name** : **Gland pharma Limited**
- Address** : UNIT II, Block C, phase I  
Vishakapatnam SEZ,  
Duvvada, Visakhapatnam-530046  
Andhra Pradesh , India
- f) **Telephone Number for Info** : +0891 2548313

## SECTION 2: HAZARDS IDENTIFICATION

### Classification of the substance and mixture:

(a) **Classification:** This product is classified as hazardous according to the OSHA Hazard Communication Standard. However, products that is subject to the labeling requirements of the Food and Drug Administration are exempt from the labeling provisions of the standard.

(b) **Signal Word:** Class 6.1

**Hazard statement(s),  
Symbol(s), and/or  
Precautionary  
statement(s):**





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(c) **Description of Hazards:** May cause local tissue damage should extravasation occur, as well as bone marrow suppression, possible bleeding, possible anaphylaxis, is potentially mutagenic.

May cause cancer, mutagenic effects, fetal harm in pregnancy, and may also produce allergic skin reactions.

(d) **Unknown Acute Toxicity** N/A

## SECTION 3 – COMPOSITION AND INGREDIENTS

### Melphalan Hydrochloride for Injection

Chemical Name	Common Name / Synonym	Qty/unit	CAS No.	Impurities / Stabilizing Additives
Melphalan Hydrochloride	N/A	55.95 mg	3223-07-2	N/A
Povidone k12	N/A	20 mg	9003-39-8	N/A
Hydrochloric Acid	N/A	q.s to pH	7647-01-0	N/A
Water for Injection	Water	q.s. to 2.5 mL	7732-18-5	N/A
Nitrogen	N/A	q.s	7727-37-9	N/A

q.s: quantity sufficient, N/A: Not Applicable

### Sterile Diluent for Melphalan Hydrochloride for Injection

Chemical Name	Common Name / Synonym	Qty/unit	%	CAS No.	Impurities / Stabilizing Additives
Ethanol (96%)	N/A	0.52 mL	5.2	64-17-5	N/A
Propylene Glycol	N/A	6.0 mL	60	57-55-6	N/A
Sodium Citrate	N/A	0.20 g	2	6132-04-3	N/A
Water for Injection	Water	q.s. to 10 mL	32.8	7732-18-5	N/A
Nitrogen	N/A	q.s	N/A	7727-37-9	N/A

q.s: quantity sufficient, N/A: Not Applicable



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## SECTION 4 - FIRST AID MEASURES

- EYE EXPOSURE** : If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
- Skin Contact** : Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
- Ingestion** : Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
- Inhalation** : Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
- Notes to Physician** : See patient package insert in shipping carton for complete information.

## SECTION 5: FIRE-FIGHTING MEASURES

- Extinguishing media** : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- Specific hazards arising from the substance** : No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.
- Flammability/ Explosivity** : Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
- Advice for firefighters** : Wear full protective clothing and a self-contained breathing apparatus with a full face piece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Wear protective clothing and equipment consistent with the degree of hazard. For all spills, isolate the spill area, restrict access, post the area or a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Collect and place it in a suitable, properly labeled container for recovery or disposal. Water can be used for clean-up and decontamination operations. Neutralize with caustic soda or soda ash.

### **Environmental precautions:**

Do not empty into drains. Avoid release to the environment.



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## Methods and material for containment and cleaning up:

DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.

## SECTION 7: HANDLING AND STORAGE

### Precautions for safe handling:

Follow recommendations for handling potent cytotoxic pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling.

**Conditions for safe storage** : Store vials as directed in pack insert. Keep vials closed when not in use.

Store away from incompatible materials. Protect from light. Store at 20 to 25°C (77°F). Protect from light

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### a) Exposure limits

Compound	Issuer	Type	Exposure limit
Melphalan	OSHA	PEL	N/A
Hydrochloride	ACGIH	TLV	N/A

### Personal protective equipment

#### Exposure/Engineering controls:

Open handling should not be performed when handling potent substances or substances of unknown toxicity. Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

#### Respiratory protection:

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known or in any other circumstances where air purifying respirators may not provide adequate protection.



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## Hand protection:

Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

## Skin protection:

Wear appropriate gloves, lab coat, or other protective over garment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

## Eye/face protection:

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

## Environmental Exposure Controls:

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

## Other protective measures:

Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Melphalan Hydrochloride for Injection

Property	Melphalan Hydrochloride for injection
Description:	White to off white lyophilized cake or powder
pH:	5.8 to 7.0
Water Solubility:	Practically insoluble
Solvent Solubility:	Propylene glycol,
Specific Gravity (g/ml):	N/A
Boiling Point (°C):	N/A
Melting Point (°C):	180°C
Flash Point (°C):	N/A
Ignition Temperature (°C):	N/A
Density	N/A
Evaporation rate	N/A
Partition coefficient (n-octanol/water)	-0.52



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## SECTION 10: STABILITY AND REACTIVITY

Property	Melphalan Hydrochloride
Chemical stability	Rapid decomposition in neutral or alkaline solutions; pharmacological stability not guaranteed beyond expiration date imprinted on package.
Conditions to avoid:	Extreme heat, any conditions that are incompatibility with water, mixing this product with incompatible chemicals
Conditions to avoid:	Avoid extreme temperatures. Avoid direct sunlight.
Hazardous decomposition products:	Carbon oxides, nitrogen oxides
Possibility of Hazardous Reactions	Hazardous polymerization will not occur

## SECTION 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure	Ingestion, skin, eyes
Symptoms related to the physical, chemical and toxicological characteristics	Hypersensitivity- skin rash, hives, itching; anemia; nausea/ vomiting; diarrhea.
Delayed and immediate effects and also chronic effects from short and long term exposure	Bone marrow suppression; toxicity to rapidly dividing cells; possible impairment in fertility; may cause toxicity in developing human offspring; See package insert for details.

### Acute Toxicity

Component	Type	Route	Species	Dosage
Drug	LD <sub>50</sub>	Oral	Mouse	N/A
Sodium Chloride	LD <sub>50</sub>	Inhalation	Rat	N/A
Water	LD <sub>50</sub>	Oral	Rat	N/A

### Hazardous Chemical Listings

NTP: Yes

IARC: Yes

OSHA: Yes

#### a) Acute toxicity

Component	Type	Route	Species	Dosage
Melphalan Hydrochloride	LD <sub>50</sub>	IV	Rat	4.7 mg/kg
		Oral		11.2 mg/kg

### Aspiration hazard :

No data available.



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## SECTION 12: ECOLOGICAL CONSIDERATIONS

<b>Ecotoxicity</b>	No toxic effects recorded in aquatic microorganisms tested
<b>Bioaccumulative potential</b>	This material contains an active ingredient that will not have a tendency to bio accumulate in the food chain.
<b>Persistence and degradability</b>  <b>Half-life (Hydrolysis-acidic)</b> Melphalan Hydrochloride <b>Half-life (Hydrolysis-basic)</b> Melphalan Hydrochloride <b>Half-life (Hydrolysis-neutral)</b> Melphalan Hydrochloride	This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism 4.9 Hours, pH 5 Buffer Solution  3.9 Hours  4.9 Hours, pH 7 Buffer Solution
<b>Mobility in soil</b>	N/A
<b>Other Adverse Effects</b>	N/A

## SECTION 13: DISPOSAL CONSIDERATIONS

**Product:** Observe all federal, state, and local environmental regulations.

**Waste Disposal:** - Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

## SECTION 14: TRANSPORT INFORMATION

### **US Domestic Transport (DOT Requirements)**

<b>UN Number</b>	: UN 3249
<b>Proper Shipping Name</b>	: Medicine, solid, toxic, nos
<b>UN/NA</b>	: None
<b>Packing Group</b>	: II
<b>Transport Hazard Class(es)</b>	: Class 6.1 toxic
<b>Classification Labeling</b>	: See 173.4, 173.153 and 173.156
<b>Limited Quantities</b>	: May be able to ship as an Excepted or limited Quantity



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## IATA classification and labeling:

UN Number	UN 3249
UN Proper Shipping Name	Medicine, solid, toxic, nos
Transport Hazard Class(es)	Class 6.1 toxic
Packing Group	II
Environmental Hazards	Not Available
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
Special Precautions	Classification and labeling: see 2.7 and 2.8

## UN classification and labeling:

UN Number	UN 3249
UN Proper Shipping Name	Medicine, solid, toxic, nos
Transport Hazard Class(es)	Class 6.1 toxic
Packing Group	II
Environmental Hazards	Not Available
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
Special Precautions	Not Available

## SECTION 15: REGULATORY INFORMATION

**Safety, health and** : This SDS complies with the requirements under US, EU and GHS (EU CLP -

**Environmental authorities Regulations/legislation** : Regulation EC No 1272/2008) guidelines. Consult your local or regional for more information.

**specific for the substance or mixture**

**Chemical safety Assessment** : Not conducted.

**OSHA Hazardous** : Yes Caution. Suspected Cancer Hazard - May cause cancer. Genotoxic. Reproductive/ Developmental Hazard - May adversely affect the developing fetus or cause adverse reproductive effects. Birth Defect Hazard - May cause birth defects. May cause hematological toxicity, gastrointestinal effects, fever and fatigue. May be harmful if swallowed.

**WHMIS classification** Not required. Drugs are not subject to WHMIS. This product has been classified





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in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

<b>TSCA status</b>	Not listed
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	Listed as a carcinogen.
<b>Additional information</b>	Melphalan hydrochloride is listed as a hazardous drug by NIOSH.

## SECTION 16: OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration



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NA	Not Applicable,
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations