SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Melphalan Hydrochloride for Injection Diluent**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	June 22, 2009
SDS Revision Date:	October 31, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

Signal Word:	Not applicable.
Hazard Statements:	Not applicable.
Precautionary Statements:	Not applicable.
Emergency Overview:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption. Injection.
Potential Health Effects:	
Eye:	Contact with eyes may cause irritation.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Propylene glycol	57-55-6	0.6 mL/mL	
Ethyl Alcohol	64-17-5	0.05 mL/mL	
Sodium Citrate Dihydrate	6132-04-3	20 mg/mL	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ethyl Alcohol :

Guideline ACGIH:	TLV-TWA: 1000 ppm
Guideline OSHA:	PEL-TWA: 1000 ppm
Guideline NIOSH:	REL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless. Clear
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.

Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	8 - 9
Molecular Formula:	Mixture
Molecular Weight:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Avoid contact with strong oxidizing agents.

SECTION 11 : TOXICOLOGICAL INFORMATION

Propylene glycol :

RTECS Number:	TY2000000
Eye:	Eye - Rabbit Standard Draize test.: 500 mg/24H [mild]
Skin:	Administration onto the skin - Rabbit LD50: 20800 mg/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit LD50: 20800 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression] Administration onto the skin - Mouse TDLo: 1284800 mg/kg/2Y (Intermittent) [Skin and Appendages - Tumors]
Ingestion:	Oral - Rat LD50: 20 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 22 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 20300 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression]
Other Toxicological Information:	Intravenous. - Rat LD50: 6423 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 6630 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LD50: 6500 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 8000 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Rat LD50: 6800 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Rabbit LDLo: 4200 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Rat LD50: 22500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 17370 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - cyanosis] Subcutaneous - Guinea pig LDLo: 15500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 17400 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Rat LD50: 28000 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Guinea pig LDLo: 15500 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Mouse DNA inhibition: 8000 mg/kg Subcutaneous - Mouse Cytogenetic analysis: 8000 mg/kg Intraperitoneal. - Rat LD50: 6660 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 9718 mg/kg [Lungs, Thorax, or Respiration - chronic pulmonary edema Kidney/Ureter/Bladder - changes in both tubules and glomeruli Blood - changes in spleen] Intraperitoneal. - Mouse LD50: 11400 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Intraperitoneal. - Rat TDLo: 19500 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression] Intraperitoneal. - Mouse TDLo: 100 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Intraperitoneal. - Mouse TDLo: 100 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]

Ethyl Alcohol :

RTECS Number:	KQ6300000
Eye:	Eye - Rabbit Rinsed with water.: 100 mg/4S
Skin:	Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Open irritation test: 400 mg Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H
Inhalation:	Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 39 gm/m3/4H [Details of toxic effects not reported other than lethal dose value]

Ingestion:	Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Propylene glycol :

TSCA Inventory Status:	Listed
EINECS Number:	200-338-0
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.1362(1454)

Ethyl Alcohol :

TSCA Inventory Status:	Listed
EINECS Number:	200-578-6
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	June 22, 2009
SDS Revision Date:	October 31, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Updated name to display in full as 'Melphalan Hydrochloride for Injection Diluent'.

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