

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Melphalan HCl for Injection**
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: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Respiratory sensitisation. category 1.
 Carcinogenicity. Category 1A.
 Reproductive toxicity. Category 1A.
 Germ cell mutagenicity. Category 1A.
 Skin Sensitization. category 1.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause cancer.
 May damage fertility or the unborn child.
 May cause genetic defects.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.
 IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF exposed or concerned: Get medical advice/attention.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: Highly Toxic. May cause cancer. May cause heritable genetic damage. Very toxic by inhalation, in contact with skin and if swallowed. Possible risk of harm to the unborn child.

Route of Exposure: Inhalation, Ingestion, skin absorption

Potential Health Effects:

Skin: May be fatal if absorbed through skin.

Inhalation: May be fatal if inhaled.

Ingestion: May be fatal if ingested.

Signs/Symptoms: Possible adverse reactions include: Bone marrow suppression, gastrointestinal disturbances, hypersensitivity reactions including anaphylaxis, ulceration at the injection site, hemolytic anemia, pulmonary fibrosis (including fatal outcomes), and interstitial pneumonitis.

Target Organs: Reproductive system. Bone marrow.

Aggravation of Pre-Existing Conditions: May cause allergic reactions and pulmonary toxicity
 Individuals who have demonstrated hypersensitivity to melphalan

Melphalan Hydrochloride

Carcinogenicity: IARC: Group 1: Carcinogenic to humans.
 NTP: Known to be a human carcinogen.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Melphalan Hydrochloride	3223-07-2	56 mg/vial	
Povidone	9080-59-5	20 mg/vial	

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.
NFPA Ratings:	
NFPA Health:	
NFPA Flammability:	
NFPA Reactivity:	
NFPA Other:	

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:	Clean up spilled material immediately to prevent from becoming airborne or waterborne. Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation. 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].
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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	White off-white
Boiling Point:	Not established.
Melting Point:	180 °C
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Weight:	305.2 AMU
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.
Special Decomposition Products:	Carbon monoxide, Carbon dioxide, Nitrogen oxides.

SECTION 11 : TOXICOLOGICAL INFORMATION

Melphalan Hydrochloride :

RTECS Number:	AY3675000
Ingestion:	Oral - Rat LD50: 11200 ug/kg [Details of toxic effects not reported other than lethal dose value] Oral - Human TDLo: 1200 ug/kg/5D (Intermittent) [Gastrointestinal - Nausea or vomiting] Oral - Human TDLo: 700 mg/kg/7D [Gastrointestinal - Nausea or vomiting]
Carcinogenicity:	Intraperitoneal. - Rat TDLo: 70 mg/kg/26W (intermittent) [Tumorigenic - Neoplastic by RTECS criteria Tumorigenic - Tumors at site of application] Administration onto the skin - Mouse TDLo: 58 mg/kg/9W (intermittent) [Tumorigenic - Equivocal tumorigenic agent by RTECS criteria Lungs, Thorax, or Respiration - Tumors Skin and Appendages - Tumors] Intraperitoneal. - Mouse TDLo: 60 mg/kg/26W (intermittent) [Tumorigenic - Carcinogenic by RTECS criteria Lungs, Thorax, or Respiration - Tumors Blood - Lymphoma, including Hodgkin's disease] Intraperitoneal. - Mouse TD: 15 mg/kg/6W (intermittent) [Tumorigenic - Neoplastic by RTECS criteria Skin and Appendages - Tumors]
Other Toxicological Information:	Subcutaneous - Mouse LD10: 32 mg/kg [Details of toxic effects not reported other than lethal dose value],,br>Intravenous. - Rat LD50: 4100 ug/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: Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Toxic solids, organic, n.o.s.
DOT UN Number: UN2811
DOT Hazard Class: 6.1
DOT Packing Group: II

IATA Shipping Name: Toxic solid, organic, n.o.s.
IATA UN Number: 2811
IATA Hazard Class: 6.1
IATA Packing Group: II

ICAO UN Number : UN3249
ICAO Shipping Name: Medicine, solid, toxic, n.o.s. (Melphalan Hydrochloride).
ICAO Hazard Class : 6.1
ICAO Packing Group : II

SECTION 15 : REGULATORY INFORMATION

Melphalan Hydrochloride :

TSCA Inventory Status: Listed
California PROP 65: Listed: cancer.
Listed: developmental.
Canada DSL: Listed
Risk Phrases: R: 45-46-26/27/28-63; May cause cancer. May cause heritable genetic damage. Very toxic by inhalation, in contact with skin and if swallowed. Possible risk of harm to the unborn child.;
Safety Phrase: S: 53-22-36/37/39-45; Avoid exposure - obtain special instructions before use. Do not breathe dust. Wear suitable protective clothing, gloves, and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).;

Povidone :

TSCA Inventory Status: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 4*
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

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